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BIOVERIS CORP
Form 10-Q
February 13, 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 December 31, 2003

Commission File Number: 000-50583

BIOVERIS CORPORATION
(Exact name of registrant as specified in its charter)

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

16020 INDUSTRIAL DRIVE, GAITHERSBURG, MD 20877
(Address of principal executive offices) (Zip Code)

301-869-9800
(Registrant's telephone number, including area code)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Act of 1934 during the preceding 12 months, (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes____ No X__

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

| Class | Outstanding at February 13, 2004 |
|---------------------------------|----------------------------------|
| Common Stock, \$0.001 par value | 26,726,950 |

BIOVERIS CORPORATION
FORM 10-Q
FOR THE QUARTER ENDED DECEMBER 31, 2003

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ITEM 1: CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

BIOVERIS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
UNAUDITED

| | December 31, 2003 ----- | March 31, 2003 ----- |
|----------------------------|----------------------------|-------------------------|
| ASSETS | | |
| CURRENT ASSETS: | | |
| Accounts receivable, net | \$ 3,842 | \$ 5,434 |
| Inventory | 5,450 | 5,448 |
| Prepaid expenses and other | 1,024 | 2,286 |
| | ----- | ----- |
| Total current assets | 10,316 | 13,168 |

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| | | |
|--|----------|----------|
| EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET | 5,535 | 6,456 |
| OTHER NONCURRENT ASSETS: | | |
| Investment in joint venture | 16,682 | 9,164 |
| Other | 358 | 372 |
| | ----- | ----- |
| Total assets | \$32,891 | \$29,160 |
| | ===== | ===== |
| LIABILITIES AND NET INVESTMENT BY IGEN | | |
| CURRENT LIABILITIES: | | |
| Accounts payable and accrued expenses | \$ 4,331 | \$ 4,758 |
| Accrued wages and benefits | 1,930 | 3,170 |
| Deferred revenue | 708 | 507 |
| | ----- | ----- |
| Total current liabilities | 6,969 | 8,435 |
| DEFERRED REVENUE | 14 | 60 |
| | ----- | ----- |
| Total liabilities | 6,983 | 8,495 |
| COMMITMENTS AND CONTINGENCIES | - | - |
| NET INVESTMENT BY IGEN | 25,908 | 20,665 |
| | ----- | ----- |
| Total liabilities and net investment by IGEN | \$32,891 | \$29,160 |
| | ===== | ===== |

See notes to condensed consolidated financial statements.

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BIOVERIS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
UNAUDITED

| | Three months ended | | |
|-------------------------------|--------------------|----------|--------|
| | December 31, | | |
| | 2003 | 2002 | |
| | ----- | ----- | ----- |
| REVENUES: | | | |
| Product sales | \$ 3,500 | \$ 5,163 | \$ 13, |
| Royalty income | 250 | 316 | |
| Contract fees | 34 | 49 | |
| | ----- | ----- | ----- |
| Total revenues | 3,784 | 5,528 | 14, |
| | ----- | ----- | ----- |
| OPERATING COSTS AND EXPENSES: | | | |

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| | | | |
|-------------------------------------|-------------|-------------|---------|
| Product costs | 3,260 | 2,438 | 9, |
| Research and development | 4,343 | 5,498 | 14, |
| Selling, general and administrative | 4,647 | 5,600 | 13, |
| Merger related costs | 3,901 | - | 4, |
| | ----- | ----- | ----- |
| Total operating costs and expenses | 16,151 | 13,536 | 41, |
| | ----- | ----- | ----- |
| LOSS FROM OPERATIONS | (12,367) | (8,008) | (26, |
| INTEREST EXPENSE | - | (3) | |
| OTHER, NET | 125 | 27 | |
| EQUITY IN LOSS OF JOINT VENTURE | (3,742) | (3,329) | (13, |
| | ----- | ----- | ----- |
| NET LOSS | \$ (15,984) | \$ (11,313) | \$ (39, |
| | ===== | ===== | ===== |
| PRO FORMA NET LOSS PER COMMON SHARE | \$ (0.60) | \$ (0.42) | \$ (1, |
| | ===== | ===== | ===== |
| PRO FORMA COMMON SHARES OUTSTANDING | 26,727 | 26,727 | 26, |
| | ===== | ===== | ===== |

See notes to condensed consolidated financial statements.

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BIOVERIS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
UNAUDITED

OPERATING ACTIVITIES:

Net loss
Adjustments to reconcile net loss to net cash
used for operating activities:
Depreciation and amortization
Loss on disposal of equipment
Expense related to stock options
Equity in loss of joint venture
Changes in assets and liabilities:
Accounts receivable
Inventory
Prepaid expenses and other
Accounts payable and accrued expenses
Deferred revenue

Net cash used for operating activities

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INVESTING ACTIVITIES:

Expenditures for equipment and leasehold improvements
Increase in other long-term assets
Investment in joint venture

Net cash used for investing activities

FINANCING ACTIVITIES:

Cash contributed by IGEN, net
Payments under capital lease obligations

Net cash provided by financing activities

NET CHANGE IN CASH

CASH, BEGINNING OF PERIOD

CASH, END OF PERIOD

SUPPLEMENTAL DISCLOSURES:

Cash payments of interest

See notes to condensed consolidated financial statements.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

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

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

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

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Prior to the completion of the merger and related transactions, the assets and businesses of the Company had historically been owned and operated by IGEN. 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. Accordingly, IGEN's net investment in the Company is shown in lieu of stockholders' equity in the accompanying condensed consolidated balance sheets. Prior to the completion of the merger and related transactions, IGEN held all cash in a centralized treasury and provided all of the necessary funding for the operations of the Company. Accordingly, no cash is reflected on the accompanying condensed consolidated balance sheets.

For each of the periods presented in the condensed consolidated financial statements, the Company was fully integrated with IGEN and these financial statements reflect the application of certain estimates and allocations. The Company's condensed consolidated statements of operations include all revenues and costs that are directly attributable to the Company's businesses. In addition, certain expenses of IGEN have been allocated to the Company using various assumptions. These expenses include an allocated share of general and administrative salaries as well as certain other shared costs (primarily facility, human resources, legal, accounting and other administrative costs). General and administrative salaries have been allocated primarily based upon an estimate of actual time spent on the businesses of the Company.

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Facilities costs and centralized administrative services have been allocated based upon a percentage of total product sales as well as a percentage of total headcount. Allocated expenses of \$4.6 million, \$5.6 million, \$13.7 million and \$15.8 million are included in selling, general and administrative expenses in the accompanying condensed consolidated statements of operations for the three months ended December 31, 2003 and 2002 and nine months ended December 31, 2003 and 2002, respectively. These allocated expenses were derived from total IGEN selling, general and administrative expenses of \$5.3 million and \$6.5 million, \$17.3 million and \$18.8 million for the three months ended December 31, 2003 and 2002 and the nine months ended December 31, 2003 and 2002, respectively. In addition, certain merger related costs have been allocated to the Company based upon an estimate of actual time spent by professional service providers (see Note 4 to condensed consolidated financial statements for discussion of other allocated merger costs). 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 may not be indicative of the financial position, results of operations and cash flows of the Company in the future or what they would have been had BioVeris been operating as a stand-alone entity in the past.

