

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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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	44	43
Total inventory, non-current	\$ 316	\$319

Inventory, non-current represents 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 and enriched barium. 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. The Company anticipates obtaining enough Cesium-131 under this arrangement to obtain over 4,000 curies of Cesium-131. During the quarter ended September 30, 2018, the Company obtained 230 curies under this agreement which has been used in production. At June 30, 2018, the Company estimated that the remaining enriched barium will result in at least 2,399 curies: 430 of which we believe will be obtained in the year ended June 30, 2019, and 1,969 of which we believe will be obtained after June 30, 2019. There is no assurance as to whether the agreement 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 September 30, 2018 and June 30, 2018 (in thousands):

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	September	June
	30,	30,
	2018	2018
Land	\$ 366	\$366
Equipment	4,153	4,152
Leasehold improvements	4,136	4,136
Other ¹	437	328
Property and equipment	9,092	8,982
Less accumulated depreciation	(7,698)	(7,671)
Property and equipment, net	\$ 1,394	\$1,311

1. Plant and equipment, not placed in service are 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, and therefore, no depreciation expense has been recognized. Also included at September 30, 2018 and June 30, 2018 are costs associated with advance planning and design work on the Company's new production facility of \$207,000.

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The following table presents the share-based compensation expense recognized during the three months ended September 30, 2018 and 2017 (in thousands):

	Three Months ended September 30,	
	2018	2017
Cost of product sales	\$ 10	\$ 16
Research and development expenses	18	19
Sales and marketing expenses	22	17
General and administrative expenses	43	38
Total share-based compensation	\$ 93	\$ 90

As of September 30, 2018, total unrecognized compensation expense related to stock-based options was approximately \$615,000 and the related weighted-average period over which it is expected to be recognized is approximately 1.12 years.

A summary of stock options within the Company's share-based compensation plans as of September 30, 2018 was as follows (in thousands except for exercise prices and terms):

	Number of	Weighted Exercise Price	Weighted Average Contractual Term (Years)	Intrinsic Value
As of September 30, 2018	Options			
Outstanding	3,787	\$ 0.69	7.55	\$ 128
Vested and expected to vest	3,779	\$ 0.68	7.55	\$ 128
Vested and exercisable	2,082	\$ 0.82	6.15	\$ 78

There were no stock options exercised during the three months ended September 30, 2018 and 2017, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 82,500 and 75,000 option awards granted with a fair value of approximately \$35,000 and \$33,000 during the three months ended September 30, 2018 and 2017, respectively.

There were 10,000 and no stock option awards which expired during three months ended September 30, 2018 and 2017, respectively.

There were 38,750 and 59,666 stock option awards forfeited during three months ended September 30, 2018 and 2017, respectively.

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 Cesium-131 manufactured by the Institute of Nuclear Materials. The purchase agreement provided the Company with one year's supply of Cesium-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 Cesium-131 manufactured at the Research Institute of Atomic Reactors ("SSC RIAR") and extended it until December 31, 2018. On March 19, 2018, an addendum was signed increasing the amount of Cesium-131 to be provided to the Company through December 31, 2018.

Research and Development - Collaborative Arrangement

On March 13, 2017, IsoRay Medical, Inc., a wholly owned subsidiary of the Company ("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 incurs all costs in connection with the collaboration project which will be shared equally by both parties as of November 8, 2016, which is when they informally began the collaboration. The arrangement 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."

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During the three months ended September 30, 2018 and 2017, costs incurred in connection with the collaboration agreement were \$116,000 and \$147,000, respectively.

As of September 30, 2018 and June 30, 2018, the Company had outstanding receivables from GammaTile LLC of \$82,000 and \$22,000 respectively.

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 September 30, 2018			
Total	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$2,193	\$2,193	\$ -	\$ -

	Fair Value at June 30, 2018			
Total	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$2,600	\$2,600	\$ -	\$ -

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

There were no related party transactions during the three months ended September 30, 2018 and 2017.

