

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

Table of Contents

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 December 31, 2017

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

Edgar Filing: IsoRay, Inc. - Form 10-Q

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, 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, 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	(Do not check if a smaller reporting company)
	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 February 7, 2018</u>
Common stock, \$0.001 par value	55,100,229

---

Table of Contents

**ISORAY, INC.**

**Table of Contents**

PART I FINANCIAL INFORMATION

Item 1	<u>Consolidated Unaudited Financial Statements</u>	1
	<u>Consolidated Balance Sheets</u>	1
	<u>Consolidated Statements of Operations (Unaudited)</u>	2
	<u>Consolidated Statements of Cash Flows (Unaudited)</u>	3
	<u>Notes to the Consolidated Unaudited Financial Statements</u>	4

Item 2	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	11
--------	--	----

Item 3	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	17
--------	---	----

Item 4	<u>Controls and Procedures</u>	17
--------	--------------------------------	----

PART II OTHER INFORMATION

Item 1	<u>Legal Proceedings</u>	18
--------	--------------------------	----

Item 1A	<u>Risk Factors</u>	18
---------	---------------------	----

Item 2	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	18
--------	--	----

Item 3	<u>Defaults Upon Senior Securities</u>	18
--------	--	----

Item 4	<u>Mine Safety Disclosures</u>	19
--------	--------------------------------	----

Item 5	<u>Other Information</u>	19
--------	--------------------------	----

Item 6	<u>Exhibits</u>	19
--------	-----------------	----

	<u>Signatures</u>	20
--	-------------------	----

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

	<b>December 31, 2017</b>	<b>June 30, 2017</b>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,951	\$5,932
Certificates of deposit (Note 3)	2,725	3,039
Accounts receivable, net of allowance for doubtful accounts of \$26 and \$26, respectively	987	726
Inventory	459	323
Prepaid expenses and other current assets	295	271
Total current assets	7,417	10,291
Property and equipment, net	1,168	1,054
Restricted cash	181	181
Inventory, non-current	408	513
Other assets, net of accumulated amortization	204	230
Total assets	\$ 9,378	\$12,269
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 581	\$630
Accrued protocol expense	43	75
Accrued radioactive waste disposal	19	125
Accrued payroll and related taxes	165	138
Accrued vacation	123	138
Total current liabilities	931	1,106
Long-term liabilities:		
Asset retirement obligation	576	561

Edgar Filing: IsoRay, Inc. - Form 10-Q

Total liabilities	1,507	1,667
Commitments and contingencies (Note 8)		
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; 55,100,229 and 55,017,419 shares issued and outstanding	55	55
Additional paid-in capital	83,430	83,151
Accumulated deficit	(75,614 )	(72,604)
Total shareholders' equity	7,871	10,602
Total liabilities and shareholders' equity	\$ 9,378	\$12,269

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

Table of Contents

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

	<b>Three months ended</b>		<b>Six months ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>
Product sales, net	\$1,536	\$1,028	\$2,747	\$2,109
Cost of product sales	1,005	1,029	1,951	2,062
Gross profit / (loss)	531	(1 )	796	47
Operating expenses:				
Research and development				
Proprietary research and development	311	150	597	322
Collaboration arrangement, net of reimbursement (Note 8)	29	-	104	-
Total research and development	340	150	701	322
Sales and marketing	674	496	1,288	1,020
General and administrative	985	880	1,827	1,807
Change in estimate of asset retirement obligation	-	(48 )	-	(48 )
Total operating expenses	1,999	1,478	3,816	3,101
Operating loss	(1,468 )	(1,479 )	(3,020 )	(3,054 )
Non-operating income:				
Interest income, net	5	29	10	60
Change in fair value of warrant derivative liability	-	-	-	27
Other income	-	-	-	20
Non-operating income, net	5	29	10	107
Net loss	(1,463 )	(1,450 )	(3,010 )	(2,947 )
Preferred stock dividends	(3 )	(2 )	(5 )	(5 )
Net loss applicable to common shareholders	\$(1,466 )	\$(1,452 )	\$(3,015 )	\$(2,952 )
Basic and diluted loss per share	\$(0.03 )	\$(0.03 )	\$(0.05 )	\$(0.05 )
Weighted average shares used in computing net loss per share:				
Basic and diluted	55,056	55,017	55,037	55,014

The accompanying notes are an integral part of

these  
consolidated  
financial  
statements.

2

---

Table of Contents

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

	<b>Six months ended December 31, 2017      2016</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$(3,010)	\$(2,947)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	36	32
Loss on equipment disposals	-	5
Amortization of other assets	26	23
Change in fair value of warrant derivative liability	-	(27 )
Accretion of asset retirement obligation	15	15
Change in estimate of asset retirement obligation	-	(48 )
Share-based compensation	240	122
Changes in operating assets and liabilities:		
Accounts receivable, gross	(261 )	(22 )
Inventory	(31 )	(24 )
Prepaid expenses and other current assets	(24 )	79
Accounts payable and accrued expenses	(49 )	(299 )
Accrued protocol expense	(32 )	34
Accrued radioactive waste disposal	(106 )	18
Accrued payroll and related taxes	27	18
Accrued vacation	(15 )	7
Net cash used by operating activities	(3,184)	(3,014)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property and equipment	(150 )	(239 )
Additions to other assets	-	(151 )
Proceeds from maturity of certificates of deposit	3,868	-
Purchases of and interest from certificates of deposit	(3,554)	(58 )
Net cash provided (used) by investing activities	164	(448 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Preferred dividends paid	(11 )	(11 )
Proceeds from sales of common stock, pursuant to exercise of options	50	2
Net cash provided (used) by financing activities	39	(9 )
Net decrease in cash and cash equivalents	(2,981)	(3,471)
Cash and cash equivalents, beginning of period	5,932	10,139



<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<i>\$2,951</i>	<i>\$6,668</i>
---	----------------	----------------

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

Table of Contents

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the six months ended December 31, 2017 and 2016**

**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, 2017*.

The unaudited consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission. 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 2018 will be 0%.

