IGEN INTERNATIONAL INC /DE
Form 10-Q
November 07, 2003

SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

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

For Quarter Ended September 30, 2003

Commission File Number 0-23252

IGEN International, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	94-2852543
(State or other jurisdiction incorporation or organization)	(IRS Employer Identification No.)

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

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

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

Yes X No _____

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

Class	Outstanding at November 4, 2003
Common Stock, $0.001 par value	24,971,486

IGEN International, Inc.
Form 10-Q
For the Quarter Ended September 30, 2003

INDEX

IGEN International, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)

	September 30, 2003	March
ASSETS	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	$ 42,478	
Short-term investments	7,362	
Accounts receivable, net	5,286	
Inventory	5,176	
Other current assets	3,181	
Total current assets	63,483	
EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET	5,793	
OTHER NONCURRENT ASSETS:		
Investment in affiliate	14,790	
Other	608	

TOTAL	$ 84,674
LIABILITIES AND STOCKHOLDERS' EQUITY	
CURRENT LIABILITIES:	
Accounts payable and accrued expenses	$ 12,908
Current portion of notes payable	15,361
Deferred revenue	551
Total current liabilities	28,820
NONCURRENT LIABILITIES:	
Note payable	-
Subordinated convertible debentures	-
Deferred revenue	26
Total noncurrent liabilities	26
COMMITMENTS AND CONTINGENCIES	
STOCKHOLDERS' EQUITY:	
Convertible preferred stock, $0.001 par value, 10,000,000 shares authorized, issuable in Series: Series A, 600,000 shares designated, none issued; Series B, 25,000 shares designated, none issued	-
Common stock, $0.001 par value, 50,000,000 shares authorized, 24,967,429 and 23,750,461 shares issued and outstanding	25
Additional paid-in capital	279,470
Stock notes receivable	(2,061)
Accumulated other comprehensive loss	(179)
Accumulated deficit	(221,427)
Total stockholders' equity	55,828
TOTAL	$ 84,674

See notes to condensed consolidated financial statements.

IGEN International, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
Unaudited

	Three months ended September 30, 2003	2002	Six S 200
REVENUES:			
Roche revenue	$ 15,310	$ 8,407	$ 26,68
Product sales	6,152	4,698	11,57

Royalties and contract fees	333	320	61
Roche litigation judgment	18,600	-	18,60
Total	40,395	13,425	57,46
OPERATING COSTS AND EXPENSES:			
Product costs	3,512	2,213	6,15
Research and development	5,060	6,339	10,53
Selling, general and administrative	5,892	6,319	12,00
Roche litigation and merger costs	4,265	885	7,86
Total	18,729	15,756	36,56
INCOME (LOSS) FROM OPERATIONS	21,666	(2,331)	20,90
OTHER (EXPENSE) INCOME:			
Interest expense	(3,535)	(1,444)	(4,85
Other income, net	132	465	21
Total	(3,403)	(979)	(4,63
EQUITY IN LOSS OF AFFILIATE	(4,450)	(5,032)	(9,68
NET INCOME (LOSS)	13,813	(8,342)	6,58
PREFERRED DIVIDENDS	-	(3)	
NET INCOME (LOSS) ATTRIBUTABLE TO COMMON SHAREHOLDERS	$ 13,813	$ (8,345)	$ 6,58
NET INCOME (LOSS) PER COMMON SHARE-BASIC	$ 0.57	$ (0.35)	$ 0.2
NET INCOME (LOSS) PER COMMON SHARE-DILUTED	$ 0.55	$ (0.35)	$ 0.2
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING-BASIC	24,044	23,717	23,90
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING-DILUTED	25,133	23,717	24,88

See notes to condensed consolidated financial statements.

IGEN International, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
Unaudited

	Six mo Sept 2003
OPERATING ACTIVITIES	
Net income (loss)	$ 6,584
Adjustments to reconcile net income (loss) to net cash provided by (used for) operating activities:	
Depreciation and amortization	1,734
Equity in loss of affiliate	9,680
Amortization of debt discount	3,166
Expense related to stock options	261
Changes in assets and liabilities:	
Decrease (increase) in accounts receivable	9,250
Decrease (increase) in inventory	265
Decrease in other current assets	1,503
Increase in non-current assets	-
Increase (decrease) in accounts payable and accrued expenses	849
Increase (decrease) in deferred revenue	10
Net cash provided by (used for) operating activities	33,302
INVESTING ACTIVITIES:	
Expenditures for equipment and leasehold improvements	(939)
Investments in affiliate	(15,306)
Purchase of short-term investments	(1,694)
Maturities of short-term investments	6,837
Sales of short-term investments	2,371
Net cash used for investing activities	(8,731)
FINANCING ACTIVITIES:	
Issuance of common stock, net	1,165
Payments on notes payable and capital lease obligations	(2,705)
Principal collected on note receivable	-
Preferred stock dividends paid	-
Net cash used for financing activities	(1,540)
NET INCREASE (DECREASE) CASH AND CASH EQUIVALENTS	23,031
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	19,447
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 42,478
SUPPLEMENTAL DISCLOSURES:	
Cash payments of interest	$ 1,598
Accrued preferred dividends	$ -

See notes to condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. BASIS OF PRESENTATION

The accompanying condensed consolidated financial statements of IGEN International, Inc. (the Company) have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements have been condensed or omitted. In the opinion of the Company's management, the financial statements reflect all adjustments necessary to present fairly the results of operations for the three and six month periods ended September 30, 2003 and 2002, the Company's financial position at September 30, 2003 and the cash flows for the six month periods ended September 30, 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 Annual Report on Form 10-K for the year ended March 31, 2003 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. Certain amounts from the prior years have been reclassified to conform to the current year presentation.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, IGEN Europe, Inc., BioVeris Corporation (BioVeris) and IGEN International, K.K. All significant inter-company transactions and balances have been eliminated.

2. ROCHE TRANSACTION

On July 24, 2003, the Company and Roche Holding Ltd. (Roche) jointly announced that they had reached definitive agreements pursuant to which Roche will acquire the Company and the Company will simultaneously distribute the common stock of a new company, BioVeris, to its stockholders. The transaction will occur in the following steps:

- The Company will restructure its operations so that BioVeris, a newly formed wholly-owned subsidiary of the Company, will assume the Company's biodefense, life sciences and industrial product lines as well as the Company's opportunities in the clinical diagnostics and healthcare fields, and will own the Company's intellectual property, the Company's equity interest in Meso Scale Diagnostics, LLC. (MSD), cash and certain other rights and licenses currently held by the Company; and

- A wholly-owned subsidiary of Roche will merge with and into the Company, as a result of which the Company will become a wholly-owned

subsidiary of Roche and BioVeris will become an independent, publicly-traded company owned by the Company's stockholders. Simultaneously with the completion of the merger, certain ongoing commercial agreements between BioVeris and certain affiliates of Roche will become effective.

The obligations of the parties to complete the merger are subject to certain conditions, including the adoption of the merger agreement by the Company's stockholders, the receipt by the Company of a solvency opinion substantially to the effect that BioVeris will not be insolvent after giving effect to the merger and related transactions and the execution and delivery of the ongoing commercial agreements, and that Roche will have loaned the Company up to $214 million, such loan remaining the obligation of the Company following the completion of the merger. All cash on hand at the Company will be transferred to BioVeris as part of the restructuring.

Upon completion of the merger, each outstanding share of the Company's common stock will be converted into the right to receive $47.25 in cash, without interest, and one share of BioVeris common stock. In addition, upon completion of the merger, all outstanding options granted under the Company's stock option plans, including unvested options, will be canceled and the holder of any such options will have 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 (without interest) and one share of BioVeris common stock.

Effective, simultaneously with the completion of the merger, Roche will hold a new worldwide, non-exclusive, fully-paid, royalty-free, perpetual license under patents and technology that relate to detection methods and systems which employ electrochemiluminescence (ECL) technology, but specifically excluding technology related to gene amplification or compounds composed of or capable of binding with nucleotides. The license may be used only in a specific field, generally described as the human in vitro diagnostics field, to develop, make, reproduce, modify, use, sell and otherwise commercially exploit specified products. The Company's rights, as licensor under the license agreement, will be transferred to BioVeris as part of the restructuring.

