Isoray, Inc.
Form 10-Q
February 13, 2019

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, 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)

Delaware	41-1458152
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
350 Hills St., Suite 106, Richland, Washington	99354
(Address of principal executive offices)	(Zip Code)

(509) 375-1202

(Registrant's telephone number, including area code)

IsoRay, Inc

(Former name, former address and former fiscal year, if changed
since last report)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 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	(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:

Class	Outstanding as of February 11, 2019
Common stock, $0.001 par value	67,331,147

Table of Contents

ISORAY, INC.

Table of Contents

Table of Contents

PART I – FINANCIAL INFORMATION

ITEM 1 – FINANCIAL STATEMENTS

Isoray, Inc. and Subsidiaries
Consolidated Balance Sheets (Unaudited)
(In thousands, except shares)

	December 31, 2018	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ *3,201*	$ *2,600*
Short-term investments (Note 3)	*4,667*	*825*
Accounts receivable, net	*1,107*	*1,192*
Inventory	*494*	*494*
Prepaid expenses and other current assets	*351*	*335*
Total current assets	*9,820*	*5,446*
Property and equipment, net	*1,471*	*1,311*
Restricted cash	*181*	*181*
Inventory, non-current	*266*	*319*
Other assets, net of accumulated amortization	*173*	*198*
Total assets	$ *11,911*	$ *7,455*
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ *1,196*	$ *1,391*
Accrued protocol expense	*113*	*77*
Accrued radioactive waste disposal	*55*	*37*
Accrued payroll and related taxes	*120*	*155*
Accrued vacation	*156*	*175*
Total current liabilities	*1,640*	*1,835*
Long-term liabilities:		
Asset retirement obligation	*606*	*590*

Total liabilities	*2,246*	*2,425*
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,000,000 shares authorized:		
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	-	-
Common stock, $.001 par value; 200,000,000 shares authorized; 67,331,147 and 56,331,147 shares issued and outstanding	*67*	*56*
Additional paid-in capital	*91,868*	*84,322*
Accumulated deficit	*(82,270*)	*(79,348*)
Total shareholders' equity	*9,665*	*5,030*
Total liabilities and shareholders' equity	$ *11,911*	$ *7,455*

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)

	Three months ended December 31,		Six months ended December 31,	
	2018	**2017**	**2018**	**2017**
Product sales, net	$*1,904*	$*1,536*	$*3,466*	$*2,747*
Cost of product sales	*1,139*	*1,005*	*2,177*	*1,951*
Gross profit	*765*	*531*	*1,289*	*796*
Operating expenses:				
Research and development:				
Proprietary research and development	*395*	*311*	*789*	*597*
Collaboration arrangement, net of reimbursement (Note 8)	*19*	*29*	*45*	*104*
Total research and development	*414*	*340*	*834*	*701*
Sales and marketing	*702*	*674*	*1,351*	*1,288*
(Gain) on Equipment Disposal	*(23)*	-	*(23)*	-
General and administrative	*1,101*	*985*	*2,074*	*1,827*
Total operating expenses	*2,194*	*1,999*	*4,236*	*3,816*
Operating loss	*(1,429)*	*(1,468)*	*(2,947)*	*(3,020)*
Non-operating income:				
Interest income, net	*15*	*5*	*25*	*10*
Non-operating income, net	*15*	*5*	*25*	*10*
Net loss	*(1,414)*	*(1,463)*	*(2,922)*	*(3,010)*
Preferred stock dividends	*(2)*	*(3)*	*(5)*	*(5)*
Net loss applicable to common shareholders	$*(1,416)*	$*(1,466)*	$*(2,927)*	$*(3,015)*
Basic and diluted loss per share	$*(0.02)*	$*(0.03)*	$*(0.04)*	$*(0.05)*
Weighted average shares used in computing net loss per share:				
Basic and diluted	*67,331*	*55,056*	*66,743*	*55,037*

The accompanying notes are an integral part of these consolidated

financial
statements.