**2. New Accounting Pronouncements**

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 will be effective for the Company in the *first* quarter of its fiscal year 2019, but early adoption is permitted starting in the *first* quarter of fiscal year 2018. The Company intends to adopt the new standard in the *first* quarter of fiscal year 2019 and expects to use the modified retrospective method. The Company has evaluated the impact of the future adoption of

ASU 2014-09 on its consolidated financial statements and does *not* currently expect significant changes in the timing of revenue recognition compared to the existing methodology.

In *July 2015*, the FASB issued ASU No. 2015-11: Inventory. The guidance requires an entity's management to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after *December 15, 2016*. Early application is permitted. The ASU became effective for the Company on *July 1, 2017*. This update did *not* have a material impact on the Company's consolidated financial statements upon adoption.

In *November 2015*, the FASB issued an ASU 2015-17 to simplify the balance sheet classification of deferred taxes. This update requires all deferred tax assets and liabilities to be reported as non-current in the consolidated balance sheets. The ASU became effective for the Company on *July 1, 2017*. This update did *not* to have a material impact on the Company's consolidated financial statements upon adoption.

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.

Table of Contents

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 is currently evaluating the impact of implementing this update on the consolidated financial statements.

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. Certificates of Deposit**

Certificate of Deposit Account Registry Service (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. CDARS held by the Company as of *December 31, 2017* and *June 30, 2017* are as follows (in thousands):

As of December 31, 2017				
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$1,075	\$ 825	\$ 825	\$ -

As of June 30, 2017				
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
CDARS	\$3,039	\$ -	\$ -	\$ -

**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 *December 31, 2017* and *2016*, 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 *December 31, 2017* and *2016*, were as follows (in thousands):

	December 31,	
	2017	2016
Series B preferred stock	59	59
Common stock warrants	250	5
Common stock options	3,295	2,565
Total potential dilutive securities	3,604	2,629

## 5. Inventory

Inventory consisted of the following at *December 31, 2017* and *June 30, 2017* (in thousands):

	December	June
	31,	30,
	2017	2017
Raw materials	\$ 367	\$191
Work in process	82	121
Finished goods	10	11
Total inventory, current	\$ 459	\$323

Table of Contents

	December 31, 2017	June 30, 2017
Enriched barium, non-current	\$ 347	\$470
Raw materials, non-current	61	43
Total inventory, non-current	\$ 408	\$513

Inventory, non-current is raw materials that were ordered in quantities to obtain volume cost discounts which based on current and anticipated sales volumes will *not* be consumed within an operating cycle.

On *August 25, 2017*, the Company entered into a Consignment Agreement and related Services Agreement with MedikorPharma-Ural LLC to begin utilizing our enriched barium-130 carbonate inventory beginning in *November 2017*. The Company anticipates obtaining enough Cesium-131 under this arrangement to obtain over *4,000* curies of Cesium-131 over a *ten-year* period but there is *no* assurance as to whether the agreements will be terminated before this full amount is obtained and other supply sources are used, nor is there assurance that the agreements with the *third-party* Cesium-131 suppliers will be executed.

**6. Property and Equipment**

Property and equipment consisted of the following at *December 31, 2017* and *June 30, 2017* (in thousands):

	December 31, 2017	June 30, 2017
Land	\$ 366	\$366
Equipment	3,799	3,776
Leasehold improvements	4,134	4,130
Other <sup>1</sup>	496	373
Property and equipment	8,795	8,645
Less accumulated depreciation	(7,627 )	(7,591)
Property and equipment, net	\$ 1,168	\$1,054

<sup>1</sup> – Represents items that meet the capitalization threshold or which management believes will meet the threshold at the time of completion and which have yet to be placed into service as of the date of the balance sheet. Also included at *December 31, 2017* and *June 30, 2017* are costs associated with automation of production processes and advance planning and design work on the Company's new production facility.

**7. Share-Based Compensation**

The following table presents the share-based compensation expense recognized for stock-based options during the *three* months ended *December 31, 2017* and *2016* (in thousands):

	Three Months ended December 31, 2017 2016	
Cost of product sales	\$ 13	\$ 17
Research and development expenses	19	7
Sales and marketing expenses	17	11
General and administrative expenses	29	17
Total share-based compensation	\$ 78	\$ 52

Table of Contents

The following table presents the share-based compensation expense recognized for stock-based options during the *six* months ended *December 31, 2017* and *2016* (in thousands):

	Six Months ended December 31, 2017 2016	
Cost of product sales	\$29	\$44
Research and development expenses	38	15
Sales and marketing expenses	34	26
General and administrative expenses	67	37
Total share-based compensation	\$168	\$122

As of *December 31, 2017*, total unrecognized compensation expense related to stock-based options was approximately *\$722,000* and the related weighted-average period over which it is expected to be recognized is approximately *1.27* years.