As part of the merger and related transactions, the Company and Roche have entered into an ongoing litigation agreement providing that all litigation between the parties be suspended pending the completion of the merger (see Note 8). As partial consideration for the ongoing litigation agreement and for Roche's use of ECL technology pending completion of the merger, Roche is obligated to pay the Company a fixed monthly fee of $5.0 million which commenced in July 2003 and will be payable until the completion of the merger. Effective July 1, 2003, there were no further royalties owed to the Company under the Roche license agreement. In addition, in July 2003, Roche paid the Company $18.6 million in cash for damages arising out of the Maryland contract action. See Note 3 for a description of the presentation of Roche revenue in the accompanying consolidated statements of operations.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Short-Term Investments - Short-term investments consist primarily of corporate debt securities that are classified as "available for sale." These "available for sale" securities, which are all due within one year, are accounted for at their fair market value and unrealized gains and losses on these securities, if any, are reported in accumulated other comprehensive loss in stockholders' equity. As of September 30, 2003, the Company had unrealized losses on "available for sale" securities of approximately $179,000.

The Company uses the specific identification method in computing realized gains and losses on the sale of investments, which are included in results of operations as generated. Any realized gains or losses were not material as of and for the periods ended September 30, 2003 and 2002.

Concentration of Credit Risk - The Company has invested its excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds. The Company invests its excess cash in accordance with a policy objective that seeks to ensure both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on their terms and concentrations by type and issuer. The Company has not experienced any losses on its investments due to credit risk.

Restricted Cash - The Company has a debt service reserve of approximately $1.7 million that is restricted in use and held in trust as collateral (see Note 5).

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 (in thousands):

	September 30, 2003	March 31, 2003
Finished goods	$ 2,050	$ 2,255
Work in process	425	869
Raw materials	2,701	2,345
	$ 5,176	$ 5,469

Equipment and Leasehold Improvements - Equipment and leasehold improvements are carried at cost, less accumulated depreciation and amortization. Depreciation on equipment 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 September 30, 2003.

Warranty Reserve - The Company warrants its products against defects in materials 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.

Warranty reserve activity during the six months ended September 30, 2003 is as follows (in thousands):

Balance at March 31, 2003	$ 250
Provisions recorded	743
Actual costs incurred	(743)
Balance at September 30, 2003	$ 250

Comprehensive Income (Loss) - Comprehensive income (loss) is comprised of net income (loss) and other items of comprehensive income (loss) as follows (in thousands):

	Three Months Ended September 30,		Six Month Septemb	
	2003	2002	2003	
Net income (loss)	$ 13,813	$ (8,342)	$ 6,584	$
Unrealized gain (loss) on available for sale securities	(37)	(72)	78	
Comprehensive income (loss)	$ 13,776	$ (8,414)	$ 6,662	$

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. Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. 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 over the term of the underlying customer contract or at the end of the contract, when obligations under the contract have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Amounts received in advance of performance under contracts are recorded as deferred revenue until earned.

Roche Revenue - Roche revenue is comprised of revenues earned by the Company from Roche, including:

- A fixed monthly fee of $5.0 million for the use of ORIGEN (R) technology. The fixed monthly fee commenced in July 2003 and will be payable to the Company until the completion of the merger,
- Royalties paid under the 1992 license agreement between the Company and Roche for the period through June 30, 2003, which are no longer required as a result of a new agreement between the parties that provides for fixed monthly payments, as described above,
- Fees earned in connection with the Company's performance under an assay development contract with Roche.

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 six months ended September 30, 2003 and 2002.

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

Stock-Based Compensation - The Company has elected to continue 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 its employee stock options. Accordingly, no stock-based employee compensation cost is reflected in net income (loss) for the three and six months ended September 30, 2003 and 2002, as all options granted under those plans had an exercise price equal to the market value of a share of the underlying common stock on the date of the grant.

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

	Three Months Ended September 30,		Six Months Septemb
	2003	2002	2003
Net income (loss), as reported	$ 13,813	$ (8,342)	$ 6,584
Deduct: Total stock-based employee compensation expense determined under fair value method	(773)	(1,138)	(1,564)
Pro forma net income (loss)	$ 13,040	$ (9,480)	$ 5,020
Net income (loss) per common share:			
Basic net income (loss) per common share-as reported	$ 0.57	$ (0.35)	$ 0.28
Basic net income (loss) per common share-pro forma	$ 0.54	$ (0.40)	$ 0.21
Diluted net income (loss) per common share-as reported	$ 0.55	$ (0.35)	$ 0.26
Diluted net income (loss) per common share-pro forma	$ 0.52	$ (0.40)	$ 0.20

The pro forma net income (loss) and net income (loss) per share disclosed above is not likely to be representative of the effects on net income (loss) and net income (loss) per share on a pro forma basis in future years, as future years may include additional grants of options for the Company's stock and continued vesting. In addition, upon completion of the merger, all options for the Company's common stock will become fully vested and will be canceled.

No stock options were granted during the three months ended September 30, 2003. For all other periods presented, the fair value of options for the Company's common stock was estimated at the date of grant using a Black-Scholes option pricing model with the following assumptions:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2003	2002	2003	2002
Expected dividend yield	-	0%	0%	0%
Expected stock price volatility	-	69%	65%	69%
Risk-free interest rate	-	3.6%	2.3%	3.8%
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 September 30, 2002 and the six months ended September 30, 2003 and 2002 was $16.43, $21.09 and $21.37, respectively.

Income (Loss) Per Share - The Company uses SFAS No. 128, "Earnings per Share",

for the calculation of basic and diluted earnings per share. For periods when the Company recorded a loss, the loss has been adjusted by dividends accumulated on the Company's Series B Convertible Preferred Stock (Series B) for all periods during which the Series B was outstanding.

For the three and six months ended September 30, 2002, the Company incurred a net loss; therefore the net loss per common share does not reflect the potential dilution that could occur to common shares related to outstanding stock options, warrants, convertible preferred stock and convertible debentures. The weighted average number of common shares outstanding together with potentially dilutive shares was 25,570,451 and 25,323,420 for the three and six months ended September 30, 2002, respectively.

New Accounting Standards - In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46 provides guidance on variable interest entities and the framework through which an enterprise assesses consolidation of a variable interest entity. FIN 46 was effective immediately for variable interest entities created or acquired after January 31, 2003. In October 2003, the FASB issued Staff Position FIN 46-6, which extended the effective date of FIN 46 for variable interest entities created or acquired before February 1, 2003 to the first interim or annual period ending after December 15, 2003. The Company has adopted FIN 46 and has determined that MSD qualifies as a variable interest entity under FIN 46 because substantially all of MSD's funding is being provided by the Company and the Company's voting rights are not proportional to its obligation to absorb a majority of the potential future losses of MSD. Accordingly, beginning October 1, 2003, the Company will consolidate the financial results of MSD. Consolidation accounting will require certain reclassifications within the Company's consolidated financial statements but is not expected to materially affect its financial position or net loss, as the Company has recorded approximately 100% of MSD's losses.

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 accounting 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 improve financial reporting by requiring that contracts with comparable characteristics be accounted similarly. SFAS 149 is 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 or results of operations.

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 or result of operations.

4. MESO SCALE DIAGNOSTICS JOINT VENTURE

MSD is a joint venture formed by MST and the Company 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 the Company's technology. MST is a company established and wholly-owned by Jacob Wohlstadter, a son of the Company's chief executive officer. In August 2001, the Company 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 Company's board of directors, with the advice of independent advisors and counsel, negotiated and approved the MSD agreements.

As part of the restructuring, the Company will transfer its equity interest in MSD to BioVeris and will assign the MSD agreements to BioVeris. The Joint Venture Oversight Committee (JVOC), a committee of the Company's board of directors, consisting of independent directors, with the advice of independent counsel, negotiated and approved certain agreements with MSD made in connection with the proposed transaction between IGEN and Roche, which amendments include BioVeris's obligation to make a final capital contribution of $37.5 million to MSD following the completion of the merger.

Under the MSD agreements, the Company's funding commitment was based on an annual budget of MSD approved by the JVOC. The JVOC approved funding for MSD by the Company 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%. As of September 30, 2003, the Company's remaining funding commitment to MSD was $5.4 million. This remaining funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. For the six months ended September 30, 2003 and 2002, the Company made total contributions to MSD of $15.3 million and $10.8 million, respectively, including $3.7 million in the current year which related to permitted budget variances from prior years. In addition, in the event the proposed transaction between IGEN and Roche is not completed prior to December 1, 2003, the Company has agreed to provide continued interim funding to MSD, payable monthly on the first day of each month commencing on December 1, 2003 until the earlier to occur of completion of the merger or termination of the merger agreement.

The monthly funding will equal approximately $1.7 million, which is 1/12th of the Company's aggregate funding commitment under the MSD budget for 2003 approved by the JVOC. Any interim funding will reduce the amount of BioVeris's final capital contribution following the completion of the merger.

The Company holds a 31% voting equity interest in MSD and is entitled to a preferred return on $72.2 million of the funds previously invested by it in MSD through September 30, 2003 and on all additional funds invested by it 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.

