

# **IOMED LLC**

### FORM 10-Q (Quarterly Report)

## Filed 11/13/98 for the Period Ending 09/30/98

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CIK 0001041652

SIC Code 3841 - Surgical and Medical Instruments and Apparatus

Industry Medical Equipment, Supplies & Distribution

Sector Healthcare

Fiscal Year 06/30



### **IOMED INC**

# FORM 10-Q (Quarterly Report)

### Filed 11/13/1998 For Period Ending 9/30/1998

Address 3385 WEST 1820 SOUTH

SALT LAKE CITY, Utah 84104

Telephone 801-975-1191

CIK 0001041652

Industry Biotechnology & Drugs

Sector Healthcare

Fiscal Year 06/30



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

## [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended SEPTEMBER 30, 1998

or

[ ] TRANSACTION REPORT PURSUANT TO SECTION 13 OR 15(d) (	)F TH	Е
SECURITIES EXCHANGE ACT OF 1934		

# IOMED, INC.

(Exact name of registrant as specified in its charter)

UTAH (State or other jurisdiction of incorporation or organization)

87-0441272 (I.R.S. Employer Identification No.)

#### 3385 WEST 1820 SOUTH, SALT LAKE CITY, UTAH 84104

(Address of principal executive offices) (Zip Code)

(801) 975-1191 (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 Exchange 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 [X] Yes [] No.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of OCTOBER 31, 1998:

CLASSES OF COMMON STOCK
-----Common Stock, no par value

NUMBER OF SHARES OUTSTANDING
----6,499,518

### IOMED, INC.

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# IOMED, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

#### **ASSETS**

	SEPTEMBER 30, 1998	JUNE 30, 1998
Current assets:	(unaudited)	
Cash and cash equivalents	\$ 16,261,000	\$ 16,709,000
Accounts receivable	1,412,000	1,570,000
Inventories	1,076,000	876,000
Prepaid expenses	52,000	53,000
Total current assets		19,208,000
Equipment and furniture, net	756,000	783,000
Other assets	201,000	210,000
TOTAL ASSETS	\$ 19,758,000	\$ 20,201,000
	=========	========
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Trade accounts payable	\$ 323,000	\$ 626,000
Accrued liabilities	514,000	687,000
Current portion of long-term obligations	53,000	50,000
Total current liabilities	890,000	
Long-term obligations	171,000	187,000
Commitments		
Shareholders' equity:		
Common shares	34,408,000	34,408,000
Convertible preferred shares	6,881,000	6,881,000
Accumulated deficit	(22,592,000)	(22,638,000)
Total shareholders' equity	18,697,000	18,651,000
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 19,758,000 ======	\$ 20,201,000 =======

See accompanying notes.

# IOMED, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Three Months Ended September 30,

	-	•	
	1998	1997	
	(unaudited)		
Revenues:			
Product sales	\$ 2,155,000	\$ 1,997,000	
Contract research revenue, royalties and license fees	428,000	503,000	
Total revenues	2,583,000	2,500,000	
Operating costs and expenses:			
Cost of products sold	986,000	893,000	
Research and development	376,000	375,000	
Selling, general and administrative		1,061,000	
Total costs and expenses	2,759,000	2,329,000	
Income (loss) from operations	(176,000)	171,000	
Interest expense	6,000	287,000	
Interest income	228,000	80,000	
Net income (loss)	\$ 46,000	\$ (36,000)	
	========	========	
BASIC AND DILUTED INCOME (LOSS) PER COMMON SHARE	\$ 0.01	\$ (0.01)	
	========	========	

See accompanying notes.