11. Concentrations of Credit and Other Risks

One group of customers, facilities or physician practices accounts for revenues that aggregate to greater than 10% of total Company product sales. This group of facilities individually do not aggregate to more than 10% of total Company product sales. They are serviced by the same physician group, one of whom is our Medical Director:

	Three months ended	
	September	September
Facility	30,	30,
	2018	2017
El Camino Hospital of Los Gatos, & other facilities	25.18%	25.98%

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

12. Stockholders' Equity

On July 11, 2018, the Company completed the closing of a registered direct offering with several institutional and accredited investors (each an "Investor") for the sale of a total of 11,000,000 shares of common stock of the Company ("Shares") at a price per share of \$0.75, for aggregate gross proceeds to the Company of \$8.25 million. Cash expenses relating to this offering were approximately \$0.75 million.

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In a concurrent private placement, the Company sold to each Investor, at no additional consideration, unregistered warrants to purchase up to the number of shares of common stock of the Company equal to 50% of such Investor's Shares or a total of 5,500,000 shares, with an exercise price of \$0.75 per share, exercisable from January 11, 2019 until January 11, 2024 (the "Investor Warrants"). The Company also issued warrants to purchase up to 330,000 shares of common stock of the Company, at an exercise price of \$0.9375, to representatives of H.C. Wainwright & Co., LLC ("Wainwright"), the placement agent for the registered direct offering, as part of its compensation (the "Placement Agent Warrants" and together with the Investor Warrants, the "Warrants").

The aggregate number of shares of our common stock issuable upon the exercise of the Warrants is 5,830,000 shares relating to this offering. We will receive gross proceeds from this offering solely to the extent any Warrants are exercised for cash.

13. Contracts with Customers

We have adopted ASC 606, *Revenue from Contracts with Customers* effective July 1, 2018 using the modified retrospective method applied to those contracts which were not substantially completed as of July 1, 2018. These standards provide guidance on recognizing revenue, including a five-step model to determine when revenue recognition is appropriate. The standard requires that an entity recognize revenue to depict the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Revenues for fiscal year 2019 are reported under ASC 606, while prior period amounts are not adjusted and continue to be reported under ASC 605, *Revenue Recognition*.

We routinely enter into agreements with customers that include general commercial terms and conditions, notification requirements for price increases, shipping terms and in most cases prices for the products that we offer. However, these agreements do not obligate us to provide goods to the customer and there is no consideration promised to us at the onset of these arrangements. For customers without separate agreements, we have a standard list price established for all products and our invoices contain standard terms and conditions that are applicable to those customers where a separate agreement is not controlling. Our performance obligations are established when a customer submits a purchase order or e-mail notification (in writing, electronically or verbally) for goods, and we accept the order. We identify performance obligations as the delivery of the requested product(s) in appropriate quantities and to the location specified in the customer's e-mail/or purchase order. We generally recognize revenue upon the satisfaction of these criteria when control of the product has been transferred to the customer at which time we have an unconditional right to receive payment. Our prices are fixed and are not affected by contingent events that could impact the transaction price. We do not offer price concessions and do not accept payment that is less than the price stated when we accept the purchase order, except in rare credit related circumstances. We do not have any material performance obligations where we are acting as an agent for another entity.

Revenues for all products are typically recognized at the time the product is shipped, at which time the title passes to the customer, and there are no further performance obligations.

Sources of Revenue

We have identified the following revenues disaggregated by revenue source:

1. Domestic Physicians – direct sales of products.

2. International – direct sales of products.

For the three months ended September 30, 2018 and 2017 the Company had revenue from both sources. International revenues in both periods was immaterial.

Contract Balances

We incur agreement obligations on general customer purchase orders and e-mails that have been accepted but unfulfilled. Due to the short duration of time between order acceptance and delivery of the related product, we have determined that the balance related to these obligations is generally immaterial at any point in time. We monitor the value of orders accepted but unfulfilled at the close of each reporting period to determine if disclosure is appropriate.

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Warranty

Our general product warranties do not extend beyond an assurance that the product delivered will be consistent with stated specifications and do not include separate performance obligations.

Returns

Generally, we allow returns if not implanted and we are notified within a few weeks after satisfying our performance obligations of a return.