Under the terms of one of the MSD agreements, the Company granted to MSD a worldwide, perpetual, exclusive license (with certain exceptions) to the Company's technology, including ECL technology, for use in MSD's research program, 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 Company's patents.

During the term of the MSD joint venture agreement, MSD is the Company's and MST's exclusive means of conducting the MSD research program, and the Company is obligated to refrain from developing or commercializing any products, processes or services that are related to the MSD research program in the diagnostic field, as defined for purposes of the MSD agreements, or to MSD's research technologies as described in the MSD agreements, subject to certain exceptions. After the expiration or termination 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.

As part of the merger agreement and related transactions, the Company, BioVeris and MSD agreed that the MSD joint venture agreement will expire on the later of (1) November 30, 2003, or (2) the earlier of (a) the date of the completion of the merger or (b) the termination of the merger agreement. In addition, in accordance with the MSD agreements, MST and MSD have the right to terminate the MSD joint venture agreement prior to its expiration under certain circumstances, including (1) breach of the Company's obligations, including the Company's funding obligations to MSD, (2) MSD's termination of Mr. Jacob Wohlstadter's employment (other than for cause or disability), (3) if Mr. Jacob Wohlstadter is entitled to terminate his employment agreement for good reason (as defined in his employment agreement) or (4) upon a change in control of the Company, as defined. MSD, MST 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 Jacob Wohlstadter employment agreement.

Upon the expiration of the MSD joint venture as a result of the completion of the merger or termination of the merger agreement or the expiration or termination of the MSD joint venture agreement for any other reason, MSD and MST will have the right to purchase the Company's or BioVeris's, as the case may be, entire interest in MSD 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 shall include a determination by appraisers if the parties are unable to agree on fair market value) minus a discount factor varying from 7.5% to 15%. If MSD or MST exercises this right, it will be required to pay the Company or BioVeris, as the case may be, the purchase price, plus simple, cumulated but not compounded interest at the fixed annual rate of 0.5% over the prime rate in effect on the date 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 debt or equity securities in any third-party financing after the date of the sale of the Company's or BioVeris's, as the case may be, interest in MSD. As security for the payment obligation, BioVeris 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 will continue indefinitely.

Following the expiration or termination of the MSD joint venture agreement, MSD will be entitled to continue to lease certain facilities and related equipment

from the Company or BioVeris, as the case may be, (including laboratory facilities located in the Company's corporate headquarters) pursuant to the terms of existing sublease agreements with MSD. The term of each sublease will expire one day prior to the expiration of the prime lease. Following termination or expiration of the MSD joint venture agreement, MSD or the Company (or BioVeris as the case may be) may unilaterally terminate any or all of the subleases by providing at least 18 months' prior written notice of termination. If the Company or BioVeris, as the case may be, elects to terminate a sublease for a facility, MSD may elect to remain in that 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). The Company or BioVeris, as the case may be, has an obligation to MSD to exercise all available extension rights under its lease agreements which are subject to sublease arrangements with MSD. After a notice of termination of a sublease has been sent, MSD will be required to pay its pro rata share of all rent and other expenses incurred by the Company or BioVeris, as the case may be, under the prime lease. MSD and MST may elect, if either exercises its right to purchase the Company's or BioVeris's, as the case may be, interests in MSD, to have its rent 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 and provides for a salary of $250,000 for the year ending December 31, 2003. In addition, Mr. Jacob Wohlstadter is also eligible to receive, at the discretion of the JVOC, an annual cash bonus in an amount not to exceed 20% of his annual salary. During year ended December 31, 2003, Mr. Jacob Wohlstadter is expected to receive $250,000 from his employment at MSD. 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 imposed on payments made or benefits provided pursuant to the agreement. In addition, upon such a termination prior to the expiration of the MSD joint venture agreement, MSD and MST shall have a joint right to purchase the Company's interest in MSD on terms described above.

The Company will be responsible for all amounts payable, costs incurred and other obligations under the employment agreement prior to the termination of the Company's funding obligation to MSD following the completion of the merger, which generally are expected to be paid out of the Company's funding commitment to MSD. MSD, MST and 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 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 Company ceasing to be a member of MSD by reason of the fact that such person is or was a board member or an officer of MSD.

Since inception of the MSD joint venture, the equity method has been utilized to

account for the investment. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, it was determined that future contributions to MSD would be made based on the future investment benefit to be obtained by it. Therefore, the Company share of MSD losses since July 1, 2001, has been recorded as Equity in Loss of Affiliate. During the three months ended September 30, 2003 and 2002 and the six months ended September 30, 2003 and 2002, operating costs allocated to MSD by the Company in connection with shared personnel and facilities totaled $1.9 million, $3.2 million, $4.1 million and $5.8 million, respectively. These allocated operating costs reduced certain operating costs and expenses and increased Equity in Loss of Affiliate in the accompanying consolidated statements of operations. The Company's investment in affiliate totaled $14.8 million at September 30, 2003. See Note 3 for discussion of consolidation accounting of the MSD investment as of October 1, 2003.

5. NOTE PAYABLE

In March 1999, the Company entered into a debt financing with John Hancock Mutual Life Insurance Company under a Note Purchase Agreement (Notes) from which the Company received $30 million. The 8.5% Senior Secured Notes mature in March 2006 with principal and interest payments of $1.7 million due quarterly through March 2006. Collateral for the debt is represented by royalty payments and rights of the Company to receive monies due pursuant to the Company's license agreement with Roche. Additional collateral is represented by restricted cash (see Note 3), which had a balance of $1.7 million at September 30, 2003. Covenants within the Note include compliance with annual and quarterly Royalty Payment Coverage Ratios, which are tied to royalty payments and debt service.

On July 9, 2003, the Appellate Court affirmed the Company's right to terminate the Roche license agreement and the Company immediately issued a notice confirming termination of that agreement. Termination of the Roche license led to, among other things, termination of the Company's right to receive royalty payments from Roche on its net sales of products based on the Company's ECL technology. As part of the merger and related transactions, Roche is obligated to pay the Company a monthly fee of $5.0 million for the period from July 1, 2003 through the closing of the merger for Roche's use of ECL technology pending completion of the merger (see Notes 2 and 3). Termination of the Roche license agreement is an event of default under the Notes. Pursuant to the agreement under which the Notes were issued, if an event of default has occurred and is continuing, the holder of the Notes may declare all of the Notes immediately due and payable. If accelerated, the Company would be obligated to pay the remaining principal amount due plus accrued interest and a make-whole amount. The holder of the Notes has indicated that it is not planning to declare an event of default or accelerate payment of the Notes pending the closing of the Roche Transaction. As a result of the potential acceleration, the outstanding Notes balance of $15.4 million, as well as the $1.7 million restricted cash collateral, has been reflected as a current liability and current asset, respectively, in the accompanying condensed consolidated balance sheet as of September 30, 2003.

6. SUBORDINATED CONVERTIBLE DEBENTURES

In January 2000, the Company completed a placement of $35.0 million principal amount of Subordinated Convertible Debentures. The 5% debentures, if not converted, were to mature in January 2005 with semi-annual interest payments to be made in cash or an equivalent value of common stock.

In September 2003, all debentures were converted by the holders and the Company issued 1,129,032 shares of common stock, representing a fixed conversion price of $31 per share. Upon conversion, the face value of the debentures totaling $35.0 million was reclassified from liabilities to stockholders' equity and the remaining unamortized discount of approximately $2.4 million was recorded as a non-recurring, non-cash interest expense. In addition, upon conversion, the Company paid $400,000 of accrued interest on the debentures.

As part of this financing, the Company also issued detachable warrants to purchase 282,258 shares of the Company's common stock with an exercise price of $31 per share. Using the Black-Scholes option pricing model and the relative fair value of the warrants and the debentures at the time of issuance, these warrants were valued at approximately $7.0 million. As of September 30, 2003, all warrants remain outstanding.

Following the completion of the merger, the holder of outstanding warrants of the Company will, upon exercise, be entitled to receive from BioVeris the number of shares of BioVeris common stock as if such holder had exercised the warrants for the shares of the Company's common stock issuable upon exercise of the warrants immediately prior to the completion of the merger; and receive from Roche or the Company the amount of cash as if such holder had exercised the warrants for the shares of the Company's common stock issuable upon exercise of the warrants immediately prior to the completion of the merger.

7. STOCKHOLDERS' EQUITY

In connection with the exercise of stock in July 2000, the Company granted a loan to the Company's Chief Executive Officer in the principal amount of $2.1 million, maturing in July 2007. The loan is a 6.62% simple interest (paid annually), full recourse loan against all assets of the borrower, collateralized by the pledge of 100,000 shares of the Company's common stock owned by the borrower. Upon completion of the proposed merger with Roche, this loan will become immediately due.

