

IsoRay, Inc.
Form 10-Q
November 09, 2018

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended September 30, 2018

or

Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 001-33407

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota 41-1458152
(State or other jurisdiction of incorporation or (I.R.S. Employer
organization) Identification No.)

350 Hills St., Suite 106, Richland, Washington 99354
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (509) 375-1202

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 the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

Number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date:

<u>Class</u>	<u>Outstanding as of November 9, 2018</u>
Common stock, \$0.001 par value	67,331,147

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ISORAY, INC.

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Table of Contents**PART I – FINANCIAL INFORMATION****ITEM 1 – FINANCIAL STATEMENTS****IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets (Unaudited)
(In thousands, except shares)**

	September 30, 2018	June 30, 2018
ASSET		
Current assets:		
Cash and cash equivalents	\$ 2,193	\$2,600
Short-term investments (Note 3)	7,000	825
Accounts receivable, net of allowance for doubtful accounts of \$26 and \$26, respectively	1,071	1,192
Inventory	487	494
Prepaid expenses and other current assets	517	335
Total current assets	11,268	5,446
Property and equipment, net	1,394	1,311
Restricted cash	181	181
Inventory, non-current	316	319
Other assets, net of accumulated amortization	185	198
Total assets	\$ 13,344	\$7,455
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,167	\$1,391
Accrued protocol expense	125	77
Accrued radioactive waste disposal	45	37
Accrued payroll and related taxes	125	155
Accrued vacation	175	175
Total current liabilities	1,637	1,835
Long-term liabilities:		
Asset retirement obligation	598	590
Total liabilities	2,235	2,425
Commitments and contingencies (Note 8)		

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Shareholders' equity:

Preferred stock, \$.001 par value; 7,001,671 shares authorized:

Series A: 1,000,000 shares allocated; no shares issued and outstanding

- -

Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding

- -

Series C: 1,000,000 shares allocated; no shares issued and outstanding

- -

Series D: 1,671 shares allocated; no shares issued and outstanding

- -

Common stock, \$.001 par value; 192,998,329 shares authorized; 67,331,147 and 56,331,147 shares issued and outstanding

67 56

Additional paid-in capital

91,898 84,322

Accumulated deficit

(80,856) (79,348)

Total shareholders' equity

11,109 5,030

Total liabilities and shareholders' equity

\$ 13,344 \$ 7,455

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

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IsoRay, Inc. and Subsidiaries
Consolidated Statements of Operations (Unaudited)
(Dollars and shares in thousands, except for per-share amounts)

	Quarter ended	
	September 30,	
	2018	2017
Product sales, net	\$1,562	\$1,211
Cost of product sales	1,038	946
Gross profit	524	265
Operating expenses:		
Research and development		
Propriety research and development	394	287
Collaboration arrangement, net of reimbursement	26	75
Total research and development	420	362
Sales and marketing	649	614
General and administrative	973	841
Total operating expenses	2,042	1,817
Operating loss	(1,518)	(1,552)
Non-operating income:		
Interest income, net	10	6
Non-operating income, net	10	6
Net loss	(1,508)	(1,546)
Preferred stock dividends	(3)	(3)
Net loss applicable to common shareholders	(1,511)	(1,549)
Basic and diluted loss per share	\$(0.02)	\$(0.03)
Weighted average shares used in computing net loss per share:		
Basic and diluted	66,147	55,017

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

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IsoRay, Inc. and Subsidiaries
Consolidated Statements of Cash Flows (Unaudited)
(In thousands)

	Quarter ended	
	September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(1,508)	\$(1,546)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	32	18
Amortization of other assets	12	13
Accretion of asset retirement obligation	8	7
Share-based compensation	93	90
Changes in operating assets and liabilities:		
Accounts receivable, gross	121	(17)
Inventory	10	(44)
Prepaid expenses and other current assets	(182)	(143)
Accounts payable and accrued expenses	(224)	181
Accrued protocol expense	48	(10)
Accrued radioactive waste disposal	9	(114)
Accrued payroll and related taxes	(30)	(104)
Accrued vacation	(1)	8
Net cash used by operating activities	(1,612)	(1,661)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(114)	(54)
Proceeds from maturity of certificates of deposit	575	3,043
Purchases of and interest from certificates of deposit and U.S. Treasury Securities	(6,750)	(3,304)
Net cash used by investing activities	(6,289)	(315)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sales of common stock and warrants, pursuant to registered direct offering, net	7,494	-
Net cash provided by financing activities	7,494	-
Net decrease in cash, cash equivalents, and restricted cash	(407)	(1,976)
Cash, cash equivalents, and restricted cash beginning of quarter	2,781	6,113
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH END OF QUARTER	\$2,374	\$4,137
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	\$2,193	\$3,956
Restricted cash	181	181

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Total cash, cash equivalents, and restricted cash shown on the consolidated statement of cashflows \$2,374 \$4,137

Non-cash financing activities:

Warrants issued to placement agent of registered direct offering \$163 \$-

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

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IsoRay, Inc.