#### IOMED, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

THREE MONTHS ENDED

SEPTEMBER 30, 1997 -----1998 (unaudited) CASH FLOWS FROM OPERATING ACTIVITIES: 46,000 \$ (36,000) Net income (loss) Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: ,000 Depreciation and amortization 102,000 57,000 57,000 287,000 Non-cash interest expense Other non-cash charges 11,000 Changes in assets and liabilities: (102,000) Accounts receivable 158,000 (200,000) (5,000) Inventories (131,000) Prepaid expenses and other assets 1,000 Other current liabilities (303,000) 43,000 (170,000) (318,000) \_\_\_\_\_ \_\_\_\_\_ Net cash provided by (used in) operating activities (366,000) (194,000) CASH FLOWS FROM INVESTING ACTIVITIES: (60,000) Purchases of equipment and furniture (69,000) Net cash provided by (used in) investing activities (69,000) (60,000) CASH FLOWS FROM FINANCING ACTIVITIES: Proceeds from exercise of stock options (2,000) Payments on long-term obligations (13,000) --Redemptions of redeemable preferred stock (180,000) Net cash provided by (used in) financing activities (13,000) (182,000) Net increase (decrease) in cash and cash equivalents (448,000) (436,000) Cash and cash equivalents at beginning of period 16,709,000 6,346,000 Cash and cash equivalents at end of period \$ 16,261,000 \$ 5,910,000 ----------

See accompanying notes.

#### IOMED, INC.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Description of Business**

IOMED, Inc., a Utah corporation (the "Company"), develops, manufactures and commercializes controllable drug delivery systems using proprietary iontophoretic technology. Iontophoresis is a method of enhancing and controlling the transport of drugs through the skin utilizing a low level electrical current.

#### **Basis of Presentation**

In the opinion of management, the accompanying condensed consolidated financial statements contain all normal recurring adjustments necessary to present fairly the financial position of the Company as of September 30, 1998, and the results of its operations and cash flows for the interim periods ended September 30, 1998, and 1997. The operating results for the interim periods are not necessarily indicative of the results for a full year. Certain information and footnote disclosures normally included in financial statements in accordance with generally accepted accounting principles have been condensed or omitted. Therefore, these statements should be read in conjunction with the Company's audited consolidated financial statements for the year ended June 30, 1998, included in the Company's Annual Report on Form 10-K, dated September 28, 1998.

#### Earnings (Loss) Per Share

For all periods presented, basic and diluted earnings per share are computed in accordance with Statement of Financial Accounting Standards (SFAS) No. 128-Earnings per Share.

Net income (loss) as presented in the condensed consolidated statements of operations represents the numerator used in computing both basic and diluted earnings per share and the following table sets forth the computation of the weighted average shares representing the denominator used in determining basic and diluted earnings per share:

	1998	1997
	(IN THO	USANDS)
Denominator for basic earnings per share weighted average shares outstanding Dilutive securities: preferred stock and certain stock options	6,500	3,134
	928	==
Denominator for diluted earnings per share adjusted weighted average shares outstanding and assumed		
conversions	7,428	3,134
	=====	=====

At September 30, 1998, the following securities were outstanding but were not included in the computation of diluted earnings per share due to their anti-dilutive effect: options to purchase 280,270 common shares at a weighted average exercise price of \$5.04 per share; and warrants to purchase 339,792 common shares at a weighted average price of \$13.70 per share. Due to their anti-dilutive effect, no dilutive securities were included in the computation of diluted earnings per share for the three month period ended September 30, 1997.

#### 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### **Reverse Stock Split**

On November 7, 1997, pursuant to a vote of the shareholders, the Company effected a one for 4.8 reverse share split for each common and preferred share then outstanding. For comparative purposes, all share amounts in the accompanying financial statements and related footnotes have been retroactively restated to reflect the effects of the reverse stock split.

#### Reclassifications

Certain reclassifications have been made to the prior year's financial statements to conform to the financial statement presentation included herein.

#### 2. INVENTORIES

Inventories are stated at the lower of cost or market. Cost is determined using the first-in, first-out method. Inventories consisted of the following at September 30, 1998, and June 30, 1998:

	SE	PTEMBER 30, 1998	JUNE 30, 1998
Raw materials	.\$	873,000	\$ 687,000
Work-in-progress		10,000	30,000
Finished goods		193,000	159,000
	\$	1,076,000	\$ 876,000 =====

#### 3. RESEARCH AND DEVELOPMENT

In July 1995, the Company entered into various research and development agreements (the "R&D Agreements") with Ciba-Geigy Corporation ("Ciba") to evaluate the feasibility of delivering a number of Ciba compounds utilizing the Company's iontophoretic drug delivery technologies. In 1997, Ciba was merged with Sandoz Corporation to form Novartis Pharma A.G. ("Novartis").