A summary of stock options within the Company's share-based compensation plans as of *December 31, 2017* was as follows (in thousands except for exercise prices and terms):

	Number of Options	Weighted Exercise Price	Weighted Average Contractual Term (Years)	Intrinsic Value
As of December 31, 2017				
Outstanding	3,295	\$ .76	7.40	\$ 36
Vested and expected to vest	3,192	\$ .76	7.34	\$ 36
Vested and exercisable	1,747	\$ .91	5.54	\$ 36

There were *82,810* and *6,800* stock options exercised, with approximately *nil* and *\$3,000* of intrinsic value associated with these exercises during the *three* months ended *December 31, 2017* and *2016*, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were *no* and *10,000* option awards granted with a fair value of approximately *\$0* and *\$4,000* during the *three* months ended *December 31, 2017* and *2016*, respectively.



There were *no* stock option awards which expired during the *three* months ended *December 31, 2017* and *2016*, respectively.

There were *16,875* and *47,669* stock option awards forfeited during the *three* months ended *December 31, 2017* and *2016*, respectively.

There were *82,810* and *6,800* stock options exercised, with approximately *nil* and *\$3,000* of intrinsic value associated with these exercises during the *six* months ended *December 31, 2017* and *2016*, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were *75,000* and *10,000* option awards granted with a fair value of approximately *\$33,000* and *\$4,000* during the *six* months ended *December 31, 2017* and *2016*, respectively.

There were *no* and *280,534* stock option awards which expired during the *six* months ended *December 31, 2017* and *2016*, respectively.

There were *76,541* and *83,005* stock option awards forfeited during the *six* months ended *December 31, 2017* and *2016*, respectively.

Table of Contents

**8. Commitments and Contingencies**

Isotope Purchase Agreement

In *December 2015*, the Company completed negotiations with The Open Joint Stock Company (located in Russia) for the purchase of Cs-131 manufactured by the Institute of Nuclear Materials. The purchase agreement provided the Company with *one year's* supply of Cs-131. The original agreement was due to expire on *March 31, 2017*, but in *December 2016* an addendum was signed extending it until *December 31, 2017*. On *October 23, 2017*, the Company, together with The Open Joint Stock Company signed an addendum to the contract to include Cs-131 manufactured at SSC RIAR and extending it until *December 31, 2018*.

Research and Development - Collaborative Arrangement

On *March 13, 2017*, Medical entered into a Collaborative Development Agreement (CDA) with GammaTile, LLC to further develop a brachytherapy medical device for the treatment of cancerous tumors in the brain and to seek regulatory approval for the new product. As the project manager, Medical will incur all costs in connection with the collaboration project which has been shared equally by both parties as of *November 8, 2016* when they informally began the collaboration. The start of the formal collaboration has been extended from *December 2017* until *March 2018*. In accordance with ASC 808 "Collaborative Arrangements", this activity is accounted for as a collaborative arrangement and related costs are incurred, shared, and separately stated in connection with a collaborative research and development project. These costs are reported on the financial statements under "Research and development: Collaboration arrangements, net of reimbursement." The Company collaborated with GammaTile LLC in filing applications to the U.S. Food and Drug Administration (FDA) to clear GammaTile™ for clinical use, and a New Technology Add-on Payment (NTAP) to the Center for Medicare and Medicaid Services (CMS) seeking re-imburement for the GammaTile™ treatment in the in-patient setting. The application with the FDA is ongoing, however, the NTAP was filed in *October 2017*.

During the *three* months ended *December 31, 2017* and *2016*, costs incurred in connection with the collaboration agreement were *\$58,000* and *\$0*, respectively.

During the *six* months ended *December 31, 2017* and *2016*, costs incurred in connection with the collaboration agreement were *\$205,000* and *\$0*, respectively.

As of *December 31, 2017* and *June 30, 2017*, the Company had outstanding receivables from GammaTile LLC of *\$15,000* and *\$66,000* respectively. These amounts are included in the Prepaid expenses and other current assets on the consolidated balance sheet.

#### Derivative Complaint related to Shareholder Value

On *September 29, 2016*, David M. Kitley, purportedly on behalf of IsoRay, filed a derivative lawsuit in the United States District Court for the District of Minnesota under the case caption *Kitley v. IsoRay, Inc., Case No. 0:16-cv-03297-DTS*. The complaint named as defendants current and former IsoRay directors Dwight Babcock, Thomas LaVoy, Philip J. Vitale and Michael W. McCormick, alleging that they violated their fiduciary duties to IsoRay in connection with a press release allegedly containing false and misleading statements concerning the results from a peer reviewed study of its Cesium-131 isotope seeds for the treatment of non-small cell lung cancers, thereby artificially inflating the price of IsoRay stock. The complaint sought unspecified damages, in an amount *not* presently determinable, among other forms of relief.

On *November 17, 2016*, IsoRay moved to dismiss the complaint, arguing that plaintiff was *not* entitled to pursue his derivative claims due to his failure to serve a pre-suit demand on IsoRay's board. Rather than respond to the motion to dismiss, plaintiff filed an amended complaint on *January 23, 2017*. The amended complaint alleged the same derivative claims as the original, and added IsoRay director Alan Hoffmann as a defendant. Plaintiff sought an award of damages and an order directing IsoRay to undertake reforms of its corporate governance and internal procedures. IsoRay moved to dismiss the amended complaint on *March 9, 2017*. Plaintiff responded on *April 20, 2017*, and IsoRay replied on *May 17, 2017*. The court heard oral argument on the motion on *August 22, 2017*, and took the matter under advisement at that time. On *October 19, 2017*, the court granted IsoRay's motion to dismiss. The matter is now resolved.