Notes to the Unaudited Consolidated Financial Statements

For the three months ended September 30, 2018 and 2017

1. Basis of Presentation

The accompanying unaudited interim consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries, referred to herein as “IsoRay” or the “Company”. All significant intercompany accounts and transactions have been eliminated in the consolidation. In the opinion of management, all adjustments necessary for the fair presentation of the consolidated financial statements have been included. These unaudited interim consolidated financial statements should be read in conjunction with our audited consolidated financial statements and related footnotes as set forth in the Company’s annual report filed on Form 10-K for the year ended June 30, 2018.

The unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP) have been condensed or omitted pursuant to those rules and regulations, although we believe that the disclosures are adequate for the information not to be misleading.

Certain prior period amounts have been reclassified to conform to the current period’s presentation. The results of operations for the periods presented may not be indicative of those which may be expected for a full year. The Company anticipates that as the result of continuing operating losses and the significant net operating losses available from prior fiscal years, its effective income tax rate for fiscal year 2019 will be 0%.

2. New Accounting Standards

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09 Revenue Recognition, replacing guidance currently codified in Subtopic 605-10 Revenue Recognition-Overall with various SEC Staff Accounting Bulletins providing interpretive guidance. The guidance establishes a new five step principle-based framework in an effort to significantly enhance comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets. The standard became effective for the Company in the first quarter of its fiscal year 2019. The Company adopted the new standard in the first quarter of fiscal year 2019 and used the modified retrospective method. The adoption of ASU 2014-09 did not have a material impact on the consolidated financial statements of the Company and did not significantly change the timing of

revenue recognition compared to the previous methodology.

In February 2016, the FASB issued ASU 2016-02 Leases (Subtopic 842), which will require lessees to recognize assets and liabilities on the balance sheet for the rights and obligations created by most leases. The update is effective for annual and interim reporting periods beginning after December 15, 2018. Early adoption is permitted. The ASU will be effective for the Company in the first quarter of fiscal year 2020. We are currently evaluating the impact of the guidance on the Company's consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15 Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The update provides guidance on classification for cash receipts and payments related to eight specific issues. The update is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, with early adoption permitted. The Company adopted ASU 2016-15 as of July 1, 2018. The adoption of ASU 2016-15 did not have a material effect on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230): Restricted Cash". ASU 2016-18 is intended to clarify how entities present restricted cash in the statement of cash flows. The guidance requires entities to show the changes in the total of cash and cash equivalents and restricted cash in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash in the statement of cash flows. When cash and cash equivalents and restricted cash are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. This reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 and is to be applied retrospectively. Early adoption is permitted, including adoption in an interim period. The Company adopted ASU 2016-18 in the first quarter of fiscal 2019. This update resulted in an increase of \$181,000 in cash, cash equivalents, and restricted cash at the beginning of the first period presented on the consolidated statement of cash flows.

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Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the consolidated financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

3.Short-Term Investments

The Company had short-term investments consisting of U.S. Treasury Securities and Certificate of Deposit Account Registry Service (CDARS) as of September 30, 2018 and June 30, 2018 respectively.

CDARS is a system that allows the Company to invest in certificates of deposit through a single financial institution that exceed the \$250,000 limit to be fully insured by the Federal Deposit Insurance Corporation (FDIC). That institution utilizes the CDARS system to purchase certificates of deposit at other financial institutions while keeping the investment at each institution fully insured by the FDIC.

Short-term investments held by the Company as of September 30, 2018 and June 30, 2018 mature as follows (in thousands):

	As of September 30, 2018			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
U.S. Treasury Securities	\$2,333	\$2,333	\$2,334	\$ -

	As of June 30, 2018			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$825	\$ -	\$ -	\$ -

4.Loss per Share

Basic and diluted earnings (loss) per share are calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding, and does not include the impact of any potentially dilutive common stock equivalents. At September 30, 2018 and 2017, the calculation of diluted weighted average shares did not include convertible preferred stock, common stock warrants, or options that are potentially convertible into common stock, as those would be antidilutive due to the Company's net loss position.

Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of September 30, 2018 and 2017, were as follows (in thousands):

	September 30,	
	2018	2017
Series B preferred stock	59	59
Common stock warrants	6,080	-
Common stock options	3,794	3,395
Total potential dilutive securities	9,933	3,454

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Inventory consisted of the following at September 30, 2018 and June 30, 2018 (in thousands):

	September 30, 2018	June 30, 2018
Raw materials	\$ 348	\$371
Work in process	102	96
Finished goods	37	27
Total inventory, current	\$ 487	\$494

	September 30, 2018	June 30, 2018
Enriched barium, non-current	\$ 272	\$276
Raw materials, non-current		