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

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

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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 for the three and nine month periods ended December 31, 2003 and 2002, the Company's financial position at December 31, 2003 and the cash flows for the nine month periods ended December 31, 2003 and 2002.

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, 2003 contained in the Company's Form S-4 Registration Statement filed with the Securities and Exchange Commission (SEC).

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.

2. PRO FORMA BALANCE SHEET

The following pro forma consolidated balance sheet as of December 31, 2003 has been prepared as if the merger and related transactions were completed as of December 31, 2003 and should be read in conjunction with the Company's consolidated financial statements and notes and the other information contained in this Form 10-Q as well as the Company's Form S-4 Registration Statement filed with the SEC.

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BioVeris Pro Forma Consolidated Balance Sheet
As of December 31, 2003
(in thousands, except per share data)

| | Historical | A |
|---|------------|--------|
| | ----- | ----- |
| ASSETS | | |
| CURRENT ASSETS: | | |
| Cash | \$ | - |
| Accounts receivable, net | | 3,842 |
| Inventory | | 5,450 |
| Prepaid expenses and other | | 1,024 |
| | | ----- |
| Total current assets | | 10,316 |
| | | ----- |
| EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET | | 5,535 |
| OTHER NONCURRENT ASSETS: | | |

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| | |
|---|-----------|
| Investment in joint venture (6) | 16,682 |
| Other | 358 |
| | ----- |
| Total assets | \$ 32,891 |
| | ===== |
| LIABILITIES AND STOCKHOLDERS' EQUITY | |
| CURRENT LIABILITIES: | |
| Accounts payable and accrued expenses | \$ 4,331 |
| Accrued wages and benefits | 1,930 |
| Deferred revenue | 708 |
| | ----- |
| Total current liabilities | 6,969 |
| DEFERRED REVENUE | |
| | 14 |
| | ----- |
| Total liabilities | 6,983 |
| | ----- |
| COMMITMENTS AND CONTINGENCIES | |
| | - |
| 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, historical and pro forma | - |
| Series B, 1,000 shares designated, none issued, historical; 1,000 shares issued and outstanding, pro forma | - |
| Common stock, par value \$0.001 per share, 100,000,000 shares authorized, 1,000 issued, historical; 26,726,950 shares issued and outstanding, pro forma | - |
| Additional paid-in capital | - |
| Net investment by IGEN | |
| | 25,908 |
| | ----- |
| Total stockholders' equity | 25,908 |
| | ----- |
| Total liabilities and stockholders' equity | \$ 32,891 |
| | ===== |

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- (1) Reflects cash to be transferred from IGEN to BioVeris prior to the completion of the merger and related transactions.
- (2) Assumes payment of \$50 million to certain affiliates of Roche for a worldwide, non-exclusive license under patents that cover certain PCR inventions.
- (3) Assumes payment of the capital contribution of \$37.5 million to MSD less interim funding of \$1.8 million to MSD for the month of December 2003 which has been paid pursuant to an agreement by which 1/12th of IGEN's aggregate funding commitment under the MSD budget for 2003 would be payable monthly commencing December 1, 2003 until the completion of the merger. After the restructuring, and subject to MSD's and MST's right to buy BioVeris's interests in MSD, BioVeris will hold a 31% voting interest in MSD and after the capital contribution of \$35.7 million to MSD, will be entitled to a

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preferred return on \$113.6 million.

- (4) Assumes purchase by Mr. Samuel Wohlstadter of \$7.5 million of shares of series B preferred stock to be issued by BioVeris. The terms of the Series B preferred stock economically mirror the class C interest in MSD to be held by BioVeris.
- (5) Pursuant to the tax allocation agreement among Roche, a subsidiary of Roche, IGEN and BioVeris, BioVeris may be required to make a payment to IGEN of up to \$20 million within 10 days of receiving notice from Roche. If paid in full, the amount of cash, on a pro forma basis at December 31, 2003 would be approximately \$125 million. See Management's Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources.
- (6) 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. BioVeris will adopt FIN 46 as of January 1, 2004. See Note 3 to Condensed Consolidated Financial Statements, New Accounting Standards, for a discussion of consolidation accounting for the investment in joint venture beginning January 1, 2004.
- (7) Reflects the reclassification of net investment by IGEN to common stock and additional paid-in capital upon distribution of 26,726,950 shares of BioVeris common stock.
- (8) BioVeris's net loss will increase in the three months ended March 31, 2004 as a result of BioVeris's recognition of an allocated one-time noncash compensation charge associated with the cancellation of IGEN stock options and the payment of the merger consideration for each share covered by IGEN stock options in connection with the merger. See Note 4 to Condensed Consolidated Financial Statements, Stock Option Plans.

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3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Concentration of Credit Risk -- During the three months ended December 31, 2003 and 2002 and the nine months ended December 31, 2003 and 2002, agencies of the U.S. government accounted for 18%, 36%, 17% and 26% of total revenue, respectively, and 18% and 43% of total accounts receivable as of December 31, 2003 and March 31, 2003, respectively.

Allowance for Doubtful Accounts -- The Company maintains reserves on customer accounts where estimated losses may result from the inability of its customers to make required payments. These reserves are determined based on a number of factors, including the current financial condition of specific customers, the age of accounts receivable balances and historical loss rates.

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

| | December 31, 2003 | March 31, 2003 |
|-----------------|-------------------|----------------|
| | ----- | ----- |
| Finished goods | \$ 2,179 | \$ 2,234 |
| Work in process | 503 | 869 |
| Raw materials | 2,768 | 2,345 |
| | ----- | ----- |
| | \$ 5,450 | \$ 5,448 |

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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 or accelerated methods. Leasehold improvements are amortized on a straight-line basis over the life of the lease.

Capitalized Software Costs -- Software development costs incurred after technological feasibility is established are capitalized in accordance with Statement of Financial Accounting Standards (SFAS) No. 86, "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed." To date, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

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 December 31, 2003 and March 31, 2003.

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

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Warranty reserve activity is as following:

| | |
|------------------------------|---------|
| Balance at March 31, 2003 | \$ 250 |
| Provisions recorded | 1,231 |
| Actual costs incurred | (1,231) |
| | ----- |
| Balance at December 31, 2003 | \$ 250 |
| | ===== |

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

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. 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

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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 three and nine months ended December 31, 2003 and 2002.

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Income Taxes -- The assets and businesses of the Company have historically been owned and operated by IGEN. The Company was not a separate legal or tax entity and the operating results of the Company were included in IGEN's consolidated Federal and state income tax returns. As a result, income taxes have been calculated as if the Company was a stand-alone entity filing a separate tax return.