8. LITIGATION

Roche

In 1997, the Company filed a lawsuit, which is referred to as the Roche litigation, against Roche in the U.S. District Court for the District of Maryland (District Court). The lawsuit arose out of the Roche license agreement, under which the Company licensed to Roche certain rights to develop, manufacture and sell diagnostic products based on the Company's ORIGEN technology. In the Roche litigation, the Company alleged, among other things, that Roche failed to perform certain material obligations under the Roche license agreement and engaged in unfair competition against the Company.

The jury trial in this litigation was completed in January 2002, and the jury rendered a verdict that Roche had materially breached the license agreement, had violated its duty to the Company of good faith and fair dealing, and had engaged in unfair competition against the Company. In February 2002, the District Court issued a final order of judgment that confirmed the jury's decisions to award $105 million in compensatory damages and $400 million in punitive damages, entitled the Company to terminate the Roche license agreement, and directed Roche to grant to the Company for use in its retained fields a license to certain improvements.

Roche was also ordered, at its sole cost and expense, to deliver such improvements to the Company and to provide all other information and materials required or necessary to enable the Company to commercialize these improvements. Improvements, as defined in the final order of judgment, include Roche's Elecsys 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and certain aspects of Roche's nucleic acid amplification technology called PCR. The final order of judgment also barred Roche from marketing, selling, placing or distributing outside of its licensed field any products, including its Elecsys diagnostics product line, that are based on the Company's ORIGEN technology. In April 2002, the District Court denied Roche's motions challenging the judgment.

Roche appealed certain aspects of the final order of judgment to the U.S. Court of Appeals for the Fourth Circuit (Appellate Court). During the appeal process Roche was obligated to continue to comply with the terms of the Roche license agreement, including its obligation to continue to pay the Company royalties on Roche's sales of royalty bearing products and to share and deliver improvements. Roche's obligation to pay the $505 million of monetary damages awarded to the Company was suspended until completion of the appeal process. On July 9, 2003, the Appellate Court issued its ruling on the Roche appeal. The ruling eliminated damages of $486.8 million previously awarded to the Company by the jury, while affirming $18.6 million in compensatory damages, the Company's right to terminate the license agreement between the companies, and the Company's right to certain improvements in certain fields developed by Roche under the license agreement.

As part of the merger and related transactions, the Company and Roche have entered into an ongoing litigation agreement providing that all litigation between the parties be suspended pending the completion of the merger. The Company has suspended its patent infringement actions against Roche in Maryland and Germany pending completion of the merger, with the right to resume the actions should the merger not be completed. Roche has withdrawn its petition for rehearing before the Appellate Court and both companies have agreed not to file any further appeals of the opinion issued by that court.

Other Proceedings

The Company is involved, from time to time, in various other routine legal proceedings arising out of the normal and ordinary operation of its business, which it does not anticipate will have a material adverse impact on its business, financial condition, results of operations or cash flows.

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations as of September 30, 2003 and for the three and six month periods ended September 30, 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 Annual Report on Form 10-K for the year ended March 31, 2003.

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 that are not statements of historical fact are forward-looking statements. 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 in this quarterly report.

These forward-looking statements are based on management's current expectations, estimates and projections and 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. The forward-looking statements contained in this quarterly report include statements about revenue growth, market acceptance of new products, business operations, trends and changes in financial or operating performance, technology or product plans and the proposed transaction with Roche. 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 factors, among others, could cause actual results to differ materially from those described in the forward-looking statements:

- the failure of our stockholders to approve the proposed merger with Roche;
- the value of the proposed transaction with Roche to our stockholders;
- the inability to satisfy the conditions for the completion of the proposed transaction with Roche;
- the timing of the closing for the proposed transaction with Roche;
- costs relating to the proposed transaction with Roche;
- our relationship with Roche;
- our ability to renew certain ongoing patent litigation if the proposed transaction with Roche is not completed;
- domestic and foreign governmental and public policy changes, particularly related to healthcare costs, that may affect new investments and purchases made by customers;
- availability of financing and financial resources in the amounts, at the times and on the terms required to support our future business;
- protection and validity of patent and other intellectual property rights; and
- changes in general economic, business and industry conditions affecting our business generally.

These and other risk factors are discussed in our annual report on Form 10-K for the year ended March 31, 2003, and BioVeris's registration statement on Form S-4, each filed with the SEC and available at the Investor Relations section of our web site at www.igen.com or the SEC's web site at www.sec.gov. We disclaim any intent or obligation to update any forward looking statements.

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

In connection with the proposed transaction between IGEN and Roche Holding, BioVeris filed with the Securities and Exchange Commission on September 26, 2003, a registration statement on Form S-4 (Registration Statement No. 333-109196) that included the preliminary proxy statement/prospectus relating to the transaction. Investors and security holders are urged to read the preliminary proxy statement/prospectus, which is available now, because it contains important information and also to read the definitive proxy statement/prospectus, when it becomes available, because it will contain important information. BioVeris and IGEN will continue to file with the SEC documents regarding the proposed transaction with Roche Holding, including one or more amendments to the registration statement on Form S-4. After the registration statement on Form S-4, as amended, is declared effective by the SEC, the definitive proxy statement/prospectus will be mailed to IGEN stockholders in connection with a special meeting of IGEN stockholders to vote on the proposed transaction and any other matters that might be properly brought before the meeting. Investors and security holders may obtain a free copy of the preliminary proxy statement/prospectus and the definitive proxy statement/prospectus (when it becomes available) and other documents filed by BioVeris and IGEN with the SEC at the SEC's web site at www.sec.gov. The definitive proxy statement/prospectus (when it becomes available) and these other documents may also be obtained for free from IGEN by directing a request to IGEN International, Inc., 16020 Industrial Drive, Gaithersburg, MD 20877, (301) 869-9800, Attention: Secretary.

We, BioVeris, and our respective directors and executive officers may be considered participants in the solicitation of proxies from our stockholders in connection with the proposed transaction with Roche. Such individuals may have interests in the proposed transaction with Roche, including as a result of holding shares of our common stock or our stock options as well as other interests unrelated to such holdings. Information about our directors and executive officers and their ownership of our common stock is set forth in our Proxy Statement with respect to our Annual Meeting for the year ended March 31, 2003. Additional information about our directors and executive officers, BioVeris's directors and officers and their ownership of our common stock and expected ownership of BioVeris common stock and other interests in the proposed transaction with Roche is set forth in the preliminary proxy statement/prospectus relating to the proposed transaction and will be set forth in the definitive proxy statement/prospectus relating to the proposed transaction when it becomes available.

Roche Transaction

On July 24, 2003, IGEN and Roche jointly announced that they had reached definitive agreements pursuant to which Roche will acquire us and we will simultaneously distribute the common stock of a new company, BioVeris, to our stockholders. The transaction will occur in the following steps:

- We will restructure our operations so that BioVeris, a newly formed wholly-owned subsidiary of IGEN, will assume our biodefense, life sciences and industrial product lines as well as our opportunities in the clinical diagnostics and healthcare fields, and will own our intellectual property, our equity interest in Meso Scale Diagnostics, LLC. (MSD), cash and certain other rights and licenses currently held by us; and

- A wholly-owned subsidiary of Roche will merge with and into us, as a result of which we will become a wholly-owned subsidiary of Roche and BioVeris will become an independent, publicly-traded company owned by our stockholders. Simultaneously with the completion of the merger, certain ongoing commercial agreements between BioVeris and certain affiliates of Roche will become effective.

The obligations of the parties to complete the merger are subject to certain conditions, including the adoption of the merger agreement by our stockholders, the receipt by us of a solvency opinion substantially to the effect that BioVeris will not be insolvent after giving effect to the merger and related transactions and the execution and delivery of the ongoing commercial agreements, and that Roche will have loaned us up to $214 million, such loan remaining the obligation of IGEN following the completion of the merger. All our cash on hand will be transferred to BioVeris as part of the restructuring.

Upon completion of the merger, each outstanding share of our common stock will be converted into the right to receive $47.25 in cash, without interest, and one share of BioVeris common stock. In addition, upon completion of the merger, all outstanding options granted under our stock option plans, including unvested options, will be canceled and the holder of any such options will have 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 (without interest) and one share of BioVeris common stock.