Significant Judgments in the Application of the Guidance in ASC 606

There are no significant judgments associated with the satisfaction of our performance obligations. We generally satisfy performance obligations upon delivery of the product to the customer. This is consistent with the time in which the customer obtains control of the products. Therefore the value of unsatisfied performance obligations at the end of any reporting period is generally immaterial. We use historical information along with an analysis of the expected value to properly calculate and to consider the need to constrain estimates of variable consideration. Such amounts are included as a reduction to revenue from the sale of products in the periods in which the related revenue is recognized and adjusted in future periods as necessary.

Commissions and Contract Costs

We pay and expense commissions on orders to our sales team upon satisfaction of our performance obligations. We generally do not incur incremental charges associated with securing agreements with customers which would require capitalization and recovery over the life of the agreement.

Practical Expedients

Our payment terms for sales direct to customers and distributors are substantially less than the one year collection period that falls within the practical expedient in determination of whether a significant financing component exists.

Shipping and Handling Charges

Fees charged to customers for shipping and handling of products are included as revenue and the costs for shipping and handling of products are included as a component of cost of products.

Taxes Collected from Customers

As our products are used in another service and are exempt, to this point we have not collected taxes. If we were to collect taxes they would be on the value of transaction revenue and would be excluded from product revenues and cost of sales and would be accrued in current liabilities until remitted to governmental authorities.

Effective Date and Transition Disclosures

Adoption of the new standards related to revenue recognition did not have a material impact on our consolidated financial statements, and is not expected to have a material impact in future periods.

14. Subsequent Events

On October 19, 2018, the Company filed a Form S-1 registration statement for the registration of 5,830,000 shares of common stock to be received by the investors and representatives of Wainwright on exercise of Warrants issued in connection with a registered direct offering completed on July 11, 2018 whereby the Company received gross proceeds of \$8,250,000. The Company may receive up to \$4,434,375 in gross proceeds solely to the extent the Warrants are exercised for cash, but they can't be exercised until January 11, 2019.

On November 7, 2018, the Company entered into an Amendment and Termination of Share Rights Agreement (the "Amendment") with Computershare Trust Company, N.A. (the "Rights Agent"), which amended that certain Share Rights Agreement (the "Rights Agreement"), dated as of February 1, 2007, as amended, by and between the Company and the Rights Agent. The Amendment accelerates the expiration date of the Rights Agreement to November 7, 2018, such that, as of 5:00 p.m. Richland, Washington time on November 7, 2018, the Series C Junior Participating Preferred Shares purchase rights expired and are no longer outstanding and the Rights Agreement terminated and is of no further force or effect.

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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 17 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 26, 2018 are those that depend most heavily on these judgments and estimates. As of September 30, 2018 there had been no material changes to any of the critical accounting policies contained therein.

Overview

IsoRay 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.

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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 tradeshow.

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, Switzerland, and the Russian Federation, with \$18,000 of reported revenues in the quarter ended September 30, 2018.

Results of Operations**Three months ended September 30, 2018 and 2017 (in thousands):**

	Three months ended September 30,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	\$ 1,562	100	\$ 1,211	100	29
Cost of product sales	1,038	66	946	78	10
Gross profit	524	34	265	22	98
Operating expenses:					
Research and development expenses - proprietary	394	25	287	24	37
Research and development expenses – collaboration agreement, net of reimbursement	26	2	75	6	(65)
Sales and marketing expenses	649	42	614	51	6
General and administrative expenses	973	62	841	69	16
Total operating expenses	2,042	131	1,817	150	12
Operating loss	(1,518)	(97)	(1,552)	(128)	(2)

(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 continued to result in ongoing positive sales growth in the first quarter of fiscal 2019 when compared to prior year first 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.

Three months ended September 30, 2018 and 2017 (in thousands)

	Three months ended September 30,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Prostate brachytherapy	\$1,376	88	\$1,084	89	27
Other brachytherapy	186	12	127	11	46
Product sales, net	1,562	100	1,211	100	29

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

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Prostate Brachytherapy

Prostate brachytherapy sales were impacted by changes in sales account managers and by the schedules of some key accounts in the first quarter of the fiscal year. During the quarter ended September 30, 2018, 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.

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 September 30, 2018.

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.

Contributing to the quarters ended September 30, 2018 and 2017 comparison were increased isotope and other direct materials purchases as well as increased labor to meet production demand due to improved sales. Also contributing to the increase are higher depreciation costs due to completed automation projects placed into service.