#### Media Advertising Agreement

On *October 3, 2017*, the Company entered into a Media Advertising Agreement with AI & J Media Inc., a corporation incorporated in the State of New York (the "Consultant").

Pursuant to the agreement, the Consultant was to introduce the Company to potential sources of media, marketing agreements, and/or strategic alliances, including but *not* limited to radio and television media advertising, various media publications, and Internet podcasts. The Consultant did *not* promote the Company as part of the agreement; it acted only as a media agent for advertising.

On *December 29, 2017*, the Company notified the Consultant of its decision to terminate the agreement between the parties because the Consultant's services were *no* longer needed.

As compensation for the services provided prior to termination, the Company paid the Consultant \$60,000 and issued the Consultant 250,000 warrants upon execution of the agreement, which vested immediately, entitling the Consultant to purchase shares of Company common stock, exercisable on or before *October 3, 2020*, at an exercise price of \$0.54 per share.

Table of Contents**9. Fair Value Measurements**

The following table sets forth the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement (in thousands):

Fair Value at December 31, 2017				
Total	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$2,951	\$2,951	\$ -	\$ -

Fair Value at June 30, 2017				
Total	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$5,932	\$5,932	\$ -	\$ -

The Company's cash and cash equivalent instruments are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices.

**10. Related Party Transactions**

During the quarter ended *June 30, 2016*, the Company engaged GO Intellectual Capital, LLC (GO) for marketing services in support of the Company's rebranding effort. Michael McCormick, a member of the Company Board of Directors, is a 1/3 owner of GO. A statement of work was developed defining the scope of the effort and the deliverables to the Company including a new logo with brand messaging and communication tools including a website, sales presentation tools and a public relations strategy. For the *six months ended December 31, 2016*, the Company paid approximately \$20,000 to GO for its performance of work related to the agreed upon statement of work. *No* such services were provided in the *six months ended December 31, 2017*.

**11. Concentrations of Credit and Other Risks**

One group of customers, facilities or physician practices has revenues that aggregate to greater than 10% of total Company product sales:

Facility	Six months ended		
	December 31, 2017	December 31, 2016	
El Camino Hospital of Los Gatos, Fremont Surgery Center & other facilities <sup>1</sup>	23.60%	23.10%	%

<sup>1</sup> – This group of facilities individually each comprise less than 10% of total Company product sales. They are serviced by the same physician group, *one* of whom is our Medical Director.

The Company routinely assesses the financial strength of its customers and provides an allowance for doubtful accounts as necessary.

## 12. Shareholders' Equity

### *Warrants*

As part of the compensation for the services performed by Al & J Media Inc. (the "Consultant") pursuant to the Media Advertising Agreement discussed on page 8, the Consultant received 250,000 warrants upon execution of the agreement, which vested immediately, entitling the Consultant to purchase shares of Company common stock, exercisable on or before *October 3, 2020*, at an exercise price of \$0.54 each. These warrants, using the Black-Scholes model, resulted in approximately \$72,000 of additional share based compensation during the *three* months ended *December 31, 2017*. On *December 29, 2017*, the Company notified the Consultant of its decision to terminate the Media Advertising Agreement.

Table of Contents

The key assumptions used in the Black-Scholes valuation model to calculate the fair value of the warrants are as follows:

	October 3, 2017
Grant date fair value	\$0.2874
Options issued	250,000
Exercise price	\$0.54
Expected term (in years)	3
Risk-free rate	1.62 %
Volatility	81.66 %

The following table summarizes all warrants outstanding as of the beginning of the fiscal year, all activity related to warrants issued, cancelled, exercised or expired during the period and weighted average prices by category.

	Warrants	Weighted average exercise price
Outstanding as of June 30, 2017	-	\$ -
Warrants issued	250,000	\$ 0.54
Outstanding as of December 31, 2017	250,000	\$ 0.54

The following table summarizes additional information about the Company's common warrants outstanding as of *December 31, 2017*:

Number of Warrants	Exercise Price <sup>1</sup>	Expiration Date
250,000	\$ 0.54	October 2020

<sup>1</sup> – Exercise prices have been rounded to the nearest whole cent.

**13. Subsequent Events****Manufacturing and Supply Agreement between Medical and GT Medical Technologies**

On *January 3, 2018*, Medical and GT Medical Technologies, Inc. (“GT Tech”) entered into a Manufacturing and Supply Agreement (the “Supply Agreement”).

Pursuant to the Supply Agreement, Medical will manufacture and supply a brachytherapy product that incorporates Cesium-*131* seeds within customizable carriers configured as squares or rectangles for the treatment of brain tumors (the “GammaTile™ Product”), developed pursuant to the Collaborative Development Agreement. Once regulatory clearance from the U.S. Food and Drug Administration permitting marketing of the GammaTile™ Product is received (the “*510(k)* Clearance”), Medical will exclusively manufacture and supply the GammaTile™ Product for end users designated by GT Tech. Additionally, Medical will supply loose or braided Cesium-*131* seeds for brachytherapy brain cancer treatment to GT Tech on a non-exclusive basis. The prices for the GammaTile™ Product and Cesium-*131* seeds are set forth on Exhibit B of the Supply Agreement, subject to periodic adjustment, with an initial price per seed of between \$*130* and \$*150* depending on quantity ordered. As part of the Supply Agreement, Medical has agreed to transfer the *510(k)* Clearance to GT Tech within *30* days of receipt. The term of the Supply Agreement is *10* years.



