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IGEN INTERNATIONAL INC /DE  
Form 10-Q  
August 14, 2002

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

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

For Quarter Ended June 30, 2002

Commission File Number 0-23252

IGEN INTERNATIONAL, INC.

-----  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction  
incorporation or organization)

94-2852543  
(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 July 23, 2002 -----
Common Stock, \$0.001 par value	23,720,879

IGEN INTERNATIONAL, INC.  
FORM 10-Q  
FOR THE QUARTER ENDED JUNE 30, 2002

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IGEN INTERNATIONAL, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE DATA)

	June 30, 2002	Marc
ASSETS	-----	-----
-----	(Unaudited)	
CURRENT ASSETS:		
Cash and cash equivalents	\$ 44,503	\$
Short-term investments	16,275	
Accounts receivable, net	10,950	
Inventory	4,109	
Other current assets	2,167	
	-----	-----
Total current assets	78,004	
EQUIPMENT AND LEASEHOLD IMPROVEMENTS, NET	7,079	
OTHER NONCURRENT ASSETS:		

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Investment in affiliate	6,865	
Restricted cash	2,322	
Other	894	
	-----	---
TOTAL	\$ 95,164	\$
	=====	==
LIABILITIES AND STOCKHOLDERS' EQUITY		
-----		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 8,102	\$
Current portion of note payable	5,185	
Convertible preferred stock dividends payable	2,821	
Current portion of deferred revenue	416	
Obligations under capital leases	42	
	-----	---
Total current liabilities	16,566	
	-----	---
NONCURRENT LIABILITIES:		
Note payable	16,727	
Subordinated convertible debentures	30,482	
Deferred revenue	83	
	-----	---
Total noncurrent liabilities	47,292	
	-----	---
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 designated, 2,000 and 8,500 shares issued and outstanding-liquidation value of \$2,000 and \$8,500 plus accrued and unpaid dividends	1	
Common stock, \$0.001 par value, 50,000,000 shares authorized: 23,577,238 and 23,064,392 shares issued and outstanding	24	
Additional paid-in capital	242,376	
Stock notes receivable	(3,710)	
Accumulated deficit	(207,385)	(
	-----	---
Total stockholders' equity	31,306	
	-----	---
TOTAL	\$ 95,164	\$
	=====	==

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

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	June 30,	
	2002	2001
	-----	
REVENUES:		
Royalty income	\$ 8,107	\$ 5,324
Product sales	3,592	2,791
Contract fees	300	143
	-----	
Total	11,999	8,258
	-----	
OPERATING COSTS AND EXPENSES:		
Product costs	1,136	740
Research and development	5,911	8,346
Selling, general and administrative	5,987	5,531
Litigation related costs	1,141	4,260
	-----	
Total	14,175	18,877
	-----	
LOSS FROM OPERATIONS	(2,176)	(10,619)
	-----	
OTHER (EXPENSE) INCOME:		
Interest expense	(1,417)	(1,555)
Other income, net	654	257
	-----	
Total	(763)	(1,298)
	-----	
EQUITY IN LOSS OF AFFILIATE	(4,423)	-
	-----	
NET LOSS	(7,362)	(11,917)
	-----	
PREFERRED DIVIDENDS	(198)	(418)
	-----	
NET LOSS ATTRIBUTED TO COMMON SHAREHOLDERS	\$ (7,560)	\$ (12,335)
	=====	
BASIC AND DILUTED NET LOSS PER COMMON SHARE	\$ (0.33)	\$ (0.69)
	=====	
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING-		
BASIC AND DILUTED	23,171	17,878
	=====	

See notes to condensed consolidated financial statements.

IGEN INTERNATIONAL, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)  
UNAUDITED

	Three months en	
	June 30,	
	2002	2001
	-----	
OPERATING ACTIVITIES:		
Net loss	\$ (7,362)	\$ (11,917)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation and amortization	1,159	1,000