Table of Contents

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

	Six months ended December 31, 2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(2,922)	$(3,010)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	65	36
Gain on equipment disposals	(23)	-
Amortization of other assets	25	26
Accretion of asset retirement obligation	16	15
Share-based compensation	190	240
Changes in operating assets and liabilities:		
Accounts receivable, net	85	(261)
Inventory	53	(31)
Prepaid expenses and other current assets	(20)	(24)
Accounts payable and accrued expenses	(195)	(49)
Accrued protocol expense	36	(32)
Accrued radioactive waste disposal	18	(106)
Accrued payroll and related taxes	(35)	27
Accrued vacation	(19)	(15)
Net cash used by operating activities	(2,726)	(3,184)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(225)	(150)
Proceeds from sale of equipment	23	-
Proceeds from maturity of certificates of deposit	4,418	3,868
Purchases of and interest from certificates of deposit and U.S. Treasury Securities	(8,259)	(3,554)
Net cash (used) provided by investing activities	(4,043)	164
CASH FLOWS FROM FINANCING ACTIVITIES:		
Preferred dividends paid	(11)	(11)
Proceeds from sales of common stock, pursuant to registered direct offering, net	7,381	-
Proceeds from sales of common stock, pursuant to exercise of options	-	50
Net cash provided by financing activities	7,370	39
Net increase (decrease) in cash, cash equivalents, and restricted cash	601	(2,981)
Cash, cash equivalents, and restricted cash beginning of period	2,781	6,113
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH END OF PERIOD	$3,382	$3,132

Reconciliatoin of cash, cash equivalents, and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	$*3,201*	$*2,951*
Restricted cash	$*181*	$*181*
Total cash, cash equivalents, and restricted cash shown on the consolidated statements of cashflows	$*3,382*	$*3,132*
Non-cash investing and financing activities:		
Warrants issued to placement agent of registered direct offering	$*163*	$-

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

Table of Contents

Isoray, Inc.

Notes to the Unaudited Consolidated Financial Statements

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. 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 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 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 fiscal years beginning after *December 15, 2018,* including interim periods within those fiscal years. 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.

Table of Contents

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 *December 31, 2018* and *June 30, 2018* respectively.

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.

Short-term investments held by the Company as of *December 31, 2018* and *June 30, 2018* are as follows (in thousands):

	As of December 31, 2018			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
U.S. Treasury Securities	$*2,333*	$*2,334*	$ -	$ -

	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 *December 31, 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 *December 31, 2018* and *2017,* were as follows (in thousands):

	December 31,	
	2018	2017
Series B preferred stock	*59*	*59*
Common stock warrants	*6,080*	*250*
Common stock options	*3,917*	*3,295*
Total potential dilutive securities	*10,056*	*3,604*

Table of Contents

5. **Inventory**

Inventory consisted of the following at *December 31, 2018* and *June 30, 2018 (*in thousands):

	December 31, 2018	June 30, 2018
Raw materials	$ *379*	$*371*
Work in process	*97*	*96*
Finished goods	*18*	*27*
Total inventory, current	$ *494*	$*494*

	December 31, 2018	June 30, 2018
Enriched barium, non-current	$ *234*	$*276*
Raw materials, non-current	*32*	*43*
Total inventory, non-current	$ *266*	$*319*

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. The Company anticipates obtaining enough Cesium-*131* under this arrangement to obtain over *4,000* curies of Cesium-*131.* At *December 31, 2018,* the Company estimates that the remaining enriched barium will result in at least *2,090* curies: approximately *420* of which we believe will be obtained within the next *12* months, and *1,670* of which we believe will be obtained after the next *12* months. 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, 2018* and *June 30, 2018 (*in thousands):

	December 31, 2018	June 30, 2018
Land	$ *366*	$ *366*
Equipment	*3,778*	*4,152*
Leasehold improvements	*4,138*	*4,136*
Other[1]	*487*	*328*
Property and equipment	*8,769*	*8,982*
Less accumulated depreciation	*(7,298*)	*(7,671)*
Property and equipment, net	$ *1,471*	$ *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 *December 31, 2018* and *June 30, 2018* are costs associated with advance planning and design work on the Company's new production facility of *$207,000.*

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, 2018* and *2017* (in thousands):