Table of Contents

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

***Caution Regarding Forward-Looking Information***

*In addition to historical information, this Form 10-Q contains certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). This statement is included for the express purpose of availing IsoRay, Inc. of the protections of the safe harbor provisions of the PSLRA.*

*All statements contained in this Form 10-Q, other than statements of historical facts, that address future activities, events or developments are forward-looking statements, including, but not limited to, statements containing the words “believe,” “expect,” “anticipate,” “intends,” “estimate,” “forecast,” “project,” and similar expressions. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements concerning proposed new products, services, developments or industry rankings; any statements regarding future revenue, economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing. These statements are based on certain assumptions and analyses made by us in light of our experience and our assessment of historical trends, current conditions and expected future developments as well as other factors we believe are appropriate under the circumstances. However, whether actual results will conform to the expectations and predictions of management is subject to a number of risks and uncertainties described under Item 1A - Risk Factors beginning on page 18 below that may cause actual results to differ materially.*

*Consequently, all of the forward-looking statements made in this Form 10-Q are qualified by these cautionary statements and there can be no assurance that the actual results anticipated by management will be realized or, even if substantially realized, that they will have the expected consequences to or effects on our business operations. Readers are cautioned not to place undue reliance on such forward-looking statements as they speak only of the Company’s views as of the date the statement was made. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

**Critical Accounting Policies and Estimates**

The discussion and analysis of the Company’s financial condition and results of operations are based upon its consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. On an on-going basis, management

evaluates past judgments and estimates, including those related to bad debts, inventories, accrued liabilities, derivative liabilities and contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The accounting policies and related risks described in the Company's annual report on Form 10-K as filed with the SEC on September 28, 2017 are those that depend most heavily on these judgments and estimates. As of December 31, 2017 there had been no material changes to any of the critical accounting policies contained therein.

## **Overview**

IsoRay, Inc. is a brachytherapy device manufacturer with FDA clearance and CE marking for a single medical device that can be delivered to the physician in multiple configurations as prescribed for the treatment of cancers in multiple body sites. The Company manufactures and sells this product as the Cesium-131 brachytherapy seed.

The brachytherapy seed utilizes Cesium-131, with a 9.7 day half-life, as its radiation source. The Company believes that it is the unique combination of the short half-life and the energy of the Cesium-131 isotope that are yielding the beneficial treatment results that have been published in peer reviewed journal articles and presented in various forms at conferences and tradeshows.

The Company has distribution agreements outside of the United States through its subsidiary IsoRay International LLC. These distributors are responsible for obtaining regulatory clearance to sell the Company's products in their territories, with the support of the Company. As of the date of this Report, the Company had distributors in Italy and the Russian Federation.

Table of Contents**Results of Operations****Three months ended December 31, 2017 and 2016 (in thousands):**

	Three months ended December 31,				
	2017		2016		2017 - 2016
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	\$1,536	100	\$1,028	100	49
Cost of product sales	1,005	65	1,029	100	(2 )
Gross profit / (loss)	531	35	(1 )	-	53,200
Operating expenses:					
Research and development expenses - proprietary	311	20	150	15	107
Research and development expenses – collaboration agreement, net of reimbursement	29	2	-	-	100
Sales and marketing expenses	674	44	496	48	35
General and administrative expenses	985	64	880	86	12
Change in estimate of ARO	-	-	(48 )	(5 )	(100 )
Total operating expenses	1,999	130	1,478	144	35
Operating loss	(1,468)	(95 )	(1,479)	(144)	1

(a) Expressed as a percentage of product sales, net

**Six months ended December 31, 2017 and 2016 (in thousands):**

	Six months ended December 31,				
	2017		2016		2017 - 2016
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	\$2,747	100	\$2,109	100	30
Cost of product sales	1,951	71	2,062	98	(5 )
Gross profit / (loss)	796	29	47	2	1,594
Operating expenses:					
Research and development expenses - proprietary	597	22	322	15	85
Research and development expenses – collaboration agreement, net of reimbursement	104	4			

Edgar Filing: IsoRay, Inc. - Form 10-Q

Sales and marketing expenses	1,288	47	1,020	48	26
General and administrative expenses	1,827	67	1,807	86	(1 )
Change in estimate of ARO	-	-	(48 )	(2 )	(100 )
Total operating expenses	3,816	140	3,101	147	23
Operating loss	(3,020)	(111)	(3,054)	(145)	1

(a) Expressed as a percentage of product sales, net

**Product Sales**

Changes in sales personnel and implementation of a revitalized sales and marketing strategy in the second quarter of fiscal 2017 has resulted in positive sales growth in the second quarter of fiscal 2018 when compared to prior year second quarter. Ongoing training and support of new sales personnel has led to not only new accounts but also reconnecting with and receiving orders from prior accounts.