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Equity in loss of affiliate	4,423	
Amortization of detachable warrant value	350	3
Expense related to stock options	103	
Changes in assets and liabilities:		
Increase in accounts receivable	(1,085)	(1,2
Increase in inventory	(467)	(2
(Increase) decrease in other current assets	(484)	3
Increase in restricted cash	(601)	(2
Increase in other long-term assets	(10)	
Decrease in accounts payable and accrued expenses	(2,629)	(1,6
Decrease in deferred revenue	(15)	(
	-----	-----
Net cash used for operating activities	(6,618)	(13,5
	-----	-----
INVESTING ACTIVITIES:		
Expenditures for equipment and leasehold improvements	(797)	(1,6
Investments in affiliate	(5,045)	
Purchase of short-term investments	(11,276)	
Sale and maturities of short-term investments	211	
	-----	-----
Net cash used for investing activities	(16,907)	(1,6
	-----	-----
FINANCING ACTIVITIES:		
Issuance of common stock, net	312	28,5
Payments on notes payable and capital lease obligations	(1,243)	(1,1
Preferred stock dividends paid	(582)	
	-----	-----
Net cash (used for) provided by financing activities	(1,513)	27,4
	-----	-----
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(25,038)	12,2
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	69,541	15,0
	-----	-----
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 44,503	\$ 27,2
	=====	=====
SUPPLEMENTAL DISCLOSURES:		
Cash payments of interest	\$ 492	\$ 5
	=====	=====
Accrued preferred dividends	\$ 198	\$ 4
	=====	=====

See notes to condensed consolidated financial statements.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. BASIS OF PRESENTATION

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. These financial statements should be read together with the audited financial statements and notes for the year ended March 31, 2002 contained in the Company's Annual Report on Form 10-K filed

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with the Securities and Exchange Commission. 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 month period ended June 30, 2002, the Company's financial position at June 30, 2002 and the cash flows for the three month period ended June 30, 2002. The results of operations for the interim period are not necessarily indicative of the results of the entire year.

### 2. 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 value and unrealized gains and losses on these securities, if any, are reported as a component of stockholders' equity. As of June 30, 2002, the Company had unrealized losses on "available for sale" securities of approximately \$68,000. This amount is included in comprehensive income and has been recorded within additional paid-in capital in the accompanying condensed consolidated balance sheets. 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.

**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 4). In conjunction with the Roche Diagnostics (Roche) litigation, the Company escrowed a total of \$601,000 as of June 30, 2002 related to Roche's counterclaim judgment (see Note 7).

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

**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)	June 30, 2002	March 31, 2002
Finished Goods	\$ 1,881	\$ 910
Work in process	1,675	1,149
Raw materials	553	1,272
	\$ 4,109	\$ 3,331
	=====	=====

**Equipment and Leasehold Improvements** — Equipment and leasehold improvements are carried at cost. Depreciation on equipment and furniture is computed over the

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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.

Equipment and leasehold improvements consist of the following:

(in thousands)	June 30, 2002	March 31, 2002
Lab instruments and equipment	9,193	\$ 9,076
Office furniture and equipment	7,741	7,492
Leasehold improvements	2,970	2,864
	19,904	19,432
Accumulated depreciation and amortization	(12,825)	(11,843)
	\$ 7,079	\$ 7,589

Capitalized Software Costs - Software development costs incurred subsequent to the establishment of technological feasibility are capitalized in accordance with SFAS No. 86 "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed." Through June 30, 2002, 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 based upon projections of undiscounted cash flows whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Management believes no impairment of these assets exists as of June 30, 2002.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

Warranty Costs - The Company generally warrants its products against defects in materials and workmanship for one year after sale and provides for estimated future warranty costs at the time revenue is recognized. At June 30, 2002, accrued product warranty costs totaled \$170,000 and are included in accrued expenses.

Revenue Recognition - The Company derives revenue principally from three sources: product sales, royalty income and contract fees. Product sales revenue is generally recognized when contractual obligations have been satisfied, title and risk of loss have been transferred to the customer and collection of the resulting receivable is reasonably assured.

Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. 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 have been satisfied. For services performed on a time and material basis, revenue is recognized upon performance. Estimates of allowances for doubtful accounts are based on the age of receivables, individual customer profiles and historical experience.

Amounts received in advance of performance under contracts or commercialization agreements are recorded as deferred revenue until earned.

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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.

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

Loss Per Share - The Company uses Statement of Financial Accounting Standard (SFAS) No. 128 "Earnings per Share" for the calculation of basic and diluted earnings per share. The Company's loss has been adjusted by dividends accumulated on the Company's Series B Convertible Preferred Stock for all periods presented. Due to the Company's net loss, the potentially dilutive common shares related to outstanding stock options and Series B Convertible Preferred Stock are not included in the calculation of diluted net loss per common share.

Estimates and Reclassifications -The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Certain amounts from the prior periods have been reclassified to conform to the current period presentation.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

New Accounting Standards - In June 2001, the FASB issued SFAS No. 143 "Accounting for Asset Retirement Obligations" (SFAS 143). SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 is effective for fiscal years beginning after June 15, 2002. The Company has elected early adoption of this pronouncement and it was implemented as of April 1, 2002. This implementation of SFAS 143 did not have a material effect on the Company's financial position or results of operations.