Effective simultaneously with the completion of the merger, Roche will hold a new worldwide, non-exclusive, fully-paid, royalty-free, license under patents and technology that relate to detection methods and systems which employ electrochemiluminescence (ECL) technology, but specifically excluding technology related to gene amplification or compounds composed of or capable of binding with nucleotides. The license may be used only in a specific field, generally described here as the human in vitro diagnostics field, to develop, make, reproduce, modify, use, sell and otherwise commercially exploit specified products. Our rights, as licensor under the license agreement, will be transferred to BioVeris as part of the restructuring.

As part of the merger and related transactions, we and Roche have entered into an ongoing litigation agreement providing that all litigation between the parties be suspended pending the completion of the merger (see Note 8). As partial consideration for the ongoing litigation agreement and for Roche's use of ORIGEN technology pending completion of the merger, Roche is obligated to pay us a fixed monthly fee of $5.0 million which commenced in July 2003, and will be payable until the completion of the merger. Effective July 1, 2003, there were no further royalties owed to us under the Roche license agreement. In addition, in July 2003 Roche paid us $18.6 million in cash for damages arising out of the Maryland contract action.

Overview

We and our licensees develop, manufacture and market products based on our electrochemiluminescence technology, which we call ORIGEN. We believe that our ORIGEN technology, which permits the detection and measurement of biological substances, offers significant advantages over competing detection and measurement methods by providing a unique combination of speed, sensitivity, flexibility and throughput in a single technology platform. Our ORIGEN technology is incorporated into our and our licensees' instrument systems and reagents, which are the fluids used in the performance of tests, or assays, on such instrument systems. In addition, we offer assay development and other services used to perform analytical testing.

Our strategy for our ORIGEN technology has been and continues to be based on entering into license arrangements and collaborations with third parties that can assist in our commercialization efforts while at the same time directly developing and commercializing our own products.

License Arrangements and Collaborations. We have entered into license arrangements and collaborations with established health care companies to commercialize our ORIGEN technology for clinical testing, which is the diagnostic testing of patient samples to measure the presence of disease and monitor medical conditions. Our licensees have developed multiple product lines for this market based on our ORIGEN technology, and have sold or placed approximately 9,000 ORIGEN-based systems with customers worldwide.

These sales and placements have been made predominantly by Roche, which uses our ORIGEN technology for certain segments of the clinical testing market and is the world's leading provider of clinical testing products. Roche has adopted our ORIGEN technology for its Elecsys immunodiagnostic product line (see Roche Transaction above).

Direct Commercialization Efforts. We also directly develop and commercialize our ORIGEN technology. We have developed, and continue to develop, ORIGEN-based products for the following worldwide markets. Many of our instruments and assays have been and are being designed to serve customers across multiple markets.

- Biodefense and Industrial Testing - We are commercializing our ORIGEN technology for use in the emerging markets for biodefense and industrial testing. The biodefense market includes products for the detection of bacteria, viruses and toxins that may pose a military or public health threat.

  Over the past year, we have worked with numerous departments within the Department of Defense (DOD) and other U.S. government agencies to develop ORIGEN-based products for the detection of biological agents such as anthrax, staphylococcus enterotoxin B and botulinum toxin, among others. We are also commercializing our ORIGEN technology for use in the emerging industrial market for the detection of foodborne and waterborne disease causing pathogens. We have begun to sell our first products for this market, the PATHIGEN panel of tests for E. coli O157, Salmonella, Campylobacter and Listeria, which we sell primarily as a quality control test method to food producers, food processors and contract laboratories for the food industry.

- Life Science - We are commercializing our ORIGEN technology for use in drug discovery and development that is performed by pharmaceutical and biotechnology companies, universities and other research

organizations. Certain of our ORIGEN-based systems are used by pharmaceutical and biotechnology companies in all phases of drug discovery, including:

- validating targets identified through genomics;
- screening of large numbers of compounds generated through combinatorial chemistry;
- re-testing and optimization of lead compounds; and
- clinical trial testing of drug candidates.

We believe the ORIGEN-based systems used in this market provide a number of advantages relative to other drug discovery technologies, including enhanced sensitivity and greater ease and speed of assay formatting.

- Clinical Testing - We are developing our ORIGEN technology to be used in certain fields in the clinical testing market, particularly to perform tests in decentralized sites outside of central hospital laboratories and clinical reference laboratories. Our present strategy is to focus our product development efforts on patient care centers such as physicians' offices, ambulatory clinics, hospital emergency rooms, surgical and intensive care units, hospital satellite laboratories and nurses' stations.

We believe our ORIGEN technology permits development of a system that can provide accurate results to a physician rapidly, thereby permitting the physician to make a more timely decision regarding the patient's course of treatment.

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

- the volume and timing of orders from our customers for biodefense products, M-SERIES systems or other products, which orders are placed from time to time by our customers based on their needs;
- the timing of instrument deliveries and installments, which are generally delivered and installed shortly after the instrument is ordered;
- 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 product sales based on the success of the product for the customer;
- the amount of revenue recognized from royalties and other contract revenues, which revenues are dependent upon the efforts of our licensees and collaborators;
- whether our instruments are sold or leased to customers, which will affect the timing of the recognition of revenue from the sale or lease;
- the timing of our introduction of new products, which could involve increased expenses associated with product development and marketing;

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

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

- the amount of expenses we incur in connection with the operation of our business, including costs associated with the Roche merger and related transactions, research and development costs, which increases or decreases based on the products in development and sales and marketing costs, which is based on products being introduced or promoted from time to time;

- the volume of sales to POL customers pending the transfer of such customers' contracts back to Roche on consummation of the Roche merger and related transactions;

- 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;

- our share of losses in MSD which are based on the operations of MSD over which we have limited control, which for the three and six months ended September 30, 2003 totaled $4.5 million and $9.7 million, respectively, compared to $5.0 million and $9.5 million for the three and six months ended September 30, 2002;

- the continued supply of the materials that we use in our products; and

- our manufacturing capabilities.

We have experienced significant operating losses each year since inception and expect those losses to continue. Losses have resulted from a combination of lower royalty revenue than we believe we were entitled to under the Roche license agreement, costs incurred in research and development, Roche litigation costs, our share of losses in affiliate, selling costs and other general and administrative costs. We expect to incur additional operating losses as a result of increases in expenses for manufacturing, marketing and sales capabilities, research and product development, general and administrative costs and equity in loss of affiliate, offset in part by lower Roche litigation costs and the $18.6 million court judgment Roche paid to us in connection with the Maryland contract litigation.

Our ability to become profitable in the future will be affected by, among other things, our ability to expand the commercialization 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 existing collaborations or establish successful new collaborations with corporate partners to develop and commercialize products that incorporate our technologies.

For a description of the BioVeris business, you should refer to the registration

statement on Form S-4 filed in connection with the proposed transaction between IGEN and Roche.

Results of Operations

Quarter and Six Months Ended September 30, 2003 and 2002.

Revenues. Total revenues were $40.4 million and $57.5 million for the quarter and six months ended September 30, 2003, an increase of $27.0 million and $32.1 million, respectively, from $13.4 million and $25.4 million for the corresponding prior year periods. The revenue growth was due primarily to the $18.6 million court judgment Roche paid to us in connection with the Maryland contract litigation between the companies, as well as to increases in product sales and revenue from Roche Diagnostics (Roche revenue).

Roche revenue is comprised of revenues earned by us from Roche, including:

- A fixed monthly fee of $5.0 million for the use of ORIGEN technology. The fixed monthly fee commenced in July 2003 and will be payable to us until the completion of the merger;
- Royalties paid under the 1992 license agreement between us and Roche for the period through June 30, 2003, which are no longer required as a result of a new agreement between the parties that provides for fixed monthly payments, as described above;
- Fees earned in connection with our performance under an assay development contract with Roche.

Roche revenue was $15.3 million and $26.7 million for the quarter and six months ended September 30, 2003, an increase of $6.9 million and $10.1 million, respectively, from $8.4 million and $16.6 million for the corresponding prior year periods. These increases were primarily due to the $5.0 million monthly fee, which was greater than royalties earned for quarters through June 30, 2003.

Product sales were $6.2 million and $11.6 million for the quarter and six months ended September 30, 2003, an increase of $1.5 million (31%) and $3.3 million (40%), respectively, from $4.7 million and $8.3 million for the corresponding prior year periods. This growth in product sales was primarily from sales of biodefense products which increased $1.1 million and $2.1 million to $1.9 million and $3.3 million for the quarter and six months ended September 30, 2003, as well as sales of products for the life science market which increased $500,000 and $1.3 million to $3.8 million and $7.1 million for the quarter and six months ended September 30, 2003. We anticipate continued increases in biodefense related sales as a result of our ongoing biodefense initiatives. We have a contract with the DOD which we entered into in June 2003, for the production of tests for the detection of specific toxins in environmental samples. Under the contract the government may, at its option, make purchases of up to $23.0 million over a period of up to four years, with up to $7.0 million of product sales through June 2004, of which $1.7 million were sold during the quarter ended September 30, 2003. For each contract year after June 2004, the DOD, at its option, may elect to purchase products from us but has no obligation to do so. Sales to physician office laboratory (POL) customers were approximately $500,000 and $1.2 million for the quarter and six months ended September 30, 2003, a decrease of approximately $100,000 in each respective period. These POL customers are being served by us under the terms of a court order related to Roche selling outside their licensed field and these customers will remain with IGEN when the proposed Roche transaction is completed.