Although the Company met all of the essential development objectives under the R&D Agreements, in July 1998, Novartis advised the Company that it would not renew the R&D Agreements beyond the scheduled December 31, 1998, expiration date. The Company is currently devoting the majority of its research and development capabilities to the development of systems for Novartis and will continue to do so through the term of the agreement. Novartis will also continue to fund research through the remainder of the term.

In connection with their collaboration, the Company granted Novartis a perpetual, non-exclusive, royalty bearing license to certain of the Company's iontophoretic technology which will survive the termination of the collaboration. Novartis may, pursuant to the royalty-bearing license, independently develop products using the licensed technology, including products which may compete directly with those currently marketed or under development by the Company.

#### 3. RESEARCH AND DEVELOPMENT (CONTINUED)

Following the expiration of the R&D Agreements, Novartis' rights to exclusivity in those fields covered by the agreements will terminate, and IOMED will be free to apply the technologies it developed for Novartis to any available drug candidates, either independently or on behalf of other parties. The Company believes the application of these technologies may shorten the Company's future product development cycles.

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

The following discussion of the financial condition and results of operations of the Company should be read in conjunction with the Condensed Consolidated Financial Statements and the related Notes thereto included elsewhere in this Report. The following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and

Section 21E of the Securities Exchange Act of 1934, that involve risks and uncertainties. The Company's actual results of operations could differ significantly from those anticipated in such forward-looking statements as a result of numerous factors including those discussed herein. Additional risks and uncertainties are described in the Company's most recent Annual Report on Form 10-K for its fiscal year ended June 30, 1998. This discussion should be read in conjunction with such report, copies of which are available upon request.

#### **OVERVIEW**

The Company develops, manufactures and commercializes controllable drug delivery systems using iontophoretic technology. The majority of the Company's revenues have been generated through the sale of its iontophoretic drug delivery products in the physical therapy market for use in the delivery of dexamethasone and contract research revenues from the Company's collaboration with Novartis. The Company recently introduced its local dermal anesthesia products into the market place and, to date, has not realized significant revenue from the sales of such products. Since its inception, the Company has generally incurred operating losses and may incur additional operating losses over the next several years as a result of anticipated costs associated with increases in internally funded research, development and clinical trial activities relating to new applications for its iontophoretic drug delivery technologies. As of September 30, 1998, the Company's accumulated deficit was approximately \$22.6 million. The Company's ability to achieve and sustain profitability will depend on its ability to achieve market acceptance and successfully expand sales of its existing products; successfully complete the development of, receive regulatory approvals for, and successfully manufacture and market its products under development; as well as successfully negotiate and enter into agreements with collaborative partners, licensors, licensees and other parties for the development, clinical testing, manufacture, marketing or sale of certain of its products or products in development, as to which there can be no assurance.

The Company's results of operations may vary significantly from quarter to quarter and depend, among other factors, on the signing of new product development agreements, the timing of contract research revenues and milestone payments made by collaborative partners, the progress of clinical trials, product sales levels and costs associated with manufacturing processes. The timing of the Company's research and development revenues may not match the timing of the associated expenses. The amount of revenue in any given period is not necessarily indicative of future revenue.

#### RESULTS OF OPERATIONS

#### THREE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997

Revenues. Product sales increased 8% to \$2.2 million in the three months ended September 30, 1998, from \$2.0 million in the three months ended September 30, 1997. The increase can be attributed primarily to higher sales of the Company's iontophoretic drug delivery products for the treatment of local inflammatory conditions resulting from continued overall growth in this market.

Contract research revenues, royalties and license fees decreased 15% to \$428,000 in the three months ended September 30, 1998, from \$503,000 in the three months ended September 30, 1997. This decrease is attributable to the decline in the Company's research revenues received from Novartis as the Company enters the final phase of this collaborative development program.

Costs of Products Sold. Costs of products sold increased 10% to \$986,000 in the three months ended September 30, 1998, from \$893,000 in the three months ended September 30, 1997, reflecting increased material and labor costs associated with higher unit sales volumes, as well as certain non-recurring engineering and tooling costs.