In October 2001, the FASB issued SFAS No. 144 "Accounting for the Impairment of Long-Lived Assets" (SFAS 144) which supersedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and the accounting and reporting provisions of APB No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions" for the disposal for a segment of business. This statement is effective for fiscal years beginning after December 15, 2001. SFAS No. 144 retains many of the provisions of SFAS No. 121 but addresses certain implementation issues associated with that Statement. The Company adopted SFAS 144 as of April 1, 2002 and implementation did not have a material effect on the Company's financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" (SFAS 145). SFAS 145 requires the classification of gains and losses from extinguishments of debt as extraordinary items only if they meet certain criteria for such classification in APB No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions". Any gain or loss on extinguishments of debt classified as an extraordinary item in prior periods that does not meet the criteria must be reclassified as other income or expense. These provisions are effective for fiscal years beginning after May 15, 2002. Additionally, SFAS 145 requires sale-leaseback accounting for certain lease modifications that have economic effects similar to

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sale-leaseback transactions. These lease provisions are effective for transactions occurring after May 15, 2002. SFAS 145 will not have a material effect on the Company's financial position or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). SFAS 146 replaces Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs incurred in a Restructuring)". SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The Company does not expect the adoption of SFAS 146 to have a material effect on its financial position or results of operations.

### 3. MESO SCALE DIAGNOSTICS JOINT VENTURE

During August 2001, the Company entered into agreements with Meso Scale Technologies, LLC. ("MST") continuing Meso Scale Diagnostics, LLC. ("MSD"), a joint venture formed solely by the Company and MST in 1995. MSD was formed for the development and commercialization of products utilizing a proprietary combination of MST's multi-array technology together with ORIGEN and other technologies owned by the Company. MST is a company established and wholly-owned by the son of IGEN's Chief Executive Officer. Under most circumstances, significant MSD governance matters require the approval of both the Company and MST.

Under the amended agreements that were negotiated by an independent committee of the Company's Board of Directors, the Company holds a 31% voting equity interest in MSD. It also owns 100% of the non-voting equity interest in MSD and is entitled to a preferred return on \$41.4 million of the funds previously invested in MSD through June 30, 2002 and on additional funds it invests thereafter. This preferred return would be payable out of a portion of both future profits and certain third-party financings, before any payments are made to other equity holders. MST owns the remaining 69% of the voting equity interest in MSD. The Company agreed, subject to certain conditions, to fund the joint venture through November 2003.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

During the 2002 calendar year, the Company agreed to fund MSD \$21.5 million, subject to a permitted variance of fifteen percent. As of June 30, 2002, the Company has satisfied \$10.3 million of this funding commitment. The 2003 calendar year funding commitment would be based on an annual budget to be approved by a committee of the Company's Board of Directors. The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities.

If the 2003 budget is not approved by the Company's Board of Directors, it would be required to provide transitional funding for an additional six months, estimated to be approximately \$11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture and purchase the Company's interest in MSD at fair market value less certain discounts.

MST and MSD have the right to terminate the joint venture prior to November 2003 under certain circumstances, including a change in control of the Company, as defined. Upon termination, expiration or non-renewal of the joint venture agreement, MSD and MST have the right to purchase the Company's interest in MSD

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at fair market value less certain discounts.

Since inception of the joint venture, the Company has utilized the equity method to account for the investment. In conjunction with the amended agreements and the progress made by MSD in the development of its products, the Company has determined that future contributions to MSD would be made based on the future investment benefit to be obtained by the Company. Therefore, the Company's share of MSD losses, since July 1, 2001, have been recorded as Equity in Loss of Affiliate. Prior to this date, the Company accounted for its equity investments in MSD as research and development funding and accordingly, recorded all MSD investments as research and development expenses as incurred. These research and development expenses totaled \$2.4 million, during the three months ended June 30, 2001.

#### 4. NOTE PAYABLE

In March 1999, the Company entered into a debt financing with John Hancock Mutual Life Insurance Company under a Note Purchase Agreement from which the Company received \$30 million. The 8.5% Senior Secured Notes mature in March 2006. The Company is required to make quarterly principal and interest payments of \$1.7 million in each fiscal year 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 a Restricted Cash account, which had a balance of \$1.7 million at June 30, 2002 and 2001. Loan covenants include compliance with annual and quarterly Royalty Payment Coverage Ratios which are tied to royalty payments and debt service.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

#### 5. SUBORDINATED CONVERTIBLE DEBENTURES

In January 2000, the Company completed a placement of \$35 million principal amount of Subordinated Convertible Debentures. The 5% debentures, if not converted, mature in January 2005 with semi-annual interest payments to be made in cash or an equivalent value of common stock. The debentures are immediately convertible into 1,129,032 shares of the Company's common stock, which represents a \$31 per share conversion price.