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 Company did not have any stock option grants. The following table illustrates the effect on net loss and net loss per share as if IGEN had applied the fair value recognition provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure -- An Amendment of SFAS No. 123," to stock-based employee compensation and the resulting costs attributable to the Company's employees were reflected in the condensed consolidated financial statements:

| | Three months ended December 31, | | |
|-----------------------|------------------------------------|-------------|--------|
| | 2003 | 2002 | |
| | ----- | | ----- |
| Net loss, as reported | \$ (15,984) | \$ (11,313) | \$ (3) |

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| | | | |
|---|-------------|-------------|------------|
| Deduct: Stock-based employee compensation recognized under intrinsic value method | 2,458 | - | |
| Add: Total stock-based employee compensation expense determined under fair value method | (2,926) | (610) | |
| | ----- | ----- | ----- |
| Net loss, as adjusted | \$ (16,452) | \$ (11,923) | \$ (4,529) |
| | ===== | ===== | ===== |
| Net loss per share: | | | |
| Net loss per common share, as reported | \$ (0.60) | \$ (0.42) | \$ (0.18) |
| Net loss per common share, as adjusted | \$ (0.62) | \$ (0.45) | \$ (0.17) |

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 net loss, as adjusted, and net loss per share, as adjusted, disclosed above is not representative of the effects on net loss and net loss per share on an as adjusted basis in future periods, as future periods will include grants by the Company of options for the Company common stock.

The fair value of options for IGEN common stock was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

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| | Three months ended | | Nine Months Ended | |
|---------------------------------|--------------------|-------|-------------------|-------|
| | December 31, | | December 31, | |
| | 2003 | 2002 | 2003 | 2002 |
| | ----- | ----- | ----- | ----- |
| Expected dividend yield | - | 0% | 0% | 0% |
| Expected stock price volatility | - | 68% | 65% | 68% |
| Risk-free interest rate | - | 3.0% | 2.3% | 3.4% |
| Expected option term (in years) | - | 5 | 5 | 5 |

Based on this calculation, the weighted average fair value of options granted during the three months ended December 31, 2002 and nine months ended December 31, 2003 and 2002 was \$16.48, \$21.09 and \$19.29, respectively. No options were granted during the three months ended December 31, 2003.

Pro Forma Net Loss Per Share -- The Company uses SFAS No. 128, "Earnings per Share," for the calculation of basic and diluted earnings per share. For all periods presented, the pro forma net loss per share is based on the number of common shares outstanding upon completion of the merger and related transactions. (See Note 1)

New Accounting Standards -- In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure -- an amendment of SFAS No. 123" (SFAS 148). SFAS 148 amends SFAS 123, "Accounting for Stock-Based Compensation" (SFAS 123), to provide alternative methods of voluntarily transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure requirements of SFAS 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported

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results in both annual and interim financial statements. This pronouncement is effective for both annual and interim periods beginning after December 15, 2002. The Company has elected to follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting For Stock Issued to Employees," in its accounting for employee stock options. In accordance with SFAS 148, the Company has adopted the annual and interim period disclosure requirements.

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. The Company will adopt FIN 46 as of January 1, 2004 and has determined that MSD qualifies as a variable interest entity based upon the following rationale:

- o The Company has 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.

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- o The Company holds 31% of the voting rights in MSD while providing 100% of MSD's funding, and the Company is thereby considered to be involved in all of MSD's activities as defined under FIN 46.

As the merger and related transactions do not change the design of or ownership interests in MSD in such a manner that could affect the status of MSD as a variable interest entity or the Company as the primary beneficiary, the Company does not believe they are deemed to be events that would require reassessment of the Company's previous conclusion that MSD qualifies as a variable interest entity under FIN 46 with the Company as the primary beneficiary. Accordingly, beginning January 1, 2004 and continuing subsequent to the completion of the merger and related transactions, the Company will consolidate the financial results of MSD. Under the transition guidance of FIN 46 because MSD was created before February 1, 2003, the Company will measure the assets, liabilities and noncontrolling interests of MSD as of January 1, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests will be 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. Such carrying amounts are expected to equal MSD's recorded values, which as of December 31, 2003, were approximately \$18.8 million, \$1.7 million and \$10,000, respectively. As the Company has historically recorded and will continue to record approximately 100% of MSD's losses, it is anticipated that upon implementation of FIN 46, the consolidated net assets of MSD will approximate the book value of the Company's investment in joint venture. As such, consolidation accounting will require certain reclassifications within the Company's consolidated financial statements, but it is not expected to materially affect its financial position or net loss. The required balance sheet reclassifications will reclassify the 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 required statement of operations reclassifications will reclassify the 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.

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In April 2003, the FASB issued SFAS No. 149, "Amendment of SFAS No. 133 on Derivative Instruments and Hedging Activities" (SFAS 149). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The amendments set forth in SFAS 149 require that contracts with comparable characteristics be accounted for similarly. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The implementation of SFAS 149 did not have a material effect on the Company's financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" (SFAS 150). SFAS 150 establishes standards regarding the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The implementation of SFAS 150 did not have a material effect on the Company's financial position, results of operations or cash flows.

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4. STOCK OPTION PLANS

In September 2003, the board of directors of the Company adopted, subject to IGEN stockholder approval, the BioVeris 2003 Stock Incentive Plan (Stock Plan). Up to 5.3 million shares of common stock of the Company (subject to adjustment in the event of stock splits and other similar events) may be issued pursuant to awards granted under the Stock Plan.

The Stock Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, non-statutory stock options, restricted stock awards and other stock-based awards, including the grant of shares based upon certain conditions, the grant of securities convertible into common stock of the Company and the grant of stock appreciation rights (collectively, Awards).

Employees, officers, directors, consultants and advisors, including any individuals who have accepted an offer for employment, of the Company and its subsidiaries are eligible to be granted awards under the Stock Plan. Incentive stock options may only be granted to employees of the Company and its subsidiaries. The Stock Plan was approved by an affirmative vote of the IGEN stockholders on February 13, 2004.

In connection with the transfer of IGEN employees to the Company, the Company's Board of Directors approved the grant to the Company's employees of options to purchase 100 shares of BioVeris common stock. Each option will have an exercise price equal to fair market value on the date of grant and will vest in full one year from the date of grant.

All IGEN stock options were canceled in connection with the merger and related transactions and the holder of any such options has the right to receive for each share covered by such option cash from Roche equal to the excess of \$47.25 over the exercise price of such option and one share of the Company's common stock. In connection with such cancellation of IGEN stock options and the payment of the merger consideration for each share covered by IGEN stock options, the Company will record an allocated noncash compensation charge for each IGEN stock option. In calculating the noncash compensation charge

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associated with the merger and related transactions, the Company applied the guidance of FIN 44 for employee stock options and SFAS 123 for nonemployee stock options. With respect to employee stock options, FIN 44 guidance provides that the compensation charge is calculated based upon the difference between the last trading price of IGEN common stock (\$64.09 per share) and the exercise price of each employee stock option, including both vested and unvested employee stock options. With respect to nonemployee stock options, SFAS 123 guidance provides that the compensation charge is calculated based upon the incremental fair value of the nonemployee stock options resulting from the merger. Upon completion of the merger and related transactions, there were options to acquire 1,277,109 shares of IGEN common stock, with a weighted average exercise price of \$19.23 per share, that will result in a noncash compensation charge of approximately \$37 million for the three months ended March 31, 2004. This amount is an allocation from IGEN to the Company based upon an estimate of actual time spent on BioVeris matters by each option holder.