Royalty and contract fees that are unrelated to Roche were $300,000 and $600,000 for the quarter and six months ended September 30, 2003, respectively, unchanged from the corresponding prior year periods. These fees relate primarily to royalties received in connection with license arrangements for ORIGEN technology with Eisai and BioMerieux.

Operating Costs and Expenses. Product costs were $3.5 million (57% of product sales) and $6.2 million (53% of product sales) for the quarter and six months ended September 30, 2003, and $2.2 million (47% of product sales) and $3.5 million (43% of product sales) for the corresponding prior year periods. Product costs, as a percentage of product sales in the current year, increased due to costs incurred in connection with the launch of our new M-SERIES 384 instrument and upgrades of detection modules for our existing life science customers.

Research and development expenses were $5.1 million and $10.5 million for the quarter and six months ended September 30, 2003, a decrease of $1.2 million (20%) and $1.6 million (13%), respectively, from $6.3 million and $12.1 million in the corresponding prior year periods. This decrease was due primarily to lower personnel and facilities costs for development projects. Research and development expenses relate primarily 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 clinical point-of-care products. We expect research and development costs to increase as product development and core research continue to expand, including costs associated with our efforts in developing biodefense testing products.

Selling, general and administrative expenses were $5.9 million and $12.0 million for the quarter and six months ended September 30, 2003, a decrease of $400,000 (7%) and 300,000 (2%), respectively, from $6.3 million and $12.3 million for the corresponding prior year periods. These decreases were primarily attributable to lower personnel costs in the current year periods.

Costs related to our litigation and the proposed transaction with Roche, which include financial and legal advisory fees were $4.3 million and $7.9 million for the quarter and six months ended September 30, 2003, an increase of $3.4 million and $5.9 million, respectively, from $900,000 and $2.0 million for the corresponding prior year periods. These increases reflect costs incurred related to the continuing Roche litigation, patent infringement actions filed by us against Roche in the United States and Europe, and legal fees and related costs associated with the proposed transaction with Roche.

Interest and Other Expense. Interest and other expense, net of interest income, were $3.4 million and $4.6 million for the quarter and six months ended September 30, 2003, an increase of $2.4 million and $2.9 million, respectively, from $1.0 million and $1.7 million in the corresponding prior year periods. These increases resulted primarily from a one-time, non-cash interest charge of approximately $2.4 million related to the unamortized debt discount on the convertible debentures that were converted in September 2003 into our common stock.

Equity in Loss of Affiliate. MSD is a joint venture formed by MST and us 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 our technology. In conjunction with entering into the MSD agreements and taking into account the progress made by MSD in the development of its products, we determined that future contributions to MSD would be made based on the future investment benefit we expect to obtain. Accordingly, our contributions to MSD

since July 1, 2001 have been recorded as Investment in Affiliate and as substantially all of MSD's funding was provided by IGEN, we have recorded approximately 100% of MSD's losses as Equity in Loss of Affiliate. For the quarter and six months ended September 30, 2003, our Equity in Loss of Affiliate was $4.5 million and $9.7 million compared to $5.0 million and $9.5 million in the corresponding prior year periods. MSD's losses changed during the quarter and six months ended September 30, 2003 due to its transition from a development stage entity to an operating company. MSD had not commenced commercial operations during the six months ended September 30, 2002 and its product sales commenced in October 2002. The changes in MSD's losses during the quarter and six months ended September 30, 2003 result primarily from increases in sales and marketing expenses offset by the growth in revenues.

As of September 30, 2003, MSD had cash and short-term investments of $5.0 million with working capital of $8.6 million. During the six months ended September 30, 2003, MSD used $2.7 million for the purchase of inventory and $2.4 million for the purchase of property, equipment and leasehold improvements. See "Liquidity and Capital Resources" for a discussion of our future funding commitments to MSD.

Net Income (Loss). The net income was $13.8 million ($0.57 per basic common share and $0.55 per diluted common share) for the quarter compared to a net loss of $8.3 million ($0.35 per basic and diluted common share, after consideration of the effect of preferred dividends) in the corresponding prior year quarter. The net income was $6.6 million ($0.28 per basic common share and $0.26 per diluted common share) for the six months ended September 30, 2003 compared to a net loss of $15.7 million ($0.68 per basic and diluted common share, after consideration of the effect of preferred dividends) in the corresponding prior year period. The earnings improvement from the prior periods is primarily due to the $18.6 million Roche litigation judgment, increased Roche revenue and growth in product sales.

Liquidity and Capital Resources

We have financed operations through the sale of preferred and common stock, debt financings and the placement of convertible debentures. In addition, we have received funds from research and licensing agreements, sales of our ORIGEN line of products and royalties from product sales by licensees. As of September 30, 2003, we had $49.8 million in cash, cash equivalents and short-term investments with working capital of $34.7 million.

Net cash provided by operations was $33.3 million for the six months ended September 30, 2003 compared to net cash used in operations of $8.7 million for the corresponding prior year period. This increase in cash provided was primarily due to our net income in the current period. We have made a commitment with a supplier to purchase approximately $800,000 of instrumentation through January 2004, primarily for use in supplying our biodefense customers.

We used $900,000 and $2.0 million of cash for the acquisition of equipment and leasehold improvements during the six months ended September 30, 2003 and 2002, respectively, and our investments in MSD were $15.3 million and $10.8 million during the same respective periods. We believe 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 in negotiations 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. If we were unable to fund such commitments, we may have to scale back or even eliminate some programs or plans.

Net cash used for financing activities was $1.5 million and $3.9 million for the six months ended September 30, 2003 and 2002, respectively. These uses of funds were due to debt service of $2.7 million and $2.5 million, for the six months ended September 30, 2003 and 2002, respectively, offset by the issuance of common stock from the exercise of stock options that provided proceeds of $1.2 million and $400,000, for the six months ended September 30, 2003 and 2002, respectively. The prior year period also included Series B Convertible Preferred Stock dividend payments of $3.4 million and the receipt of $1.6 million resulting from the repayment of a loan. During the year ended March 31, 2003, all shares of Series B Convertible Preferred Stock were converted into common stock and there are no remaining shares of Series B Convertible Preferred Stock outstanding.

As of September 30, 2003, our material future obligations were as follows:

		Six Months Ended March 31,	Years Ended		
Contractual Obligations (in thousands)	Total	2004	2005	2006	200
Notes payable	$15,361	$15,361	$ -	$ -	$
MSD funding commitment	5,354	5,354	-	-	
Operating and capital leases	5,209	1,205	2,334	654	35
Total contractual obligations	$25,924	$21,920	$ 2,334	$ 654	$ 35

MSD is a joint venture formed by MST and us in 1995. Under the MSD agreements, our funding commitment is based on an annual budget of MSD approved by a committee of our board of directors consisting of independent directors (JVOC). The JVOC approved funding for MSD by us 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%. As of September 30, 2003, our remaining funding commitment to MSD was $5.4 million. IGEN's funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. For the six months ended September 30, 2003 and 2002, we made total contributions to MSD of $15.3 million and $10.8 million, respectively, including $3.7 million in the current period which related to the permitted budget variances from prior years. Operating leases in the table above excludes amounts expected to be allocated to MSD to meet a portion of our funding commitment. In addition, in the event the merger is not completed prior to December 1, 2003, we have agreed to provide continued interim funding to MSD, payable monthly on the first day of each month commencing on December 1, 2003 until the earlier to occur of completion of the merger or termination of the merger agreement. The monthly funding will equal approximately $1.7 million, which is 1/12th of our aggregate funding commitment under the 2003 MSD budget approved by the JVOC. Any

interim funding will reduce the amount of BioVeris's final capital contribution following completion of the merger. Upon completion of the merger, the MSD joint venture agreement will expire. Following completion of the merger, BioVeris will use its cash to make a final capital contribution of $37.5 million to MSD. Of the final capital contribution of $37.5 million, any amount in excess of $30 million will be funded by IGEN's and BioVeris's chairman and chief executive officer through the purchase of shares of BioVeris Series B preferred stock that will economically mirror the Class C interests in MSD to be held by BioVeris. BioVeris's obligation to make this final capital contribution to MSD is separate from IGEN's obligation to provide funding to MSD through November 30, 2003, as described above.