As part of this financing, the Company also issued detachable warrants to purchase 282,258 shares of common stock with an exercise price of \$31 per share. Using the Black-Scholes 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. The detachable warrant value has been recorded as a reduction of the face value of the convertible debentures. Costs associated with placing the debentures totaling \$1.9 million were deferred and have been netted against the recorded convertible debenture balance. The convertible debenture discount consisting of the warrant value and debt issuance costs is being amortized over the five-year life of the debentures. All warrants remain outstanding as of June 30, 2002.

#### 6. STOCKHOLDERS' EQUITY

The Company has issued 25,000 shares of Series B Convertible Preferred Stock (Series B) with a stated value of \$1,000 per share which are convertible into shares of Common Stock of the Company at a rate of \$13.96 per share. Series B shares automatically convert into Common Stock of the Company on December 16,

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2002. During the quarter ended June 30, 2002, 6,500 shares of Series B were converted into 465,614 shares of Common Stock. The Company also notified holders of the outstanding Series B shares that it planned to redeem those shares on July 9, 2002 for their liquidation value. At June 30, 2002, 2,000 shares of Series B remained outstanding and in July 2002, they were converted into 143,266 shares of Common Stock. Dividends totaling \$582,000 were paid to Series B holders during the quarter ended June 30, 2002. During July 2002, dividends of \$2.8 million were paid related to Series B conversions, thereby satisfying all remaining Series B dividend obligations. The Series B dividend payable balance at March 31, 2002 has been reclassified to current liabilities in the accompanying condensed consolidated balance sheets.

In connection with the exercise of stock options by officers in July 2000, the Company granted loans in the principal amounts of \$3.7 million, maturing in July 2007. The loans are 6.62% simple interest (paid annually), full recourse loans against all assets of the borrowers, collateralized by the pledge of 180,000 shares of the Company's common stock owned by the borrowers.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

#### 7. LITIGATION

##### Roche

In 1997, the Company filed a lawsuit against Roche Diagnostics GmbH (formerly Boehringer Mannheim GmbH) in the Southern Division of the United States District Court for the District of Maryland. The lawsuit arises out of a 1992 License and Technology Development Agreement (the "Agreement"), under which the Company licensed to Roche certain rights to develop and commercialize diagnostic products based on the Company's ORIGEN technology. In its lawsuit, the Company alleged that Roche failed to perform certain material obligations under the Agreement and engaged in unfair competition against the Company.

The jury trial in this litigation was completed in January 2002, and in February 2002, the Court issued a final order of judgment that awarded the Company \$105 million in compensatory damages and \$400 million in punitive damages, confirmed the Company's right to terminate the Agreement, and directed and commanded 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 judgment, include Roche's Elecsys(R) 1010, 2010 and E170 lines of clinical diagnostic immunoassay analyzers, the tests developed for use on those systems, and Roche's nucleic acid amplification technology called PCR. The jury further concluded that Roche violated its duty to the Company of good faith and fair dealing, engaged in unfair competition against the Company, and materially breached the license agreement.

The judgment bars 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(R) technology. While the Company has voluntarily agreed not to terminate the Agreement until an appellate court determines that it is entitled to do so, the Company has notified Roche that the Agreement will terminate automatically once the Company's right is affirmed by the appellate court. Upon termination, Roche will be prohibited from commercializing all ORIGEN-based products in all fields. The Company is free to

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exploit its proprietary ORIGEN technology independently of Roche, both for the field currently licensed to Roche (effective upon termination of the Agreement), as well as for the Company's retained fields.

Roche filed counterclaims against the Company alleging, among other things, that IGEN breached the Agreement by permitting Eisai Co., Ltd., another of the Company's licensees, to market certain ORIGEN-based products in Japan. The final judgment issued in the litigation found in the Company's favor and against Roche on all of Roche's counterclaims, except for one in which the Company was ordered to pay \$500,000.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

Roche has filed a notice of appeal with the U.S. Court of Appeals for the Fourth Circuit. In connection with the filing of that appeal, Roche posted a \$600 million bond to support its financial obligations to the Company under the judgment. During the appeal process, which the Company expects will be completed in 2003, Roche is obligated to continue to comply with the terms of the 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 is suspended until completion of the appeal process. The Company filed a notice of appeal on the judgment issued under the Roche counterclaim and has since voluntarily dismissed its appeal. The judgment amount will be paid from a bond the Company has already posted with the court. Although the Company will vigorously oppose Roche's appeal, Roche may ultimately prevail in its attempt to modify or overturn the judgment issued in this litigation.