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In addition, in connection with the transfer of employees from IGEN to MSD on December 31, 2003 pursuant to the restructuring described in Note 1, IGEN accelerated the vesting of all unvested stock options held by such employees who accepted the offer of employment with MSD. Pursuant to the guidance of FIN 44, a noncash compensation charge of approximately \$2.5 million was recorded during the three months ended December 31, 2003 representing the difference between the trading price of IGEN common stock on December 31, 2003 and the exercise price of each employee stock option for which vesting was accelerated. This compensation charge is a component of merger related costs in the accompanying condensed consolidated statement of operations.

5. MESO SCALE DIAGNOSTICS JOINT VENTURE

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 combination of MST's multi-array technology together with IGEN's technology. MST is a company established and wholly-owned by Jacob Wohlstadter, a son of the Company's chairman and chief executive officer. In August 2001, IGEN amended the MSD joint venture agreement, the MSD limited liability company agreement and certain license and other agreements with MSD and MST to continue the MSD joint venture and entered into various related agreements (the MSD agreements). An independent committee of the IGEN board of directors, the Joint Venture Oversight Committee (JVOC), with the advice of independent advisors and counsel, negotiated and approved the MSD agreements. As part of the merger and related transactions, IGEN's equity interest in the MSD joint venture has been transferred to the Company and the MSD agreements have been assigned to the Company.

MSD manufactures, markets and sells instrument systems, including the Sector HTS and the Sector PR, which combine MST's multi-array technology and 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 JVOC, a committee of the IGEN board of directors consisting of independent directors. The JVOC approved funding for MSD by IGEN for the period from January 1, 2003 to November 30, 2003 in an amount of \$20.6

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million, subject to a permitted variance of 15%. IGEN's funding commitment was satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. For the nine months ended December 31, 2003 and 2002, IGEN made total contributions to MSD of \$20.9 million and \$16.9 million, respectively, including \$3.7 million in the nine months ended December 31, 2003, which constituted discretionary funding relating to the permitted budget variances from prior years.

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Separate from and in addition to IGEN's funding commitment under the MSD agreements for the period from January 1, 2003 to November 30, 2003, the Company agreed to make a final capital contribution of \$37.5 million to MSD following the completion of the merger. Of the \$37.5 million, Samuel Wohlstadter, Company's chairman and chief executive officer, will fund any amount in excess of \$30.0 million (including any interim funding provided by IGEN as described in the next sentence) through the purchase of the Company's series B preferred stock that economically mirror the class C interests in MSD to be held by the Company. In addition, as the merger was not completed prior to December 1, 2003, IGEN agreed to provide continued interim funding to MSD, payable monthly on the first day of each month commencing on December 1, 2003 until the completion of the merger. The monthly funding was equal to approximately \$1.7 million, which is 1/12th of IGEN's aggregate funding commitment under the MSD budget for 2003 approved by the JVOC. Such interim funding, which totaled \$5.2 million from December 1, 2003 through February 1, 2004, will reduce the amount of the Company's final capital contribution to \$32.3 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 \$77.8 million of the funds previously invested by IGEN in MSD through December 31, 2003 and on the additional funds invested by IGEN and 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. Although MST owns the remaining 69% voting equity interest in MSD, the Company generally has the right to approve significant MSD governance matters. In exercising this right, an independent committee of the Company's board of directors must consider the Company's interests and the interests of the Company's stockholders while also taking into consideration the interests of MSD.

The Company and MST are the sole members of MSD, and each holds one seat on MSD's two-member board of managers. After the restructuring, Dr. Richard Massey, the Company's president and chief operating officer, became the Company's representative on the MSD board of managers and also serves 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.

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.

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. After the expiration of the MSD joint venture agreement, 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.

Upon completion of the merger and related transactions, the MSD joint venture agreement expired. As a result, MSD and MST has the right to purchase for a purchase price equal to fair market value (to be determined in accordance with the provisions and procedures set forth in the MSD agreements, which will include a determination by appraisers if the parties are unable to agree on fair market value) less a 7.5% discount factor, the Company's entire interest in MSD including the Company's preferred interests that entitle it to a preferred return on its investment in MSD. If MSD or MST exercises this right, it 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 date that MSD or MST, as the case may be, elects to purchase the interests. 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. In the event such future net sales or third-party financings do not materialize, the Company will not receive any 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.

Following the expiration of the MSD joint venture agreement, many of the licenses and other arrangements with MSD and MST assigned to the Company continued indefinitely in accordance with their terms.

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. Following expiration of the MSD joint venture agreement, 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. If the Company elects to terminate a sublease for a facility, 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).

After a notice of termination of a sublease has been sent, MSD will be required to pay its pro rata share of all rental and other expense incurred by the Company under the prime lease. MSD and MST may elect, if either exercises its

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right to purchase the Company's interests in MSD, to have its rental and expense payment obligations for the 18-month period included in the purchase price of those interests in MSD.

MSD has an employment agreement with Mr. Jacob Wohlstadter, its president and chief executive officer, the current term of which runs through November 30, 2004. 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, 2003. 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, at the discretion of the JVOC of the Company's board of directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. During the year ended December 31, 2003, Mr. Jacob Wohlstadter received \$250,000 from his employment at MSD. 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 will 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 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 under 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. 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, 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

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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 \$3.7 million, \$3.3 million, \$13.4 million and \$12.8 million for the three months ended December 31, 2003 and 2002 and the nine months ended December 31, 2003 and 2002, respectively. During the three months ended December 31, 2003 and 2002 and the nine months ended December 31, 2003 and 2002, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled \$1.9 million, \$3.3 million, \$5.7 million and \$8.3 million, respectively. Since July 1, 2001, these allocated operating costs reduced certain operating costs and expenses and increased equity in loss of joint venture in the accompanying condensed consolidated statements of operations. The Company's investment in joint venture totaled \$16.7 million and \$9.2 million at December 31, 2003 and March 31, 2003, respectively. See Note 3 for discussion of consolidation accounting of the MSD investment as of January 1, 2004.

6. COMMITMENTS AND CONTINGENCIES

License Payment -- In connection with the merger and related transactions, the Company has committed to pay certain affiliates of Roche a fee of \$50 million after the completion of the merger for a worldwide, non-exclusive license under patents that cover certain PCR inventions.

Tax Allocation Contingency -- Pursuant to the tax allocation agreement among Roche, a subsidiary of Roche, IGEN and the Company, the Company may be required to pay IGEN up to \$20 million within 10 days of receiving notice from Roche to the extent that the average of the high and low trading prices of the Company's common stock on the first day of trading of the Company's common stock after the completion of the merger exceeds a specified threshold.

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

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This Management's Discussion and Analysis of Financial Condition and Results of Operations as of December 31, 2003 and for the three and nine month periods ended December 31, 2003 and 2002 should be read in conjunction with the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Form S-4 Registration Statement 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

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plans. The words "may," "should," "will," "expect," "could," "anticipate," "believe," "estimate," "plan," "intend" and similar expressions have been used to identify certain of the forward-looking statements. These forward-looking statements are based on management's current expectations, estimates and projections and they are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. These statements are not guarantees of future performance, involve certain risks, uncertainties, and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein.