We hold 31% voting equity interest in MSD and are entitled to a preferred return on $72.2 million of the funds previously invested by us in MSD through September 30, 2003 and on all additional funds invested by us 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.

As part of the merger and related transactions, we, BioVeris and MSD agreed that the MSD joint venture agreement will expire on the later of (1) November 30, 2003, or (2) the earlier of (a) the date of the completion of the merger or (b) the termination of the merger agreement. We, BioVeris and MSD also agreed that funding for MSD would not be extended other than pursuant to the agreements related to the merger and related transactions. In addition, in accordance with the MSD agreements, MST and MSD have the right to terminate the MSD joint venture agreement prior to its expiration under certain circumstances, including (1) breach of our obligations, including our funding obligations to MSD, (2) MSD's termination of Jacob Wohlstadter's employment (other than for cause or disability), (3) if Jacob Wohlstadter is entitled to terminate his employment agreement for good reason (as defined in his employment agreement) or (4) upon a change in control of us, as defined. MSD, MST and 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 Jacob Wohlstadter employment agreement.

Upon the expiration of the MSD joint venture agreement as a result of the completion or termination of the proposed transaction with Roche or the expiration or termination of the MSD joint venture agreement for any other reason, MSD and MST have the right to purchase our or BioVeris's, as the case may be, entire interest in MSD 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 shall include a determination by appraisers if the parties are unable to agree on fair market value) minus a discount factor varying from 7.5% to 15%. If MSD or MST exercises this right, it will be entitled to pay us or BioVeris, as the case may be, the purchase price, plus simple, cumulated but not compounded, interest at the fixed annual rate of 0.5% over the prime rate in effect on the date 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 debt or equity securities in any third-party financing after the date of the sale of our or BioVeris's, as the case may be, interest in MSD. As security for the payment obligation, BioVeris 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 or termination of the MSD joint venture agreement, MSD will be entitled to continue to lease certain facilities and related equipment from us or BioVeris, as the case may be, (including laboratory facilities located in our corporate headquarters) pursuant to the terms of 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. Following termination or expiration of the MSD joint venture agreement, we, BioVeris, as the case may be, or MSD unilaterally may terminate any or all of the subleases by providing at least 18 months prior written notice of termination. If we or BioVeris, as the case may be, elects to terminate a sublease for a facility, MSD may elect to remain in that 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 extenstions of the prime lease). We or BioVeris, as the case may be, have an obligation to MSD to exercise all available extension rights under lease agreements which are subject to sublease arrangements with MSD. After a notice of termination of a sublease has been sent, MSD will be required to pay its pro rata share of all rent and other expenses incurred by us or BioVeris, as the case may be, under our prime lease. MSD and MST may elect, if either exercises its right to purchase our or BioVeris's, as the case may be, interests in MSD, to have its rent and expense payment obligations for the 18 month period included in the purchase price of those interests in MSD.

Following the expiration of the MSD joint venture agreement, many of our or BioVeris's, as the case may be, licenses and other arrangements with MSD and MST will continue indefinitely in accordance with their terms.

MSD has an employment agreement with Jacob Wohlstadter, its President and Chief Executive Officer, the current term of which runs through November 30, 2004, and provides for a salary of $250,000 for the year ending December 31, 2003. In addition, Jacob Wohlstadter is also eligible to receive, at the discretion of an independent committee of our board of directors, an annual cash bonus in an amount not to exceed 20% of his annual salary. Jacob Wohlstadter is also entitled to receive pension, welfare and fringe benefits comparable to those received by senior executives of IGEN and other insurance and retirement benefits. If MSD terminates the employment agreement without cause, or Jacob Wohlstadter terminates the employment agreement for good reason (which includes a "change in control" of IGEN, as defined), Jacob Wohlstadter shall 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. In addition, he is entitled to a gross-up for any "parachute" excise tax that may be imposed on payments made or benefits provided pursuant to the agreement. We are responsible for all amounts payable, costs incurred and other obligations under the employment agreement, which generally are expected to be paid out of our funding commitment to MSD.

Under the terms of our ongoing litigation agreement with Roche, we have agreed, pending the completion of the proposed Roche transaction, to stay the enforcement of our termination rights under the Roche license agreement and the pending patent infringement actions that we filed against Roche in the United States and Germany. In the event the proposed Roche transaction is not completed, we may, at our option, enforce termination of the license agreement and resume our patent infringement actions against Roche. If the Roche transaction is not consummated and the monthly payments of $5.0 million from Roche to us under our ongoing litigation agreement were to cease, our results of operations and cash flows would be materially adversely affected unless, and until, we enter into one or more strategic partnerships with other companies

that are able to develop and commercialize diagnostic instruments in a manner that provides comparable revenues to us.

While we are highly confident that the proposed Roche transaction will close, we cannot assure you that it will be completed or that, if not completed, we will be able to enter into one or more strategic partnerships on favorable terms, if at all.

We have a substantial amount of indebtedness, and there is a possibility that we may be unable to generate cash or arrange financing sufficient to pay the principal of, interest on and other amounts due with respect to indebtedness when due, or in the event any of it is accelerated. In addition, our indebtedness may require that we dedicate a substantial portion of our expected cash flow from operations to service indebtedness, which would reduce the amount of expected cash flow available for other purposes, including working capital and capital expenditures.

On July 9, 2003, the Appellate Court affirmed our right to terminate the Roche license agreement and we immediately issued a notice confirming termination of that agreement. Termination of the Roche license agreement led to, among other things, termination of our right to receive royalty payments from Roche on its net sales of products based on our ECL technology. In conjunction with the proposed Roche transaction, Roche is paying a fixed fee of $5.0 million per month to us for the use of ECL technology pending completion of the proposed Roche transaction.Termination of the Roche license agreement is an event of default under the 8.5% Senior Secured Notes (Notes). Pursuant to the agreement under which the Notes were issued, if an event of default has occurred and is continuing, the holder of the Notes may declare all of the Notes immediately due and payable. If accelerated, we would be obligated to pay the remaining principal amount due of $15.4 million as of September 30, 2003, plus accrued interest and a make-whole amount. The holder of the Notes has indicated that it is not planning to declare an event of default or accelerate payment of the Notes pending the closing of the proposed Roche transaction. We intend to repay in full the Notes prior to the completion of the proposed Roche merger and related transactions.

We need substantial amounts of money to fund operations. In this regard, from time to time we 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 up-front fees or payments. In the event that the proposed Roche transaction did not close, we would evaluate the advisability and feasibility of a variety of financing alternatives, including issuance of additional debt or equity securities.

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 failure to complete the proposed Roche transaction, the volatility of the price of our common stock, continuing losses from operations, establishment of new business arrangements, the status of new product launches, general market conditions and other factors.

We believe that our existing capital resources, together with revenue from each monthly fee from Roche and other royalties, product sales and contract fees will be adequate to fund operations through the middle of calendar year 2004. If we are unable to raise additional capital, or in the event the proposed Roche

transaction was not completed, we may have to scale back, or even eliminate, some programs. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures or collaborations, on terms that may not be favorable to us.

As of September 30, 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 our management. As a result, they are subject to an inherent degree of uncertainty. In applying those policies, our management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. These estimates are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our customers, and information available from other outside sources, as appropriate. Our significant accounting polices include:

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

Product sales revenue is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed and determinable, collectibility is reasonably assured and the product is shipped to the customer thereby transferring title and risk of loss. Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. 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 over the term of underlying customer contract or at the end of the contract, when obligations have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Amounts received in advance of performance under contracts are recorded as deferred revenue until earned.

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

Joint Venture Accounting - We account for our ownership in the MSD joint venture based 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 own 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 MSD 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 effect our financial position or net loss.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46 provides guidance on variable interest entities and the framework through which an enterprise assesses consolidation of variable interest entities. We have adopted FIN 46 and have determined that MSD qualifies as a variable interest entity under FIN 46 because substantially all of MSD's funding is being provided by us and our voting rights are not proportional to our obligation to absorb a majority of the potential future losses of MSD. Accordingly, beginning October 1, 2003, we will consolidate the financial results of MSD. Consolidation accounting will require certain reclassifications within our consolidated financial statements but is not expected to materially effect our financial position or net loss as we have recorded approximately 100% of MSD's losses. See Recent Accounting Pronouncements below.

Available For Sale Securities - Our short-term investments consist primarily of corporate debt securities that classified as "available for sale". These securities, which are all due within one year, have readily determinable fair values accounted or at their fair market value in the balance sheets, and unrealized gains and losses on these securities, if any, are reported in accumulated other comprehensive loss in stockholders' equity until realized. All of our "available for sale" securities are included in current assets as management considers the securities readily available to fund current operations.