### Hitachi

In 1997, IGEN International K.K., a Japanese subsidiary of the Company, filed a lawsuit in Tokyo District Court against Hitachi Ltd. ("Hitachi"). The lawsuit sought to enjoin Hitachi from infringing a license registration held by IGEN K.K. and Eisai Co., Ltd., a company to which IGEN has licensed ORIGEN technology rights. The lawsuit requested injunctive relief preventing Hitachi from manufacturing, using or selling the Elecsys 2010, which incorporates the Company's patented ORIGEN technology, in Japan. On June 13, 2002, Hitachi and the Company reached an agreement to settle this litigation and the case has been dismissed.

### Other Proceedings

In February 2001, Brown Simpson Strategic Growth Fund L.P., Brown Simpson Strategic Growth Fund, Ltd. and Brown Simpson Partners I (collectively "Brown Simpson") initiated a shareholder derivative lawsuit for and on behalf of the shareholders of the Company in the Circuit Court for Montgomery County, Maryland against four of the Company's current directors, two former directors, three executive officers and the Company as a nominal defendant. In the complaint, Brown Simpson alleged breach of fiduciary duties by the named individual defendants in connection with transactions between the Company and other entities in which certain directors and officers are alleged to have an interest, including the Meso Scale Diagnostics, LLC. joint venture.

In March 2001, a second shareholder derivative lawsuit was filed by Laurence Paskowitz in the Circuit Court for Montgomery County, Maryland with allegations substantially the same as those set forth in the complaint filed by Brown Simpson. The complaint was later amended to add direct claims against the defendants and to seek class action certification for those direct claims.

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### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

Both lawsuits sought principally the following: that the defendants hold in trust and be required to account for and restore to the Company damages that IGEN has allegedly sustained by reason of the allegations and relief relating to board and management composition. The Paskowitz complaint also sought damages for a class of IGEN shareholders for the direct claims against the individual defendants. The complaints did not include any claims against the Company.

The Company and the individual defendants filed motions to dismiss or, in the alternative, for summary judgment in both lawsuits. On May 15, 2002, the court issued an opinion and order dismissing all claims asserted against all of the defendants in both cases. On June 19, 2002, an appeal was filed by the Paskowitz plaintiff. No appeal was filed by the Brown Simpson plaintiff and the decision in that case is now final. The Company believes that the claims are without merit and it intends to vigorously oppose the appeal filed in this case.

The Company is involved, from time to time, in various other legal proceedings arising in the ordinary course of business. In the opinion of management, the Company does not believe that any legal proceedings described as Other Proceedings will have a material adverse impact on its financial position, results of operations or cash flows.

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

#### OVERVIEW

We have devoted substantial resources to the research and development of our proprietary technologies, primarily the ORIGEN(R) technology for the clinical diagnostic, life science and industrial markets. We currently derive a majority of our revenue from royalties received from licensees that develop and market certain ORIGEN-based systems. We also generate sales of our own products, particularly the M-SERIES(R) System and related consumable reagents. We may selectively pursue additional strategic alliances, which could result in additional license fees or contract revenues. Since inception, we have incurred significant losses and, as of June 30, 2002, we had an accumulated deficit of \$207 million. We expect to continue to incur substantial research and development, manufacturing scale-up and general and administrative costs associated with our operations. As a result, we will need to generate higher revenue from present levels to achieve profitability.

In addition to historical information, this document contains forward-looking statements within the meaning of the "safe-harbor" provisions of the Private Securities Litigation Reform Act of 1995.

#### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Reference is made in particular to statements regarding the markets and potential markets and market growth for diagnostic products, potential impact of competitive products, the Company's expectations regarding the level of anticipated royalty and revenue growth in the future, the potential market for

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products in development, prospects for future business arrangements with third parties, financing plans, the outcome of litigation, the Company's plans and objectives for future operations, assumptions underlying such plans and objectives, the need for and availability of additional capital and other forward-looking statements included in this document. The words "may", "should", "could", "will", "expect", "intend", "estimate", "anticipate", "believe", "plan" and similar expressions have been used in this document to identify forward-looking statements. We have based these forward-looking statements on our current views with respect to future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties which could cause actual results to differ materially from those described in the forward-looking statements. In particular, careful consideration should be given to the cautionary statements in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and to the risks and uncertainties detailed in the Company's Annual Report on Form 10-K for the year ended March 31, 2002 previously filed with the Securities and Exchange Commission. The Company disclaims any intent or obligation to update these forward-looking statements.