Gross Profit

Contributing to the three months ended September 30, 2018 and 2017 gross profit comparison were increased sales partially offset by increased materials and labor costs to meet production demand.

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 quarters ended September 30, 2018 and 2017 proprietary research and development comparison were increases associated with participation in new protocols, as well as device development activities. These increases were partially offset by decreased legal fees and travel.

Research and development – collaborative arrangement

Collaboration arrangement related costs are incurred, shared, and separately stated in connection with a collaborative research and development project (see note 8 of the financial statements contained in this filing).

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Contributing to the quarters ended September 30, 2018 and 2017 comparison were decreased costs due to the fact that payments being made pursuant to the collaborative arrangement with GammaTile, LLC were no longer necessary at the same level, as the collaborative arrangement primarily related to work involved in obtaining 510(k) clearance, which has now been obtained.

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 additional staffing continues to increase.

Contributing to the quarters ended September 30, 2018 and 2017 comparison was a decrease in travel costs as a tradeshow that occurred in September 2017 did not occur until October 2018. Staffing differences are a major factor in the cost comparison as open positions in the quarter ended September 30, 2017 were filled in periods prior to the quarter ended September 30, 2018, thereby increasing personnel costs.

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 quarters ended September 30, 2018 and 2017 comparison were cost increases from the prior year. Those include increase in headcount, salary increases implemented in July 2018, and incentive compensation related to the increase in revenue.

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 September 30, 2018 and 2017, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

	Three months ended September 30,	
	2018	2017
Net cash used by operating activities	\$(1,612)	\$(1,661)
Net cash (used) by investing activities	(6,289)	(315)
Net cash provided by financing activities	7,494	-
Net (decrease) in cash and cash equivalents	\$(407)	\$(1,976)
Working capital	\$9,631	\$7,799
Current ratio	6.88	8.31

Cash flows from operating activities

Net cash used by operating activities in the three months ended September 30, 2018 was primarily due to a net loss of approximately \$1.51 million, net of approximately \$140,000 in adjustments for non-cash activity such as depreciation and amortization expense, and share-based compensation. Changes in operating assets and liabilities used approximately \$249,000 to fund operating activities; increases to prepaid expenses and decreases to accounts payable and accrued expenses and accrued payroll and related taxes were partially offset by decreases in accounts receivable resulting from improved collections as well as an increase in accrued protocol expense.

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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.

Cash flows from Financing activities

Financing activities in the quarter ended September 30, 2018 were due to the sale of common stock through a registered direct offering (see note 12 to the financial statements). There were no financing activities in the quarter ended September 30, 2017.

Projected 2019 liquidity and capital resources

Operating activities

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-five percent increase in revenue in fiscal 2019 and this annual growth continues, the Company anticipates reaching cashflow break-even in three to five years. The Company exceeded that target of twenty-five percent increased revenue in the first quarter of fiscal 2019. There is no assurance that targeted sales growth will continue over the next three to five years. However, management is encouraged by the results for the quarter ended September 30, 2018 and by 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 quarter ended September 30, 2018, the Company invested approximately \$50,000 in the automation of thirteen production processes, four of which have been placed into service. Through September 30, 2018, the Company has invested approximately \$430,000 in these automation projects, and management is expecting to invest approximately \$215,000 more over the next 9 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 September 30, 2018, 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 23, 2015, and the SEC file number assigned to the registration statement is 333-206559.

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On July 11, 2018, the Company sold 11,000,000 shares of its common stock at a price of \$0.75 per share, for aggregate gross proceeds of \$8.25 million, pursuant to the registration statement on Form S-3 that became effective on November 23, 2015. The Company has not yet used any proceeds from this offering. Additionally, the Company issued to the purchasers unregistered warrants to purchase up to 5,500,000 shares of common stock. The warrants have an exercise price of \$0.75 per share common stock, are exercisable commencing six months following the issuance date, and expire five and one-half years from the issuance date. If exercised for cash, future exercises of these warrants will provide additional capital to the Company. As a result of this recent capital raise, the Company does not anticipate the need to finance its operations for the next fiscal year from additional capital raises.

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.

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, 2018. There have been no material changes outside of the ordinary course of business in those obligations during the quarter ended September 30, 2018 other than those previously disclosed in note 8 of to the financial statements contained in this filing.