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

- o changes in our strategy and business plan, including our plans for the clinical diagnostics, biodefense, life science and industrial markets and other healthcare opportunities;
- o our ability to develop and introduce new or enhanced products, including incorporating unit dose cartridges and completion of pending negotiations for novel centrifuge technologies;
- o our ability to enter into new collaborations on favorable terms, if at all;
- o our ability to expand the distribution and increase sales of existing products;
- o the demand for rapid testing products in each of our markets;
- o our ability to expand our manufacturing capabilities or find a suitable manufacturer on acceptable terms or in a timely manner, including the completion of pending negotiations for contract manufacturing of one of our instruments;
- o our ability to develop our selling, marketing and distribution capabilities;

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- o our and our licensees' ability to obtain FDA and other governmental approvals for our and their clinical testing products;
- o the ability of our licensees to effectively develop and market products based on the technology we license to them;
- o domestic and foreign governmental and public policy changes, particularly related to healthcare costs, that may affect new investments and purchases made by our customers;
- o availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;
- o rapid technological developments in each of our markets and our ability to respond to those changes in a timely, cost-effective

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manner;

- o any potential future disputes regarding the scope, permitted use and other material terms of our license agreements, including those with Roche and MSD;
- o the outcome of the litigation and arbitration between Applied Biosystems and Roche;
- o protection and validity of our patent and other intellectual property rights;
- o statements regarding relationships between us and certain companies with which we are affiliated; and
- o changes in general economic, business and industry conditions.

These forward-looking statements are found at various places throughout this quarterly report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this quarterly report. We undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this quarterly report or to reflect the occurrence of unanticipated events.

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

As used herein, "BioVeris", "we", "us" and "our" refer to BioVeris Corporation and its subsidiaries. IGEN refers to IGEN International, Inc. and its subsidiaries. M-SERIES(R) and TRICORDER(R) 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.

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Overview

We develop, manufacture and market our M-SERIES(R) 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:

- o Clinical diagnostics. The clinical diagnostics market includes the testing of patient samples to measure the presence of disease and

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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.

- o 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 in this quarterly report 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 M1-M clinical analyzer is the first clinical diagnostic system being developed by us and builds on the M-SERIES instruments we sell in the biodefense and life science markets. Our initial commercial focus for the M1-M clinical analyzer will be to provide cardiac assays that test for heart attack and congestive heart failure.

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We are developing the cardiac 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 M1-M 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 M1-M 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.

Our assets and businesses have historically been owned and operated by IGEN. Our financial statements have been prepared and are presented as if we had been operating as a separate entity 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 restructuring. Results of

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

- o the volume and timing of orders and product deliveries for biodefense products, M-SERIES systems or other products, which orders and deliveries are based on our customers' requirements;
- o the success of M-SERIES system upgrades and enhancements, which upgrades and enhancements involve increased product costs at the time of the upgrade or enhancement, and customer acceptance of those enhancements and upgrades;
- o the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;
- o whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;
- o the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;
- o the volume and timing of product returns and warranty claims, which, if products are returned or have warranty claims that are unexpected, may involve increased costs in excess of amounts reserved for returns or claims;

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- o our competitors' introduction of new products, which may affect the purchase decision of or timing of orders by our customers and prospective customers while the competitors' product is assessed;
- o the amount of expenses we incur in connection with the operation of our business, including:
 - o research and development costs, which increases or decreases based on the product in development and
 - o sales and marketing costs, which are based on product launches or promotions and sales incentives that might be in effect from time to time;
- o the amount that we will record each quarter related to the amortization or impairment of the license to use PCR technology, which may increase based on the outcome of the litigation and arbitration commenced against Roche by Applied Biosystems relating to Roche's and Applied Biosystems' respective rights to PCR technology;
- o unexpected termination of government contracts or orders, which could result in decreased sales and increased costs due to excess capacity, inventory personnel and other expenses; and
- o our share of losses in MSD, which are based on results of MSD's operations, which for the three and nine months ended December 31, 2003 totaled \$3.7 million and \$13.4 million, respectively, compared to \$3.3 million and \$12.8 million for the three and nine months ended December 31, 2002.

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

We expect to incur additional operating losses as a result of our expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs, the expenses of the MSD joint venture and a compensation charge associated with the cancellation of IGEN stock options in connection with the merger. Our net loss is expected to increase in the three months ended March 31, 2004 as a result of our recognition of an allocated noncash compensation charge associated with the cancellation of IGEN stock options and the payment of the merger consideration for each share covered by IGEN stock options in connection with the merger.

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.

For a description of our business, you should refer to the Form S-4 Registration Statement filed with the SEC.

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Results of Operations

Quarter and Nine Months Ended December 31, 2003 and 2002

Revenues. Total revenues were \$3.8 million and \$14.8 million for the quarter and nine months ended December 31, 2003, respectively, a decrease of \$1.7 million and an increase of \$1.7 million, respectively, from \$5.5 million and \$13.1 million for the corresponding prior year periods. Product sales were \$3.5 million and \$13.9 million for the quarter and nine months ended December 31, 2003, respectively, a decrease of \$1.7 million (32%) and an increase of \$1.8 million (15%), respectively, from \$5.2 million and \$12.1 million for the corresponding prior year periods. The decrease in product sales during the quarter ended December 31, 2003 resulted from sales of products for the life science market of \$2.7 million, a decrease of \$500,000 from \$3.2 million for the quarter ended December 31, 2002, and sales of biodefense products of \$800,000, a decrease of \$1.2 million from \$2.0 million for the quarter ended December 31, 2002. The increase in product sales during the nine months ended December 31, 2003 resulted from sales of products for the life science market of \$9.6 million, an increase of \$700,000 from \$8.9 million for the nine months ended December 31, 2002, and sales of biodefense products of \$4.3 million, an increase of \$1.1 million from \$3.2 million for the nine months ended December 31, 2002. These changes in product sales during the three and nine months ended December 31, 2003 from 2002 reflect the periodic changes in volume and timing of orders and product deliveries for biodefense products and M-SERIES systems, 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 from IGEN. 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 December 31, 2003, the DOD had purchased approximately \$2.1 million of products and, under the

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contract, may purchase up to a maximum of \$7.0 million in the 12-month period ending June 2004. 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. Product costs were \$3.3 million (93% of product sales) and \$9.0 million (65% of product sales) for the quarter and nine months ended December 31, 2003, and \$2.4 million (47% of product sales) and \$5.4 million (44% of product sales) for the corresponding prior year periods. Product costs, as a percentage of product sales, increased due to costs incurred in connection with instrument upgrades (16% and 6% of product sales for the three and nine months ended December 31, 2003, respectively) and detection module upgrades (34% and 17% of product sales for the three and nine months ended December 31, 2003, respectively) for existing life science customers. Instrument upgrade costs as a percentage of sales were 9% and 6%, respectively for the three and nine months ended December 31, 2002.

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These voluntary upgrades were provided to enhance overall customer satisfaction. The instrument and detection module upgrade programs have been substantially completed as of December 31, 2003. Our future product costs are subject to a number of uncertainties relating to, among other things, the launch of new instrument systems.

Research and development expenses were \$4.3 million and \$14.6 million for the quarter and nine months ended December 31, 2003, respectively, a decrease of \$1.2 million (21%) and \$2.8 million (16%), respectively, from \$5.5 million and \$17.4 million for the corresponding prior year periods. These decreases were due primarily to lower personnel and facilities costs for development projects. 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.