### RESULTS OF OPERATIONS

#### QUARTER ENDED JUNE 30, 2002 AND 2001.

REVENUES. Total revenues for the quarter ended June 30, 2002 increased by approximately \$3.7 million or 45% to \$12.0 million from \$8.3 million in 2001. The revenue growth for the 2002 quarter was due to increases in all revenue categories - product sales, royalty income and contract fees. Product sales were \$3.6 million in 2002, an increase of 29% over the comparable prior year period's product sales of \$2.8 million. This growth in product sales was from the M-SERIES line of life science products (an increase of \$300,000), new sales of reagents to the U.S. Army for detection of biological agents or toxins (an increase of \$400,000) and sales of clinical diagnostic assays to physician office laboratory (POL) customers in the United States (an increase of \$100,000). We began serving these POL customers in June 2000 when Roche transferred the customers in order to comply with a court ordered preliminary injunction. In February 2002, the Maryland federal court issued a final order of judgment against Roche which does not require Roche to renew existing POL contracts, some of which are scheduled to expire during fiscal 2003. Should POL customer contracts not be renewed, future POL product sales would experience a decline.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Royalty income was \$8.1 million in the quarter ended June 30, 2002, an increase of 52% over the prior year's royalty income of \$5.3 million in 2001. Royalties from Roche represent approximately \$7.9 million (97%) of the total royalty income for 2002 as compared to approximately \$5.1 million (96%) in the prior year. These increases are attributable to higher Roche sales of its Elecsys and E170 product lines, which are based on IGEN's ORIGEN technology that was licensed to Roche under a 1992 license agreement, as well as certain modifications made by Roche to their methodology for computing and paying royalties as a result of the litigation. While we are not satisfied that Roche is properly calculating and paying the required royalties, the recent changes in the way in which Roche calculates and pays its royalties to us is expected to have a continued positive impact on our royalty income in future periods. However, we have notified Roche that their license to sell ORIGEN-based products

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will be terminated once our right to do so is affirmed on appeal, in which case our royalty income from Roche would cease.

Contract revenue in the current quarter increased to \$300,000 from \$143,000 in the prior year's quarter. These fees related to work completed in conjunction with the development of clinical assays for Roche.

OPERATING COSTS AND EXPENSES. Product costs were \$1.1 million (32% of product sales) for the quarter ended June 30, 2002 compared to \$740,000 (27% of product sales) in the prior year. This increase in product costs is due primarily to higher manufacturing costs in the current year. We expect product costs associated with POL product sales to increase in future periods as we absorb third party leasing costs previously paid by Roche for POL customers.

Research and development expenses decreased \$2.4 million (29%) in the quarter ended June 30, 2002 to \$5.9 million from \$8.3 million in 2001. Excluding funding of the MSD joint venture activities prior to the amendment and extension of the MSD joint venture agreements in August 2001, research and development expense was \$5.9 million in the prior year's quarter. Research and development expenses primarily relate to ongoing development costs and product enhancements associated with the M-SERIES family of products, development of new assays for the life sciences market and research and development of new systems and technologies, including hospital 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 bio-defense testing products. See "Equity in Loss of Affiliate" below for a discussion of MSD activity in the quarter ended June 30, 2002.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Selling, general and administrative expenses were \$6.0 million in the quarter ended June 30, 2002, an increase of \$500,000 (8%) over the prior year's quarter of \$5.5 million. This increase was primarily attributable to additional personnel costs required to support the growth in sales and customers.

Costs related to our litigation with Roche, which include financial and legal advisory fees associated with settlement discussions, decreased \$3.2 million (73%) to \$1.1 million in the current quarter from \$4.3 million in the same period last year. The decrease is attributable to the reduced legal fees since the conclusion of the Roche jury trial in January 2002 and the completion of post-trial motions in April 2002.

INTEREST AND OTHER EXPENSE. Interest and other expense, net of interest income, were \$763,000 in the current quarter and \$1.3 million in the prior year's first quarter. Increased interest income from higher cash balances during the current quarter was the primary reason for the change.

EQUITY IN LOSS OF AFFILIATE. In August 2001, we entered into agreements with MST continuing MSD, a joint venture formed solely by IGEN and MST in 1995. MSD was formed for the development and commercialization of products utilizing a propriety combination of MST's multi-array technology together with ORIGEN and other technologies owned by us. In conjunction with the amended agreements and 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 to be obtained by us. Our contributions to MSD since July 1, 2001 were recorded as "Investment in Affiliate" and we have recorded 100% of MSD's losses since

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that date as Equity in Loss of Affiliate. MSD incurred a net loss of \$4.4 million and \$2.3 million for the quarters ended June 30, 2002 and 2001, respectively.

NET LOSS. The net loss for quarter ended June 30, 2002 was \$7.4 million (\$0.33 per common share, after consideration of the effect of preferred dividends) compared to a net loss of \$11.9 million (\$0.69 per common share, after consideration of the effect of preferred dividends) in the prior year.