Table of Contents**Three months ended December 31, 2017 and 2016 (in thousands)**

	Three months ended December 31,				
	2017		2016		2017 - 2016
	Amount	%	Amount	%	%
	(a)	(a)	(a)	(a)	Change
Prostate brachytherapy	\$1,315	86	\$889	86	48
Other brachytherapy	221	14	139	14	59
Product sales, net	1,536	100	1,028	100	49

(a) Expressed as a percentage of product sales, net

**Six months ended December 31, 2017 and 2016 (in thousands)**

	Six months ended December 31,				
	2017		2016		2017 - 2016
	Amount	%	Amount	%	%
	(a)	(a)	(a)	(a)	Change
Prostate brachytherapy	\$2,399	87	\$1,855	88	29
Other brachytherapy	348	13	254	12	37
Product sales, net	2,747	100	2,109	100	30

(a) Expressed as a percentage of product sales, net

*Prostate Brachytherapy*

During the quarter ended December 31, 2017, the Company had a full sales team in place contributing to the increase in sales. Also, website improvements and significant investments in product support literature, social media and public relations are increasing the awareness of the Company in the prostate brachytherapy treatment markets providing the Company opportunities to develop new customers and reconnect with past customers.

Management believes growth in prostate brachytherapy revenues will be the result of physicians, payers, and patients increasingly considering overall brachytherapy treatment advantages including costs, better treatment outcomes and improvement in the quality of life for patients, when compared with non-brachytherapy treatments.

During the quarter ended December 31, 2017, approximately \$35,000 of reported revenues originated from the international market.

Management believes increased pressure to deliver effective healthcare in both terms of outcome and cost drove treatment options, and accordingly drove the Company's prostate revenues, in the quarter ended December 31, 2017.

#### *Other Brachytherapy*

Other brachytherapy includes, but is not limited to, brain, lung, head/neck, and gynecological treatments. Initial applications for these other brachytherapy treatments are primarily used in recurrent cancer treatments or salvage cases that are generally difficult to treat aggressive cancers where other treatment options are either ineffective or unavailable.

These other brachytherapy treatments continue to be subject to the influence of a small pool of innovative physicians who are the early adopters of the technology who also tend to be faculty at teaching hospitals training the next generation of physicians. This causes the revenue created by these types of treatment applications to be more volatile and vary significantly from quarter to quarter. This volatility resulted in the increase from the prior year.

#### **Cost of product sales**

Cost of product sales consists primarily of the costs of manufacturing and distributing the Company's products.

Table of Contents

Contributing to the three and six months ended December 31, 2017 and 2016 comparison were decreases attributed to cost savings initiatives that resulted in lower procurement costs of goods and services. Some costs shifted in the three and six months ended December 31, 2017 to research and development from cost of product sales as employees performed research and development work. Also, reduced staffing costs were realized with decreased head count. These decreases were partially offset by increased supply of isotope from MURR which increased total cost of product sales but resulted in lower supply cost per curie of Cesium-131.

**Research and development**

Research and development – proprietary

Proprietary research and development consists primarily of employee and third-party costs related to research and development activities.

Contributing to the three months ended December 31, 2017 and 2016 proprietary research and development comparison were increases associated with participation in new protocols, device development activities, as well as a reallocation of employee costs from cost of product sales as those employees performed work on research and development projects.

Contributing to the six months ended December 31, 2017 and 2016 proprietary research and development comparison were increases associated with participation in new protocols, device development activities, as well as a reallocation of employee costs from cost of product sales as those employees performed work on research and development projects. These increases were partially offset by decreased legal fees.

Research and development – collaborative arrangement

Collaboration arrangement related costs are incurred, shared, and separately stated in connection with a collaborative research and development project with GammaTile, LLC.

During the three months ended December 31, 2017 and 2016, costs incurred in connection with the collaboration agreement were \$58,000 and \$0, respectively.

During the six months ended December 31, 2017 and 2016, costs incurred in connection with the collaboration agreement were \$205,000 and \$0, respectively.

### **Sales and marketing expenses**

Sales and marketing expenses consist primarily of the costs related to the internal and external activities of the Company's sales, marketing and customer service functions of the Company. As the Company increasingly focuses on improving sales, the cost associated with marketing and greater staffing continues to increase.

Staffing differences are a major factor in the cost comparison for the three months ended December 31, 2017 and 2016 as open positions in the quarter ended December 31, 2016 were filled in periods prior to the quarter ended December 31, 2017 with increased salaries and increased travel costs. Due to increased sales, there were also increases in commission and bonus expense.

Contributing to the six months ended December 31, 2017 and 2016 comparison were increased advertising and public relations costs as part of the revitalized marketing plan. Staffing differences are a major factor in the cost comparison as open positions in six months ended December 31, 2016 were filled in periods prior to the quarter ended December 31, 2017 with increased salaries.



Table of Contents**General and administrative expenses**

General and administrative expenses consist primarily of the costs related to the executive, human resources/training quality assurance/regulatory affairs, finance, and information technology functions of the Company.

Contributing to the three months ended December 31, 2017 and 2016 comparison were cost increases associated with share-based compensation, bonus expense, public company related expense, and state tax expense. These cost increases were partially offset in the three months ended December 31, 2017 by decreases to payroll as a result of the re-organization of the finance department with reduced head count, decreased legal expenses, and decreased employee hiring costs.

Contributing to the six months ended December 31, 2017 and 2016 comparison were cost decreases from the prior year. Those include decreases to payroll as a result of the re-organization of the finance department with reduced head count, decreased legal expenses, audit and bank fees, and seminars, conference, and training expenses. These cost decreases were partially offset in the six months ended December 31, 2017 by increases associated with share-based compensation, bonus expense, state taxes, and employment hiring expenses related to the hiring of the Controller.