Research and Development Expense. Research and development expenditures of \$376,000 for the three months ended September 30, 1998, were unchanged from the \$375,000 reported for the three months ended September 30, 1997. Expenditures in the current period included a higher proportion of expenditures on internally funded projects.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased 32%, to \$1,397,000 in the three months ended September 30, 1998, from \$1,061,000 in the three months ended September 30, 1997. The increase in the current period can be attributed primarily to one-time costs associated with the restructuring of the Company's field sales force and increased marketing and promotional expenses. In addition, the Company realized increased costs associated with legal, professional and related services in connection with investor relations and SEC compliance.

Other Costs and Expenses. Interest expense decreased to \$6,000 in the three months ended September 30, 1998. This decrease can be attributed to lower interest expense resulting from the repayment of the Company's indebtedness to Elan in transactions related to the initial public offering of its common shares in April 1998. Interest income and other miscellaneous income was \$228,000 in the three months ended September 30, 1998, compared to \$80,000 in the three months ended September 30, 1997, reflecting interest earnings on the investment of the proceeds from the initial public offering during the current period.

The Company has substantial net operating loss carryforwards which, under the current "change of ownership" rules of the Internal Revenue Code of 1986, as amended, may be subject to substantial annual limitation. No income tax expense was recognized for the three months ended September 30, 1998, which reflects management's estimate of the Company's fiscal 1999 tax position. In addition, no income tax benefit was recognized on the Company's pre-tax loss for the three months ended September 30, 1997.

Net income (loss). The Company recognized net income of \$46,000 or \$0.01 per share during the three months ended September 30, 1998, compared to a net loss of \$36,000 or \$0.01 per share in the three months ended September 30, 1997. During the current period, a loss from operations was offset by interest earnings on invested proceeds from the initial public offering. With anticipated increases in internally funded research and development expenditures coupled with the loss of contract research revenue from Novartis after December 31, 1998, the Company expects to report a net loss for the fiscal year. The net loss reported for the three months ended September 30, 1997, was attributable to the non-cash interest charges recorded on the Elan indebtedness.

#### LIQUIDITY AND CAPITAL RESOURCES

Beginning in fiscal 1996, the Company's operating losses, including its research and development activities, have been internally funded with cash flows from operations and from contract research and development revenues and license fees the Company has received from Novartis.

In July 1998, Novartis elected not to renew its collaborative research and development agreement with the Company beyond its scheduled expiration date of December 31, 1998. Accordingly, the Company's contract research revenues may decline during fiscal 1999 and future years. The effect of the loss of contract research revenue on the Company's future operating results and cash flow may be offset, in part, by a reduction in research and development expenditures incurred in connection with the collaboration, as well as by additional contract research revenues, if the Company is successful in its efforts to enter into new collaborative research and development arrangements.

As of September 30, 1998, the Company had cash and cash equivalents totaling approximately \$16.3 million. Cash in excess of immediate requirements is invested in a manner which is intended to maximize liquidity and return while minimizing investment risk, and, whenever possible, the Company seeks to minimize the potential effects of concentration of credit risk.

The Company consumed \$366,000 in cash for operating activities during the three months ended September 30, 1998, compared to \$194,000 during the three months ended September 30, 1997. The increased cash consumption in the current period can be attributed to a higher net investment in working capital used to finance sales growth and expanded product offerings.

Historically, the Company's operations have not been capital intensive and investment in property, plant and equipment during the periods presented has not been significant. However, investment in facilities and equipment may increase in the future. The Company's expenditures for equipment and furniture were \$69,000 and \$60,000 in each of the three month periods ended September 30, 1998 and 1997, respectively.

Other uses of cash in the three months ended September 30, 1998, were \$13,000 in principal reductions under capital lease obligations. During the three months ended September 30, 1997, the Company paid \$180,000 for the mandatory redemption of a portion of its outstanding Series C Preferred Shares. The remaining Series C Preferred Shares were converted into common shares of the Company, on a share-for-share basis, concurrently with the closing of the initial public offering of the Company's common shares.

The Company may continue to incur costs associated with its research and development activities, including clinical trials, and make additional investments in working capital. The Company anticipates that its existing cash balances and cash generated from operations will be sufficient to fund the operations of the Company at least through fiscal 2000. However, the Company may be required or elect to raise additional capital before that time. The Company's actual capital requirements will depend on many factors, some of which are outside the Company's control.