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 for M-SERIES or other products; the timing of instrument deliveries and installations; variations in revenue recognized from royalties and other contract revenues; whether POL customers' contracts are renewed; whether Roche will continue to supply service and assays to POL customers;

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

the mix of products sold; whether instruments are sold to or placed with customers; the timing and cost of M-SERIES product upgrades; the timing of the introduction of new products; competitors' introduction of new products and the economic conditions of the markets we serve; variations in expenses incurred in connection with the operation of the business, including legal fees, research and development costs and sales and marketing costs; renewal costs for commercial insurance and employee benefit plans; equity in loss of affiliate; manufacturing capabilities; and the volume and timing of product returns and warranty claims.

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 are entitled to under the license agreement with Roche, 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 beginning in fiscal 2003. Our ability to become profitable in the future will depend, among other things, on our ability to expand the commercialization of existing products; introduce new products into the market; develop marketing, sales and distribution capabilities cost-effectively; and complete new business arrangements.

### 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 June 30, 2002, the Company had \$60.8 million in cash, cash equivalents and short-term investments with working capital of \$61.4 million.

Net cash used in operations decreased to \$6.6 million for the three months ended June 30, 2002, as compared to \$13.6 million for the corresponding prior year period, primarily due to a lower net loss and the reclassification of MSD contributions to an "investing activity" in the current period. See "Equity in Loss of Affiliate".

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We used approximately \$797,000 and \$1.6 million of cash for the acquisition of equipment and leasehold improvements during the quarters ended June 30, 2002 and 2001, respectively. We believe material commitments for capital expenditures and expanded facilities may be required in a variety of areas, such as product development programs. We have not, at this time, made commitments for any such capital expenditures or expanded facilities and have not secured additional sources, if necessary, to fund such commitments.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

	Nine Months Ended March 31,			Years Ended M	
Contractual Obligations (in thousands)	Total	2003	2004	2005	
Notes payable	\$21,912	\$ 3,848	\$ 5,523	\$ 6,007	\$ 6
Subordinated convertible debentures	35,000	-	-	35,000	
MSD funding commitment	21,910	16,535	5,375	-	
Operating and capital leases	8,168	1,690	2,476	2,331	
Interest obligations	8,725	2,634	3,112	2,628	
Total contractual obligations	\$95,715	\$24,707	\$16,486	\$45,966	\$ 7

During August 2001, we entered into agreements with MST continuing MSD, a joint venture formed solely by IGEN and MST in 1995. Under the amended joint venture agreements, we agreed, subject to certain conditions, to fund the joint venture through November 2003. During the 2002 calendar year, we agreed to fund MSD \$21.5 million, subject to a permitted variance of fifteen percent. At June 30, 2002, we satisfied \$10.3 million of this funding commitment. The 2003 calendar year funding commitment is based on an annual budget to be approved by a committee of our Board of Directors. The funding commitment may be satisfied in part through in-kind contributions of scientific and administrative personnel and shared facilities. If the 2003 budget is not approved by our Board of Directors, we would be required to provide transitional funding for an additional six months, estimated at \$11.0 million, and under certain conditions, MSD and MST have the right to terminate the joint venture and purchase our interest in MSD at fair market value less certain discounts. The operating and capital lease commitments in the table above exclude amounts expected to be allocated to MSD to meet a portion of our funding commitment.

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

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expected cash flow available for other purposes, including working capital and capital expenditures.

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 substantial up-front fees or payments. Further, we are considering and evaluating the advisability and feasibility of a variety of financing alternatives, which could be completed in the near term, including issuance of additional debt or equity securities.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

There can be no assurance that we will successfully complete any of the foregoing arrangements and access to funds could be adversely impacted by many factors, including the results of pending litigation, the volatility of the price of our common stock, continuing losses from operations and other factors. We believe that existing capital resources, together with revenue from product sales, royalties and contract fees will be adequate to fund operations through calendar year 2003. If we are unable to raise additional capital, we may have to scale back, or even eliminate, some programs. Alternatively, we may consider pursuing arrangements with other companies, such as granting licenses or entering into joint ventures, on terms and conditions that may not be favorable to us.

Roche has the right to continue to market its Elecsys products within its licensed field until our right to terminate their license is affirmed on appeal. In connection with the litigation with Roche, we have notified Roche that the license agreement will terminate upon the appellate court affirming our right to do so.

Termination of the license agreement would have a material adverse effect on our revenues unless, and until, we enter into one or more strategic relationships with other companies that are able to develop and commercialize diagnostic instruments within the field presently licensed to Roche. There can be no assurance that we will be able to enter into one or more strategic relationships on favorable terms, if at all.