**Liquidity and capital resources**

The Company assesses its liquidity in terms of its ability to generate cash to fund its operating, investing and financing activities. The Company has historically financed its operations through selling equity to investors. During the quarters ended December 31, 2017 and 2016, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

	Six months ended December 31,	
	2017	2016
Net cash used by operating activities	\$(3,184)	\$(3,014)
Net cash provided by investing activities	164	(448 )
Net cash provided by financing activities	39	(9 )
Net decreases in cash and cash equivalents	\$(2,981)	\$(3,471)

As of

	December	June
	31,	30,
	2017	2017
Working capital	\$6,486	\$9,185
Current ratio	7.96	9.30

#### Cash flows from operating activities

Net cash used by operating activities in the six months ended December 31, 2017 was primarily due to a net loss of approximately \$3.01 million, net of approximately \$317,000 in adjustments for non-cash activity such as depreciation and amortization expense, ARO accretion, and share-based compensation. Changes in operating assets and liabilities used approximately \$491,000 to fund operating activities; Increase in accounts receivable and inventory, along with decreases in accounts payable and accrued expenses were partially offset by an increase in accrued payroll and related taxes.

#### Cash flows from investing activities

Investing activities consisted of transactions related to the purchase of fixed assets, including automation of production processes and advance planning and design work on the Company's new production facility, as well as the purchase and subsequent maturity of certificates of deposit. Management will continue to invest in technology and machinery that improves and streamlines production processes and to invest maturing certificates of deposit in low-risk investment opportunities that safeguard assets and provide greater assurance those resources will be liquid and available for business needs as they arise.

Table of Contents

Cash flows from financing activities

Financing activities in the six months ended December 31, 2017 included payment of preferred dividends and proceeds of sales of common stock through option exercises.

Projected 2018 Liquidity and Capital Resources

*Operating activities*

Management forecasts that current cash and cash equivalents along with certificates of deposit will be sufficient to meet projected operating cash needs for the remainder of fiscal 2018 and into the first half of fiscal 2019. Assuming no extraordinary expenses occur (whether operating or capital), if management is successful at implementing its strategy of renewed emphasis on driving the consumer to the prostate market, meets or exceeds its annual growth targets of twenty percent increase in revenue in fiscal 2018 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. Although the Company did not reach that target of twenty percent increased revenue in the first quarter of fiscal 2018, that target was surpassed in the second quarter and the Company is continuing to project revenue growth in fiscal 2018 of at least twenty percent over fiscal 2017. There is no assurance that targeted sales growth will materialize over the next three to five years. However, management is encouraged by the results for the six months ended December 31, 2017 and with the depth and experience of its restructured sales team.

*Capital expenditures*

Management has completed the design of a future production and administration facility. If financing is obtained and the facility constructed, it is believed that the new facility will have non-cash depreciation cost equal to or greater than the monthly rental cost of the current facility.

Management is reviewing and implementing changes in all aspects of production operations (including process automation), research and development, sales and marketing, and general and administrative functions to evaluate the most efficient deployment of capital to ensure that the appropriate materials, systems, and personnel are available to support and drive product sales.

During the six months ended December 31, 2017, the Company invested approximately \$112,000 in the automation of production processes, three of which have been received, tested and evaluated, and were placed in service in the six months. One additional machine has been received and is currently being tested. Beginning in fiscal 2017 and continuing through December 31, 2017, the Company has invested approximately \$412,000 in these automation projects and management is expecting to invest approximately \$400,000 more over the next 18 months on the remaining projects. This investment is designed to allow the Company to significantly increase the output of Cs-131 brachytherapy seeds, while allowing the Company to decrease the labor costs related to seed production and also improving the overall safety of our operations.

#### *Financing activities*

There was no material change in the use of proceeds from our public offering as described in our final prospectus supplement filed with the SEC pursuant to Rule 424(b) on March 24, 2014. Through December 31, 2017, the Company had used the net proceeds raised through the March 2014 offering as described in the public offering. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

On August 25, 2015, the Company filed a registration statement on Form S-3 to register securities up to \$20 million in value for future issuance in our capital raising activities. The registration statement became effective on November 19, 2015, and the SEC file number assigned to the registration statement is 333-206559.

The Company expects to finance its future cash needs through sales of equity, possible strategic collaborations, debt financing or through other sources that may be dilutive to existing shareholders. Management anticipates that if it raises additional financing that it will be at a discount to the market price and it will be dilutive to shareholders.

The Company's common stock is currently listed on the NYSE American stock exchange, which will consider delisting a company's securities if, among other things, a company fails to maintain minimum stockholder's equity. With the Company's existing cash reserves, we believe we will not be able to maintain our listing on the NYSE American unless we raise capital in the next three to six months assuming we maintain our projected budgeted expenses and contemplated level of revenues.

Table of Contents

*Other Commitments and Contingencies*

The Company presented its other commitments and contingencies in our Annual Report on Form 10-K for the fiscal year ended June 30, 2017. There have been no material changes outside of the ordinary course of business in those obligations during the quarter ended December 31, 2017 other than those previously disclosed in Notes 8 and 13 to the interim financial statements contained in this Form 10-Q.