If we held investments that were classified as "held-to maturity" securities, these would be carried at amortized cost rather than at fair market value. If we held investments that were classified as "trading" securities, these would be carried at fair market value, with a corresponding adjustment to earnings for any change in fair market value.

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

Evaluation of Long-lived Assets - We have different long-lived assets recorded on our balance sheet that include equipment and leasehold improvements, investments and other assets. We evaluate the potential impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. In evaluating the recoverability of an asset, management's policy is to compare the carrying amount of an asset with the projected undiscounted future cash flow. While management believes that estimates are reasonable and that no impairment of these assets exists, different assumptions could affect these evaluations and result in impairment charges against the carrying value of these assets.

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

Capitalized Software Costs - We capitalize software development costs incurred after technological feasibility is established 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 January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN 46). FIN 46 provides guidance on variable interest entities and the framework through which an enterprise assesses consolidation of a variable interest entity. FIN 46 was effective immediately for variable interest entities created or acquired after January 31, 2003. In October 2003, the FASB issued Staff Position FIN 46-6, which extended the effective date of FIN 46 for variable interest entities created or acquired before February 1, 2003 to the first interim or annual period ending after December 15, 2003. We have adopted FIN 46 and have determined that MSD qualifies as a variable interest entity under FIN 46 because substantially all of MSD's funding is being provided by us and our voting rights are proportional to our obligation to absorb a majority of the potential future losses of MSD. Accordingly, beginning October 1, 2003, we will consolidate the financial results of MSD. Consolidation accounting will require certain reclassifications within our consolidated financial statements but is not expected to materially affect our financial position or net loss, as we have recorded approximately 100% of MSD's losses.

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 accounting 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 improve financial reporting by requiring that contracts with comparable characteristics be accounted similarly. SFAS 149 is 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 or results of operations.

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 our financial position or result of operations.

ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Changes in interest rates do not affect interest expense incurred on our long-term borrowing because it bears interest at a fixed rate. The principal terms of this debt are as follows:

- Note payable with John Hancock Life Insurance Company: $30 million principal ($15.4 million principal at September 30, 2003), 8.5% Senior Secured Notes secured by future royalty revenue from Roche, maturing in March 2006 with quarterly principal and interest payments. (See Item 1- Notes to Condensed Consolidated Financial Statements- Note 5)

However, we run a risk that market rates will decline and that the interest rate will exceed those based on the then-current market rate. We are currently not using interest rate derivative instruments to manage our exposure to interest rate changes.

Interest income earned on our investment portfolio is affected by changes in the general level of interest rates. We have invested excess cash generally in securities of the U.S. Treasury, money market funds, certificates of deposit and corporate bonds.

We invest excess cash in accordance with a policy approved by our board of directors. This policy is designed to provide both liquidity and safety of principal. The policy limits investments to certain types of instruments issued by institutions with strong investment grade credit ratings and places restrictions on our investments by terms and concentrations by type and issuer.

Given the amount invested as of September 30, 2003, a 1% change in the LIBOR rate would not have a material effect on our interest income.

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

ITEM 4: CONTROLS AND PROCEDURES

IGEN management, including the Chairman of the Board & Chief Executive Officer

(serving as the principal executive officer) and Chief Financial Officer, have conducted an evaluation of the effectiveness of disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chairman of the Board & Chief Executive Officer and the Chief Financial Officer have concluded that the disclosure controls and procedures are effective in ensuring that all material information required to be filed in this quarterly report has been made known to them in a timely fashion. There have been no significant changes in internal controls, or in other factors that could significantly affect internal controls during the quarter ended September 30, 2003 or subsequent to the date the Chairman of the Board & Chief Executive Officer and the Chief Financial Officer completed their evaluation.

PART II OTHER INFORMATION

Item 1: Legal Proceedings

The information required under this item is incorporated herein by reference to Part I, Item 1 - Notes to Consolidated Financial Statements - Note 8.

Item 3: Default Upon Senior Secured Notes

The information required under this item is incorporated herein by reference to Part I, Item 1 - Notes to Consolidated Financial Statements - Note 5.

Item 5: Other Information

On July 29, 2003, the Company filed with the SEC its proxy statement for the 2003 annual meeting of shareholders. As disclosed in the proxy statement, the date for the 2003 annual meeting of shareholders has been set for December 15, 2003 and the record date for the annual meeting has been fixed at November 4, 2003. The Company may decide to postpone or cancel the annual meeting based on the expected date for completion of the proposed Roche transaction. The Company will notify shareholders in a timely manner of any postponement or cancellation of the annual meeting by filing a Form 8-K with the SEC prior to the scheduled date.

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

(a) Exhibits:

2.1(1) Agreement and Plan of and Merger dated as of July 24, 2003, among Roche Holding Ltd, 66 Acquisition Corporation II, IGEN International, Inc. and IGEN Integrated Healthcare, LLC.

10.1(2) License Agreement dated as of July 24, 2003, by and between IGEN International, Inc. and IGEN LS LLC.

10.2(2) Improvements License Agreement dated as of July 24, 2003, by and between Roche Diagnostics GmbH and IGEN International, Inc.

10.3(2) Covenants Not to Sue dated as of July 24, 2003, among IGEN Integrated

Healthcare, LLC, Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., Roche Diagnostics GmbH, Roche Holding Ltd and IGEN LS LLC.

10.4(2) License Agreement (Human IVD, Veterinary IVD, HLA Typing, Paternity, DNA Manufacturing and Plasma Testing) dated as of July 24, 2003, among IGEN Integrated Healthcare, LLC, F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Roche Molecular Systems, Inc.

10.5(2) License Agreement (Human IVD Services and Animal Diagnostic Services) dated as of July 24, 2003, among IGEN Integrated Healthcare, LLC, F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH and Roche Molecular Systems, Inc.

10.6(1) Restructuring Agreement dated as of July 24, 2003, between IGEN International, Inc. and IGEN Integrated Healthcare, LLC.

10.7(1) Post-Closing Covenants Agreement dated as of July 24, 2003, among Roche Holding Ltd, IGEN International, Inc. and IGEN Integrated Healthcare, LLC.

10.8(1) Tax Allocation Agreement dated as of July 24, 2003, among Roche Holding Ltd, 66 Acquisition Corporation II, IGEN International, Inc., and IGEN Integrated Healthcare, LLC.

10.9(1) Ongoing Litigation Agreement dated July 24, 2003, by and between IGEN International, Inc., Roche Diagnostics GmbH and Roche Diagnostics Corporation.

10.10(1) Global Consent and Agreement dated as of July 24, 2003, among Roche Holding Ltd, IGEN International, Inc., IGEN Integrated Healthcare, LLC, Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., Jacob Wohlstadter and JW Consulting Services, L.L.C.

10.11(1) Release and Agreement dated as of July 24, 2003, among IGEN International, Inc., IGEN Integrated Healthcare, LLC, Hyperion Catalysis International, Wellstat Biologics Corporation, Wellstat Therapeutics Corporation, Proteinix Corporation and Integrated Chemical Synthesizers, Inc.

10.12(1) Letter Agreement, dated July 24, 2003, among Meso Scale Diagnostics, LLC., Meso Scale Technologies, LLC., JW Consulting Services, L.L.C., Jacob N. Wohlstadter and IGEN International, Inc.

10.13(1) Letter Agreement, dated July 24, 2003, between Samuel J. Wohlstadter and IGEN Integrated Healthcare, LLC.

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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(1) Previously filed as an exhibit to IGEN International, Inc.'s Current Report on Form 8-K filed July 25, 2003.

(2) Previously filed as an exhibit to IGEN International, Inc.'s Current Report on Form 8-K filed July 28, 2003.

(b) Reports on Form 8-K:

The Company filed the following reports on Form 8-K during the quarter ended September 30, 2003 and through the date of the filing of this quarterly report on Form 10-Q

- Form 8-K filed on October 30, 2003 reporting under items 12 and 7
- Form 8-K filed on September 29, 2003 reporting under items 5 and 7
- Form 8-K filed on July 30, 2003 reporting under items 12 and 7
- Form 8-K filed on July 28, 2003 reporting under items 5 and 7
- Form 8-K filed on July 25, 2003 reporting under items 5 and 7
- Form 8-K filed on July 25, 2003 reporting under item 5
- Form 8-K filed on July 10, 2003 reporting under item 5
- Form 8-K/A filed on July 10, 2003 reporting under item 5

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.

IGEN International, Inc.

Date: November 7, 2003

/s/ George V. Migausky

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