### CRITICAL ACCOUNTING POLICIES

Our significant accounting policies are more fully described in Note 2 to our Condensed Consolidated Financial Statements. However, certain accounting policies are particularly important to the portrayal of our financial position and results of operations and require the application of significant 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 policies include:

Inventory - We carry our inventory at the lower of cost or market using the first-in, first-out method. We apply judgment in determining the provisions for

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slow moving, excess and obsolete inventory based on historical experience, anticipated product demand and changes in product design.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Equipment and Leasehold Improvements - Our equipment and leasehold improvements are carried at cost. Depreciation on equipment and furniture is computed over the estimated useful lives of the assets, generally three to five years, using straight line or accelerated methods. Leasehold improvements are amortized on a straight-line basis over the life of the lease. We apply judgment in determining the appropriate useful life of these assets.

Revenue Recognition - We derive revenue principally from three sources: product sales, royalty income and contract fees. Product sales revenue is generally recognized when contractual obligations have been satisfied, title and risk of loss have been transferred to the customer and collection of the resulting receivable is reasonably assured.

Rental revenue associated with instruments that are leased is recognized ratably over the life of the lease agreements. We make estimates of allowances for doubtful accounts based on the age of receivables, individual customer profiles and historical experience.

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 or commercialization agreements are recorded as deferred revenue until earned.

Capitalized Software Costs - We record software development costs in accordance with SFAS No. 86 "Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed." We apply our judgment in determining when software being developed has reached technological feasibility, and at that point we would capitalize software development costs. Through June 30, 2002, software development has been substantially completed concurrently with the establishment of technological feasibility, and accordingly, no costs have been capitalized to date.

Equity Accounting - We account for our ownership in the MSD joint venture on the equity method as we have determined that we do not control MSD's operations. Factors considered in determining our level of control include the fact that we 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 joint venture agreements; and that we have the right to appoint only one out of two seats on MSD's board of managers. See Note 3 of Notes to Condensed Consolidated Financial Statements.

### MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### RECENT ACCOUNTING PRONOUNCEMENTS.

In June 2001, the FASB issued SFAS No. 143 "Accounting for Asset Retirement

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Obligations" (SFAS 143). SFAS 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS 143 is effective for fiscal years beginning after June 15, 2002. We have elected early adoption of this pronouncement and it was implemented as of April 1, 2002. The implementation of SFAS 143 did not have a material effect on our financial position or results of operations.

In October 2001, the FASB issued SFAS No. 144 "Accounting for the Impairment of Long-Lived Assets" (SFAS 144) which supersedes SFAS No.121 "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" and the accounting and reporting provisions of APB No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business and Extraordinary, Unusual and Infrequently Occurring Events and Transactions" for the disposal of segment business. This statement is effective for fiscal years beginning December 15, 2001. SFAS 144 retains many of the provisions of SFAS No. 121 but addresses certain implementation issues associated with that Statement. We adopted SFAS 144 as of April 1, 2002 and implementation did not have a material effect on our financial position or results of operations.

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections" (SFAS 145). SFAS 145 requires the classification of gains and losses from extinguishments of debt as extraordinary items only if they meet certain criteria for such classification in APB No. 30, "Reporting the Results of Operations- Reporting the Effects of Disposal of a Segment of a Business , and Extraordinary, Unusual, and Infrequently Occurring Events and Transactions". Any gain or loss on extinguishments of debt classified as an extraordinary item in prior periods that does not meet the criteria must be reclassified as other income or expense. These provisions are effective for fiscal years beginning after May 15, 2002. Additionally, SFAS 145 requires sale-leaseback accounting for certain lease modifications that have economic effects similar to sale-leaseback transactions. These lease provisions are effective for transactions occurring after May 15, 2002. SFAS 145 will not have a material effect on our financial position or results of operations.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). SFAS 146 replaces Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs incurred in a Restructuring)". SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. We do not expect the adoption of SFAS 146 to have a material effect on our financial position or results of operations.

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

Information about market risks for the three months ending June 30, 2002 does not differ materially from that discussed under Item 7A of the Company's Annual Report on Form 10-K for the year ended March 31, 2002.

### PART II OTHER INFORMATION

Item 1: Legal Proceedings

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

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

- (a) Exhibits:
- 10.1 Extension Agreement by and between Eisai Co., Ltd. and IGEN International, Inc. dated July 11, 2002.
- (b) Reports on Form 8-K:
- None

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: August 14 , 2002 /s/ George V. Migausky  
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George V. Migausky  
Vice President of Finance and Chief  
Financial Officer  
(On behalf of the Registrant and as  
Principal Financial Officer)