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 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 September 30, 2018, there have been no changes to the critical accounting policies and estimates discussed in Part II, Item 7 of our Form 10-K for the year ended June 30, 2018.

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, 2018, which is incorporated herein by reference.

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) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of September 30, 2018. 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.

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.

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PART II - OTHER INFORMATION

ITEM 1 – LEGAL PROCEEDINGS

Nothing to disclose.

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 annual report on Form 10-K for the year ended June 30, 2018, 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 three months ended September 30, 2018 approximately 48% of the Company’s revenues were dependent on five customers with approximately 25% being generated by one group of customers. The loss of any of these customers would have a material adverse effect on the Company’s revenues that may not be replaced by other customers particularly as these customers are in the prostate sector which is facing substantial competition from other treatments.

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

On July 11, 2018, the Company completed the closing of a registered direct offering with several institutional and accredited investors (each an “Investor”) for the sale of a total of 11,000,000 shares of common stock of the Company (“Shares”) at a price per share of \$0.75, for aggregate gross proceeds to the Company of \$8.25 million.

In a concurrent private placement, the Company sold to each Investor, at no additional consideration, unregistered warrants to purchase up to the number of shares of common stock of the Company equal to 50% of such Investor’s Shares or a total of 5,500,000 shares, with an exercise price of \$0.75 per share, exercisable from January 11, 2019 until January 11, 2024 (the “Investor Warrants”). The Company also issued warrants to purchase up to 330,000 shares of

common stock of the Company, at an exercise price of \$0.9375, to representatives of Wainwright, the placement agent for the registered direct offering, as part of its compensation (the “Placement Agent Warrants” and together with the Investor Warrants, the “Warrants”).

The aggregate number of shares of our common stock issuable upon the exercise of the Warrants is 5,830,000 shares. The offer and sale of the Warrants was made without registration in reliance on the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder. We will receive gross proceeds from this offering solely to the extent any Warrants are exercised for cash.

The Company has not yet used any proceeds from our sale of 11,000,000 shares of common stock on July 11, 2018.

Although we have identified some of the potential uses of the proceeds from this offering, we have and reserve broad discretion in the application of these proceeds. Accordingly, we reserve the right to use these proceeds for different purposes or uses which we have not listed above, particularly if there is a change in demand for certain applications of our Cesium-131 and other products which may require increased investment in protocols and research studies and the hiring of additional sales staff

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 - MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 – OTHER INFORMATION

None

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ITEM 6. EXHIBITS

Exhibits:

- 4.1 Amendment,
dated July 9,
2018, to the
Share Rights
Agreement,
dated as of
February 1,
2007, between
IsoRay, Inc.
and
Computershare
Trust
Company,
N.A., as Rights
Agent,
incorporated by
reference to the
Form 8-K filed
on July 12,
2018.
Letter
Agreement
between
IsoRay, Inc.
and H.C.
- 10.1 Wainwright &
Co., LLC dated
July 9, 2018,
incorporated by
reference to the
Form 8-K filed
on July 11,
2018.
Form of
Securities
Purchase
Agreement,
- 10.2 incorporated by
reference to the
Form 8-K filed
on July 11,
2018.
- 10.3

- 10.4 Form of Warrant, incorporated by reference to the Form 8-K filed on July 11, 2018. Professional Services Agreement, dated August 15, 2018, between IsoRay Medical, Inc. and J. Squared Partners, Inc., DBA Global IR Group, incorporated by reference to the Form 8-K filed on September 25, 2018. Services Agreement, dated August 13, 2018, between IsoRay Medical, Inc. and Schultz Public Relations, LLC, incorporated by reference to the Form 8-K filed on September 25, 2018.
- 10.5
- 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

101.DEF* XBRL Taxonomy
Extension Definition
Linkbase Document

101.LAB* XBRL Taxonomy
Extension Label
Linkbase Document

101.PRE* XBRL Taxonomy
Extension
Presentation
Linkbase Document

* Filed herewith

** Furnished herewith

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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: November 9, 2018

ISORAY, INC., a Minnesota corporation

/s/ Lori A. Woods
Lori A. Woods
Interim Chief Executive Officer
(Principal Executive Officer)

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