Selling, general and administrative expenses were \$4.6 million and \$13.7 million for the quarter and nine months ended December 31, 2003, respectively, a decrease of \$1.0 million (17%) and \$2.1 million (14%), respectively, from \$5.6 million and \$15.8 million for the corresponding prior year periods. These decreases were primarily attributable to lower personnel costs in the current year periods. For each of the periods, we were fully integrated with IGEN and the accompanying condensed consolidated financial statements reflect the application of certain estimates and allocations. Our condensed consolidated statements of operations include all revenues and costs that are directly attributable to our businesses. In addition, certain expenses of IGEN have been 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, as appropriate. These allocated expenses comprise substantially

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all of our selling, general and administrative expenses for the three and nine months ended December 31, 2003.

We have incurred merger related costs in connection with the Roche merger and related transactions, including the restructuring and the distribution of our shares by IGEN, which include primarily accounting, legal, printing and registration fees, as well as the allocation of a noncash compensation charge associated with the accelerated vesting of certain employee stock options pursuant to the restructuring. These merger related costs were \$3.9 million and \$4.1 million for the quarter and nine months ended December 31, 2003, including \$2.5 million associated with the noncash compensation charge. We will incur additional merger related costs through the February 13, 2004 closing of the merger and related transactions.

Interest Expense and Other. Interest expense, net of other income, was income of \$125,000 and \$173,000 for the quarter and nine months ended December 31, 2003, respectively.

Equity in Loss of Joint Venture. 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.

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We have recorded our proportionate share of MSD losses, representing approximately 100% of MSD's losses, for the three and nine months ended December 31, 2003 and 2002. As part of the merger and related transactions, IGEN transferred its interest in MSD to us. Equity in loss of joint venture was \$3.7 million and \$13.4 million for the three and nine months ended December 31, 2003, and \$3.3 million and \$12.8 million for the three and nine months ended December 31, 2002, respectively.

MSD's losses increased in fiscal 2004 primarily due to higher costs associated with its transition from a development stage entity to a commercial operating company. The increase in MSD's losses during the three and nine months ended December 31, 2003 results primarily from increases in sales and marketing expenses which were offset only in part by the growth in revenues which commenced in October 2002.

MSD manufactures, markets and sells instrument systems, including the Sector HTS and the Sector PR, which combine MST's multi-array technology and 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 bench-top applications such as assay development, research in therapeutic areas, cellular biology and medium throughput screening. MSD also manufactures and markets its own line of reagents, assays and plates that are used on these systems.

As of December 31, 2003, MSD had cash and short-term investments of \$4.4 million with working capital of \$9.7 million. During the nine months ended December 31, 2003, MSD used \$3.1 million for the purchase of inventory and \$1.7 million for the purchase of property, equipment and leasehold improvements. See "Liquidity and Capital Resources" for a discussion of our funding commitments to MSD.

Net Loss. The net loss was \$16.0 million and \$39.8 million for the quarter and nine months ended December 31, 2003, respectively, compared to a net loss of \$11.3 million and \$38.2 million for the quarter and nine months ended December 31, 2002, respectively. The increased net loss in the current periods is primarily due to merger related costs.

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Our net loss will increase during the three months ended March 31, 2004 due to additional merger related costs incurred through the February 13, 2004 closing of the merger and related transactions. Merger related costs will include our recognition of an allocated one-time noncash compensation charge of approximately \$37 million associated with the cancellation of IGEN stock options and the payment of the merger consideration for each share covered by IGEN stock options in connection with the merger. See Note 4 to Condensed Consolidated Financial Statements.

Liquidity and Capital Resources

In connection with the merger and related transactions, Roche loaned IGEN approximately \$210 million. These funds, less transaction costs of approximately \$25 million, were contributed by IGEN to us as part of the restructuring. The related promissory note remained the obligation of IGEN and we have no obligations associated with that debt.

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After the PCR license payment of \$50 million to certain affiliates of Roche and the final capital contribution of \$37.5 million, as adjusted, (of which any amount in excess of \$30 million will be funded by Mr. Samuel Wohlstadter, BioVeris's chairman and chief executive officer through the purchase of shares of BioVeris series B preferred stock that economically mirror the class C interests in MSD to be held by BioVeris) to MSD, we commenced operations following completion of the merger with approximately \$145 million in cash.

IGEN has historically held all cash in a centralized treasury and has provided all of the necessary funding for our operations since inception. Accordingly, as of December 31, 2003, we had no cash, cash equivalents or short-term investments.

Net cash used for operating activities was \$19.8 million and \$24.0 million, for the nine months ended December 31, 2003 and 2002, respectively. These changes between periods are primarily due to the size of each period's operating loss and changes in working capital accounts.

We used cash of \$1.4 million and \$2.6 million during the nine months ended December 31, 2003 and 2002, respectively for the acquisition of equipment and leasehold improvements. Our investments in MSD totaled \$20.9 million and \$16.9 million for the nine months ended December 31, 2003 and 2002, respectively.

The tax allocation agreement provides that Roche and IGEN will be solely liable for, will jointly and severally indemnify us against, and will be entitled to receive and retain all refunds of, taxes (other than transfer taxes) directly or indirectly resulting from, arising in connection with or otherwise related to the merger and related transactions, any transaction undertaken to prepare for the merger and related transactions and any of the actions taken pursuant to the ongoing litigation agreement. This agreement also provides for us to make a payment to IGEN of up to \$20 million within 10 days of receiving notice from Roche. The amount of the payment will depend on the average of the high and the low trading prices of our common stock on the first day of trading after the completion of the merger. A payment will be due if such average is at least approximately \$13.09 per share and the maximum payment will be due if such average exceeds approximately \$14.96, in each case based on the assumption that we will have \$225 million in cash and cash equivalents immediately after completion of the merger and prior to making any payments due pursuant to the related transaction agreements, the ongoing commercial agreements or the MSD letter agreement.

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

Net cash provided by financing activities was \$42.1 million and \$43.5 million, for the nine months ended December 31, 2003 and 2002, respectively. These amounts in each respective period primarily represent the cash contributed, net of receipts, by IGEN to us.

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As of December 31, 2003, our material future obligations were as follows:

| Contractual Obligations | Total | Three Months Ended March 31, 2004 | 2005 | 2006 | 2007 |
|-------------------------------|----------------|--|----------|----------|----------|
| | | | | | |
| | (In thousands) | | | | |
| PCR license fee | \$ 50,000 | \$ 50,000 | \$ - | \$ - | \$ - |
| MSD funding commitment(1) | 35,720 | 35,720 | - | - | - |
| Operating leases(2) | 19,847 | 650(2) | 3,181 | 3,164 | 3,241 |
| Total contractual obligations | \$105,567 | \$ 86,370 | \$ 3,181 | \$ 3,164 | \$ 3,241 |
| | ===== | ===== | ===== | ===== | ===== |

(1) Includes a final capital contribution of \$37.5 million to MSD from us following the completion of the merger, of which any amount in excess of \$30 million will be funded by our chairman and chief executive officer through the purchase of shares of our series B preferred stock that economically mirror the class C interest in MSD to be held by us, less interim funding of \$1.8 million to MSD for the month of December 2003 which has been paid pursuant to an agreement by which 1/12th of IGEN's aggregate funding commitment under the MSD budget for 2003, would be payable monthly commencing on December 1, 2003 until the completion of the merger. Excludes up to \$4.6 million that MSD has asserted we may be obligated to pay MSD under the approved 2003 funding which we do not believe is required by the agreements between MSD and us.