	Three Months ended December 31, 2018	2017
Cost of product sales	$ *10*	$ *13*
Research and development expenses	*18*	*19*
Sales and marketing expenses	*22*	*17*
General and administrative expenses	*47*	*29*
Total share-based compensation	$ *97*	$ *78*

Table of Contents

The following table presents the share-based compensation expense recognized for stock-based options during the *six* months ended *December 31, 2018* and *2017* (in thousands):

	Six Months ended December 31,	
	2018	2017
Cost of product sales	$*20*	$*29*
Research and development expenses	*36*	*38*
Sales and marketing expenses	*44*	*34*
General and administrative expenses	*90*	*67*
Total share-based compensation	$*190*	$*168*

As of *December 31, 2018,* total unrecognized compensation expense related to stock-based options was approximately *$566,000* and the related weighted-average period over which it is expected to be recognized is approximately *1.05* years.

A summary of stock options within the Company's share-based compensation plans as of *December 31, 2018* was as follows (in thousands except for exercise prices and terms):

As of December 31, 2018	Number of Options	Weighted Exercise Price	Weighted Average Contractual Term (Years)	Intrinsic Value
Outstanding	*3,917*	$ *.68*	*7.40*	$ *10*
Vested and expected to vest	*3,909*	$ *.67*	*7.40*	$ *10*
Vested and exercisable	*2,170*	$ *.80*	*6.06*	$ *10*

There were *no* and *82,810* stock options exercised, with approximately *$0* and *$0* of intrinsic value associated with these exercises during the *three* months ended *December 31, 2018* and *2017,* respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were *155,000* and *no* option awards granted with a fair value of approximately *$52,000* and *$0* during the *three* months ended *December 31, 2018* and *2017,* respectively.

There were *no* stock option awards which expired during the *three* months ended *December 31, 2018* and *2017,* respectively.

There were *32,000* and *16,875* stock option awards forfeited during the *three* months ended *December 31, 2018* and *2017,* respectively.

There were *no* and *82,810* stock options exercised, with approximately *$0* and *$0* of intrinsic value associated with these exercises during the *six* months ended *December 31, 2018* and *2017,* respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were *237,500* and *75,000* option awards granted with a fair value of approximately *$87,000* and *$33,000* during the *six* months ended *December 31, 2018* and *2017,* respectively.

There were *10,000* and *no* stock option awards which expired during the *six* months ended *December 31, 2018* and *2017,* respectively.

There were *70,750* and *76,541* stock option awards forfeited during the *six* months ended *December 31, 2018* and *2017,* 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 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 SSC RIAR and extending it until *December 31, 2018.* On *December 24, 2018,* an addendum was signed extending the term of the supply contract through *December 31, 2019* and modifying the volume of additional shipments of Cesium-*131.* Under the Addendum, current pricing and volumes for Cesium-*131* purchases will remain in place until *May 31, 2019.* Pricing for purchases beyond that date will be subject to renegotiation.

Research and Development - Collaborative Arrangement

On *March 13, 2017,* the Company's subsidiary, IsoRay Medical, Inc. ("Medical") entered into a Collaborative Development Agreement (CDA) with GammaTile, LLC (predecessor to GT Medical Technologies) 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 incurred all costs in connection with the collaboration project which was shared equally by both parties (and GT Medical Technologies reimbursed the Company for its half) since *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. The CDA terminated during *March 2018* and was *not* renewed. Since *March 2018,* the Company and GT Medical Technologies have worked collaboratively to obtain *510*(k) clearance and on the transfer of the design of this device to production without a formal agreement. As such, the costs are *no* longer shared equally and during the *three* and *six* months ended *December 31, 2018,* GT Medical Technologies was responsible for more than *50%* of the costs. The Company and GT Medical Technologies collectively completed the design transfer to production at the end of *December 2018.* Moving forward the costs are *not* and will *not* be shared equally. The net costs paid by Isoray related to the CDA and the informal agreement with GT Medical Technologies are reported in the financial statements. These costs are reported on the financial statements under "Research and development: Collaboration arrangements, net of reimbursement."

During the *three* months ended *December 31, 2018* and *2017,* gross costs incurred in connection with the collaboration agreement were *$88,000* and *$58,000,* respectively.