*Off-Balance Sheet Arrangements*

The Company has no off-balance sheet arrangements.

*Critical Accounting Policies and Estimates*

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. The Company evaluates its estimates and judgments on an ongoing basis. The Company bases its estimates on historical experience and on various other factors the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Actual results could therefore differ materially from those estimates if actual conditions differ from our assumptions.

During the quarter ended December 31, 2017, there have been no changes to the critical accounting policies and estimates, as discussed in Part II, Item 7 of our Form 10-K for the year ended June 30, 2017.

**ITEM 3 – QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

There have been no material changes to the disclosure in the “Quantitative and Qualitative Disclosures about Market Risk Factors” section of our Annual Report on Form 10-K for the year ended June 30, 2017.

## **ITEM 4 – CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined under Rules 13a-14(c) and 15d-14(c) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of December 31, 2017. Based on that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of our disclosure controls and procedures were effective. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote. However, management believes that our system of disclosure controls and procedures are designed to provide a reasonable level of assurance that the objectives of the system will be met.

Table of Contents

**Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**ITEM 1 – LEGAL PROCEEDINGS**

The Company may, in the ordinary course of business, be subject to various legal proceedings. Some legal proceedings are discussed in footnote 8 of Notes to Unaudited Consolidated Financial Statements contained in this filing. We refer you to that footnote for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought.

Derivative Complaint related to Shareholder Value

On September 29, 2016, David M. Kitley, purportedly on behalf of IsoRay, filed a derivative lawsuit in the United States District Court for the District of Minnesota under the case caption Kitley v. IsoRay, Inc., Case No. 0:16-cv-03297-DTS. The complaint named as defendants current and former IsoRay directors Dwight Babcock, Thomas LaVoy, Philip J. Vitale and Michael W. McCormick, alleging that they violated their fiduciary duties to IsoRay in connection with a press release allegedly containing false and misleading statements concerning the results from a peer reviewed study of its Cesium-131 isotope seeds for the treatment of non-small cell lung cancers, thereby artificially inflating the price of IsoRay stock. The complaint sought unspecified damages, in an amount not presently determinable, among other forms of relief.

On November 17, 2016, IsoRay moved to dismiss the complaint, arguing that plaintiff was not entitled to pursue his derivative claims due to his failure to serve a pre-suit demand on IsoRay's board. Rather than respond to the motion to dismiss, plaintiff filed an amended complaint on January 23, 2017. The amended complaint alleged the same derivative claims as the original, and added IsoRay director Alan Hoffmann as a defendant. Plaintiff sought an award of damages and an order directing IsoRay to undertake reforms of its corporate governance and internal procedures. IsoRay moved to dismiss the amended complaint on March 9, 2017. Plaintiff responded on April 20, 2017, and IsoRay replied on May 17, 2017. The court heard oral argument on the motion on August 22, 2017, and took the matter under advisement at that time. On October 19, 2017, the court granted IsoRay's motion to dismiss. The matter

is now resolved.

## **ITEM 1A – RISK FACTORS**

A description of the risk factors associated with our business is included under “Risk Factors” contained in Part I, Item 1A of our Form 10-K for the year ended June 30, 2017, and is incorporated herein by reference. There have been no material changes in our risk factors since such filing, except for the following:

### *We Rely Heavily On Five Customers*

For the six months ended December 31, 2017 approximately 46% of the Company’s revenues were dependent on five customers with approximately 24% being generated by one customer. The loss of any of these customers would have a material adverse effect on the Company’s revenues which may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments.

### *We Will Need Additional Capital In The Future To Maintain Our NYSE American Listing And For Acquisitions And Expansion Into Other Markets.*

Our common stock is currently listed on the NYSE American stock exchange which will consider delisting a company’s securities if, among other things, a company fails to maintain minimum stockholder's equity. With our existing cash reserves we believe we will not be able to maintain our listing on the NYSE American unless we raise capital in the next three to six months assuming we maintain our projected budgeted expenses and contemplated level of revenues. In the event that our common stock is delisted from the NYSE American, trading, if any, in the common stock would be conducted in the over-the-counter market. As a result, our shareholders would likely find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock. We may also need to raise capital for strategic acquisitions or expansion into other markets and there is no assurance management will not pursue this additional capital if available.

## **ITEM 2 – UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

## **ITEM 3 – DEFAULTS UPON SENIOR SECURITIES**



None.

18

---

Table of Contents

**ITEM 4 - MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5 – OTHER INFORMATION**

None

**ITEM 6. EXHIBITS**

Exhibits:

31.1\* Rule 13a-14(a)/15d-14(a) Certification of Principal Executive Officer

31.2\* Rule 13a-14(a)/15d-14(a) Certification of Principal Financial Officer

32\*\* Section 1350 Certifications

101.INS\* XBRL Instance Document

101.SCH\* XBRL Taxonomy Extension Schema Document

101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document

XBRL Taxonomy Extension Definition Linkbase Document

101.DEF\*

101.LAB\* XBRL Taxonomy Extension Label Linkbase Document

101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

\*\* Furnished herewith



Table of Contents

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.

Dated: February 9, 2018

ISORAY, INC., a Minnesota corporation

*/s/ Thomas C. LaVoy*  
Thomas C. LaVoy  
Chief Executive Officer  
(Principal Executive Officer)

*/s/ Mark J. Austin*  
Mark J. Austin  
Controller  
(Principal Financial and Accounting Officer)