(2) Excludes \$94,000 with respect to operating leases that will be allocated to MSD through the closing date of the merger and related transactions. These amounts are included in the MSD funding commitment amount in the line immediately above.

Following the completion of the merger, and after paying certain obligations including the PCR license fee and satisfying the MSD funding commitment described below, we expect to commence operations with approximately \$145 million in cash.

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After completion of the merger and related transactions, we will pay certain affiliates of Roche a fee of \$50 million for a worldwide, non-exclusive license under patents that cover certain PCR inventions in accordance with the PCR product license agreement. We will owe royalties on sales of the licensed products and on sales of any instrument, accessory, device or system sold for use with the licensed products and on the performance of licensed tests. We will amortize the license fee over an estimated useful life of 10 years 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. We do not currently sell, or have under development, any product based on the PCR technology being licensed from Roche.

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MSD is a joint venture formed by MST and IGEN in 1995. As part of the merger and related transactions, IGEN's equity interest in the MSD joint venture has been transferred to us. Under the MSD agreements, IGEN's funding commitment was based on an annual budget of MSD approved by the JVOC. IGEN's 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 nine months ended December 31, 2003 and 2002, operating costs allocated to MSD by us in connection with shared personnel and facilities totaled \$5.7 million and \$8.3 million, respectively.

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 has asserted may be obligated to pay MSD up to \$4.6 million for additional budgeted amounts up to the \$20.6 million approved funding plus the permitted variance and we do not believe this payment is required by the agreements between MSD and us. Upon the completion of the merger, the MSD joint venture agreement expired and we will make a final capital contribution of \$37.5 million to MSD. Our obligation to make the final contribution to MSD was separate from our obligation to provide funding to MSD through November 30, 2003. Of the final capital contribution of \$37.5 million, any amount in excess of \$30 million (including any interim funding provided by IGEN as described below) will be funded by our chairman and chief executive officer through the purchase of shares of our series B preferred stock that economically mirror the class C interest in MSD to be held by us. Under the terms of the series B preferred stock, we may redeem the series B preferred stock for \$0.01 per share at any time we are no longer entitled to receive distributions with respect to the class C interests described in the previous sentence pursuant to the MSD limited liability company agreement. We will redeem a proportionate part of the series B preferred stock in connection with any redemption by MSD of the class C interests held by us in MSD described in the previous sentence. No distributions on the series B preferred stock will be paid unless and until distributions are paid on such class C interests in accordance with the MSD limited liability company agreement, in which event distributions on the series B preferred stock will be paid in the same manner and amount as such distributions on the class C interests. The shares of our series B preferred stock are entitled in the aggregate to 1,000 votes on all matters on which holders of our common stock may vote. In addition, we may not consent to any adverse change to the terms of the class C interests in MSD described in this paragraph without the consent of the holders of the series B preferred stock.

As the merger was not completed prior to December 1, 2003, IGEN agreed to provide continued interim funding to MSD, payable monthly on the first day of

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each month commencing on December 1, 2003 until the completion of the merger. The monthly funding was equal to approximately \$1.7 million, which is 1/12th of IGEN's aggregate funding commitment under the MSD budget for 2003 approved by the JVOC. Such interim funding, which totaled \$5.2 million from December 1, 2003 through February 1, 2004, will reduce the amount of the Company's final capital contribution to \$32.3 million, of which \$7.5 million will be funded by our chairman and chief executive officer through the purchase of shares of our series B preferred stock that economically mirror the class C interest in MSD to be held by us. For the nine months ended December 31, 2003 and 2002, total contributions to MSD were \$20.9 million and \$16.9 million, respectively, including \$3.7 million in the nine months ended December 31, 2003, which related to the permitted budget variances from prior years.

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IGEN, BioVeris and MSD agreed that the MSD joint venture agreement expired upon completion of the merger and related transactions. As a result, MSD and MST have the right to purchase for a purchase price equal to fair market value (to be determined in accordance with the provisions and procedures set forth in the MSD agreements, which will include a determination by appraisers if the parties are unable to agree on fair market value), less a 7.5% discount factor, our entire interest in MSD, including our preferred interests that entitle us to a preferred return on our investment in MSD. If MSD or MST exercises this right, it will be required to pay us 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 date that MSD or MST, as the case may be, elects to purchase the interests. The purchase price is payable over time in installments equal to the sum of 5% of MSD net sales, as determined in accordance with MSD agreements, and 20% of the net proceeds realized by MSD from the sale of its debt or equity securities in any third-party financing after the date of the sale of our interest in MSD. In the event such future net sales or third-party financings do not materialize, we will not receive any payments from MSD or MST, as the case may be, for the purchase of our interest in MSD. As security for the payment obligation we will hold a security interest in the interests in MSD that are being purchased. MST or MSD, as the case may be, may repay all or any part of the outstanding purchase price plus accrued interest at any time and from time to time without penalty.

Following the expiration of the MSD joint venture agreement, many of the licenses and other arrangements with MSD and MST assigned to us continued indefinitely in accordance with their terms. These include:

- o the IGEN/MSD license agreement, pursuant to which we granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to our technology, including ECL technology, for use in MSD's research program, defined in the MSD agreements; and
- o the MSD/MST sublicense agreement (but only as to IGEN or our technology or improvements developed before IGEN or us ceases to be a member of MSD), pursuant to which MST was granted a worldwide, perpetual, non-exclusive sublicense to use our technology to make, use or sell products or processes applying or related to the technologies used in the MSD research program outside the diagnostic field.

In addition, certain of our obligations under the MSD joint venture agreement survived its termination, including:

- o to cooperate and work in good faith and use reasonable best efforts to

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assist MSD in securing third-party financing;

- o confidentiality obligations;
- o to make available to MSD the benefits of certain agreements with third-party licensors, suppliers, vendors, distributors and other providers;

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- o to assign to MSD all proprietary information and intellectual property within the MSD research program or research technologies, as described in the MSD agreements, and to ensure that its employees protect such proprietary information;
- o to defend and indemnify MSD against all claims arising out of the conduct of the MSD research program and to maintain liability insurance to cover the risk of liability resulting from the conduct of that program; and
- o unless MSD or MST exercises its right to purchase our interests in MSD, not to vote against or refuse to consent to, agree to or approve any action supported by MST unless a committee of our board of directors reasonably concludes, after having considered the interests of MSD, that the action is not in the best interests of us and our stockholders.

Notwithstanding expiration of the MSD joint venture agreement, we are required to continue to pay the expenses associated with prosecuting and maintaining the patents licensed by MST to MSD in connection with the original formation of the MSD joint venture unless and until MSD or MST exercises its right to purchase our interests in MSD.