#### **IMPACT OF THE YEAR 2000**

Many computer systems experience problems handling dates beyond the year 1999. The Company has evaluated its primary operating systems (including its financial systems, material requirements planning, and production lot tracking systems) and believes, based upon its evaluation as well as representations from its software suppliers, that its operating systems are substantially year 2000 compliant. To the extent that any software applications are not fully year 2000 compliant, the Company expects that software upgrades made in the normal course of business will either minimize, isolate or possibly eliminate any substantive risks associated with software or system failure.

To date, the Company has not incurred any significant costs associated with the evaluation or modification of its systems relating to year 2000 compliance and does not anticipate the need to incur any costs outside the normal course of business. In the event that any of the Company's systems should fail due to a failure to identify and address a year 2000 exposure, the Company believes that the size and scope of its operations would allow the Company to revert to manual operating systems on a timely basis.

The custom circuitry and software utilized in the Company's iontophoretic dose controllers do not include any date driven functions and therefore will not exhibit any change in performance due to the arrival of the year 2000. The Company has initiated procedures designed to evaluate the year 2000 exposure of its significant suppliers and other vendors whose systems may impact the Company's operations. To date, the Company has not identified any compliance deficiencies that might have a significant impact on the Company if not rectified by such supplier or vendor on a timely basis. There can be no assurance that such a deficiency will not be discovered or arise in the future or that the Company would be able to identify and validate an alternative source for any service or material which may be affected by such deficiency.

#### **PART II -- OTHER INFORMATION**

#### **Item 5. Other Information**

Effective September 18, 1998, Dr. Ned M. Weinshenker resigned as President and Chief Executive Officer and as a director of the Company.

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

#### **EXHIBITS:**

27.1 Financial Data Schedule for the three months ended September 30, 1998 and 1997.

#### **REPORTS ON FORM 8-K:**

On July 2, 1998, the Company filed a report on Form 8-K with regard to the decision by Novartis Pharmaceuticals Corporation not to renew the collaborative research and development agreement between the Company, Dermion, Inc., the Company's wholly owned subsidiary, and Novartis beyond its scheduled December 31, 1998, expiration date.

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#### IOMED, INC.

#### **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.

### IOMED, Inc.

(Registrant)

Date: November 13, 1998 By:/s/ James R. Weersing

James R. Weersing Chairman of the Board

Date: November 13, 1998 By:/s/ Robert J. Lollini

Robert J. Lollini

Vice President, Finance and Chief Financial Officer

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#### **ARTICLE 5**

THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION EXTRACTED FROM THE IOMED, INC. CONDENSED CONSOLIDATED BALANCE SHEETS AND STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 1998 AND 1997, AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH FINANCIAL STATEMENTS.

CIK: 0001041652 NAME: IOMED, INC.

PERIOD TYPE	3 MOS	3 MOS
FISCAL YEAR END	JUN 30 1998	JUN 30 1997
PERIOD START	JUL 01 1998	JUL 01 1997
PERIOD END	SEP 30 1998	SEP 30 1997
CASH	16,261,000	0
SECURITIES	0	0
RECEIVABLES	1,472,000	0
ALLOWANCES	60,000	0
INVENTORY	1,076,000	0
CURRENT ASSETS	18,801,000	0
PP&E	4,500,000	0
DEPRECIATION	3,744,000	0
TOTAL ASSETS	19,758,000	0
CURRENT LIABILITIES	890,000	0
BONDS	171,000	0
PREFERRED MANDATORY	0	0
PREFERRED	6,881,000	0
COMMON	34,408,000	0
OTHER SE	(22,592,000)	0
TOTAL LIABILITY AND EQUITY	19,758,000	0
SALES	2,155,000	1,997,000
TOTAL REVENUES	2,583,000	2,500,000
CGS	986,000	893,000
TOTAL COSTS	2,759,000	2,329,000
OTHER EXPENSES	(228,000)	(80,000)
LOSS PROVISION	Ó	Ó
INTEREST EXPENSE	6,000	287,000
INCOME PRETAX	46,000	(36,000)
INCOME TAX	0	Ó
INCOME CONTINUING	46,000	(36,000)
DISCONTINUED	0	Ó
EXTRAORDINARY	0	0
CHANGES	0	0
NET INCOME	46,000	(36,000)
EPS PRIMARY	0.01	(0.01)
EPS DILUTED	0.01	(0.01)
		(5.01)

**End of Filing** 



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