Following the expiration of the MSD joint venture agreement, MSD is entitled to continue to lease certain facilities and related equipment from us (including laboratory facilities located in our 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, we must exercise all available extension rights under the prime lease. Following expiration of the MSD joint venture agreement, each of MSD and BioVeris may unilaterally terminate any or all of the subleases by providing at least 18 months prior written notice of termination. If we elect to terminate a sublease for a facility, 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). After a notice of termination of a sublease has been sent, MSD will be required to pay its pro rata share of all rental and other expenses incurred by us under the prime lease. MSD and MST may elect, if either exercises its right to purchase our interests in MSD, to have its rental and expense payment obligations for the 18-month period included in the purchase price of those interests in MSD.

MSD has an employment agreement with Mr. Jacob Wohlstadter, its president and chief executive officer, the current term of which runs through November 30, 2004. 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

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of \$250,000 through November 30, 2003. 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, at the discretion of the JVOC of our board of directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. Mr. Jacob Wohlstadter is also entitled to receive pension, welfare and fringe benefits comparable to those received by our senior executives and other insurance benefits.

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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 BioVeris, 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. Upon completion of the merger, we are obligated to maintain in effect directors and officers 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 will not constitute a change in control for purposes of the MSD agreements and the employment agreement. We will also indemnify Mr. Jacob Wohlstadter against certain liabilities, including liability from the MSD joint venture relating to the period of IGEN's or our involvement with MSD. In addition, we will be obligated under 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. 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 our financial position or results of operations.

Mr. Jacob Wohlstadter has a consulting agreement with IGEN that was assumed by us. This consulting agreement will be automatically renewed on August 15, 2004, for a period of three years unless either us or Mr. Jacob Wohlstadter gives notice to the contrary no later than 90 days before that date. Pursuant to the consulting agreement, Mr. Jacob Wohlstadter will be entitled to receive such fees as we and Mr. Jacob Wohlstadter agree to when consulting services are requested by us. We have no obligation to request any consulting services from Mr. Jacob Wohlstadter. Mr. Jacob Wohlstadter did not perform any compensable consulting services during the nine months ended December 31, 2003 and 2002.

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

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

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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.

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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 December 31, 2003, we had no off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES

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

Expense Allocations -- Our assets and businesses have historically been 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. In order to fairly present our operating results, these financial statements reflect the application of certain estimates and allocations. Our condensed consolidated statements of operations include all costs that are directly attributable to our businesses, as well as certain expenses of IGEN that have been 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

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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.

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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 we believe our interpretations and judgments are reasonable, different assumptions could result in changes in the timing of revenue recognition.

Joint Venture Accounting -- We account 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 provide 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 be appropriate. Consolidation accounting would require certain reclassifications within our consolidated financial statements but would not materially affect our financial position or net loss.

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 will

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adopt FIN 46 as of January 1, 2004. See Recent Accounting Pronouncements for discussion of consolidation accounting for the investment in joint venture beginning January 1, 2004.

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Allowance for Doubtful Accounts -- We maintain reserves on customer accounts where estimated losses may result from the inability of our 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. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, an additional allowance may be required.

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 12 months. Reserves are recorded for the difference between the cost and 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 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, our policy is to compare the carrying amount of an asset with the projected undiscounted cash flow. While we believe that our 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 our review of historical results, supplemented by expectations of future costs. Unanticipated changes in actual warranty costs could impact our operating results.

Capitalized Software Costs -- We record software development costs in accordance with SFAS No. 86, "Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed." We apply our judgment in determining when software being developed has reached technological feasibility, and at that point we would capitalize software development costs. To date, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

RECENT ACCOUNTING PRONOUNCEMENTS

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation -- Transition and Disclosure -- an amendment of SFAS No. 123," or SFAS 148. SFAS 148 amends SFAS 123, "Accounting for Stock-Based Compensation," or SFAS 123, to provide alternative methods of voluntarily transitioning to the fair value based method of accounting for stock-based employee compensation. SFAS 148 also amends the disclosure requirements of SFAS 123 to require disclosure of the method used to account for stock-based employee compensation and the effect of the method on reported results in both annual and interim financial statements. This pronouncement is effective for both annual and interim periods beginning after December 15, 2002. We have elected to follow the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," in our accounting for employee stock options. In accordance with SFAS 148, we have adopted the annual and interim period disclosure requirements.

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 will adopt FIN 46 as of January 1, 2004 and have determined that MSD qualifies as a variable interest entity based upon the following rationale:

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

As the merger and related transactions do not change the design of or ownership interests in MSD in such a manner that could affect the status of MSD as a variable interest entity or us as the primary beneficiary, we do not believe they are deemed to be events that would require reassessment of our previous conclusion that MSD qualifies as a variable interest entity under FIN 46 with us as the primary beneficiary.

Accordingly, beginning January 1, 2004 and continuing subsequent to the completion of the merger and related transactions, we will consolidate the financial results of MSD. Under the transition guidance of FIN 46 because MSD was created before February 1, 2003, we will measure the assets, liabilities and noncontrolling interests of MSD as of January 1, 2004 for purposes of the initial consolidation. The amounts of the assets, liabilities and noncontrolling interests will be 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. Such carrying amounts are expected to equal MSD's recorded values, which as of December 31, 2003, were approximately \$18.8 million, \$1.7 million and \$10,000, respectively.

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As we have historically recorded and will continue to record approximately 100% of MSD's losses, it is anticipated that upon implementation of FIN 46, the consolidated net assets of MSD will approximate the book value of our investment in joint venture. As such, consolidation accounting will require certain reclassifications within our consolidated financial statements, but it is not expected to materially affect our financial position or net loss. The required balance sheet reclassifications will reclassify the 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 required statement of operations reclassifications will reclassify the 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.

In April 2003, the FASB issued SFAS No. 149, "Amendment of SFAS No. 133 on Derivative Instruments and Hedging Activities," or SFAS 149. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." The amendments set forth in SFAS 149 require that contracts with comparable characteristics be accounted for similarly. SFAS 149 is generally effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The implementation of SFAS 149 did not have a material effect on our financial position, results of operations or cash flows.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of Both Liability and Equity," or SFAS 150. SFAS 150 establishes standards regarding the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The implementation of SFAS 150 did not have a material effect on our financial position, results of operations or cash flows.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The assets and businesses of BioVeris have historically been owned and operated by IGEN, which holds all cash in a centralized treasury and has provided all of the necessary funding for the operations of BioVeris. Accordingly, no cash is reflected on the consolidated balance sheets of BioVeris and there are no market risk sensitive instruments.

BioVeris is exposed to changes in exchange rates where it sells direct in local currencies, primarily in the United Kingdom and Germany. Certain other foreign sales denominated in U.S. dollars and have no exchange rate risk. Gains and losses resulting from foreign currency transactions have historically not been material.

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ITEM 4: CONTROLS AND PROCEDURES

The Company, under the supervision and with the participation of its management, including the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the design and operation of the Company's "disclosure controls and procedures" (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

There have not been any changes in the Company's internal control over financial reporting during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, its internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 4

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 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

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

BioVeris Corporation

Date: February 13, 2004

/s/ George V. Migausky

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George V. Migausky
Vice President of Finance and
Chief Financial Officer
(On behalf of the Registrant and as
Its Principal Financial Officer.