During the *six* months ended *December 31, 2018* and *2017,* gross costs incurred in connection with the collaboration agreement were *$204,000* and *$205,000,* respectively.

As of *December 31, 2018* and *June 30, 2018,* the Company had outstanding receivables from GammaTile LLC of *$59,000* 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 December 31, 2018			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	$*3,201*	$*3,201*	$ -	$ -

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

Table of Contents

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*. 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:

	Six months ended	
	December 31, 2018	December 31, 2017
Facility		
El Camino Hospital of Los Gatos, & other facilities [1]	*22.26%*	*23.60* %

[1] – 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.

***11*. Shareholders' 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.

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.

In connection with redomiciling the Company to Delaware, *no* designations were allocated for Series A, C or D preferred stock as there were *no* shares of any of those classes outstanding at the time of redomicile. However, as Series B had outstanding shares of preferred stock, the Company allocated *5,000,000* shares to this series and had *59,065* issued and outstanding shares at *December 31, 2018.*

***12*. 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*.

Table of Contents

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* and *six* months ended *December 31, 2018* and *2017,* the Company had revenue from both sources. International revenues in all 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.

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.

Table of Contents

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.

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.

Table of Contents

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 December 31, 2018, 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. 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 approximately $32,000 reported revenues in the six months ended December 31, 2018.

The Company has a supply agreement with The Open Joint Stock Company <<Isotope>>, a Russian company, for the supply of Cesium-131, which was recently extended through December 31, 2019. The Company also has a consignment inventory agreement with MedikorPharma-Ural LLC ("Medikor") to process the Company's enriched barium at another nuclear reactor in Russia. The term of this consignment agreement began in November 2017 and is for 10 years. Our source of supply of Cesium-131 from Russia is historically produced using one of two nuclear

reactors which supply the irradiation needed for Cesium-131 production. One of the Russian nuclear reactors was shut down from December 2017 until August 2018, and the other Russian nuclear reactor is scheduled to be shut down for much of 2019 into early 2020. As a result of these scheduled shutdowns, only one of the Company's historic Russian suppliers of Cesium-131 will be available during these periods.

The Company had a third supply agreement to receive irradiated barium from the University of Missouri Research Reactor ("MURR"). However the Company terminated this agreement, effective December, 2018.

Results of Operations

Revenue for the second quarter of fiscal 2019 grew 24% to a record $1.9 million for the quarter versus $1.54 million for the second quarter of fiscal 2018. Second quarter revenue was comprised of 89% for prostate brachytherapy with the balance of 11% of revenue attributed to other brachytherapy that primarily is comprised of brain and lung.

Three months ended December 31, 2018 and 2017 (in thousands):

	Three months ended December 31,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	$1,904	100	$1,536	100	24
Cost of product sales	1,139	60	1,005	65	13
Gross profit / (loss)	765	40	531	35	44
Operating expenses:					
Research and development expenses - proprietary	395	21	311	20	27
Research and development expenses – collaboration agreement, net of reimbursement	19	1	29	2	(34)
Sales and marketing expenses	702	37	674	44	4
(Gain) on Equipment Disposal	(23)	(1)	-	-	-
General and administrative expenses	1,101	58	985	64	12
Total operating expenses	2,194	115	1,999	130	11
Operating loss	(1,429)	(75)	(1,468)	(95)	(1)

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

Table of Contents

Six months ended December 31, 2018 and 2017 (in thousands):

	Six months ended December 31,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Product sales, net	$3,466	100	$2,747	100	26
Cost of product sales	2,177	63	1,951	71	12
Gross profit / (loss)	1,289	37	796	29	62
Operating expenses:					
Research and development expenses - proprietary	789	23	597	22	32
Research and development expenses – collaboration agreement, net of reimbursement	45	1	104	4	(57)
Sales and marketing expenses	1,351	39	1,288	47	5
(Gain) on Equipment Disposal	(23)	(1)	-	-	-
General and administrative expenses	2,074	60	1,827	67	14
Total operating expenses	4,236	122	3,816	140	12
Operating loss	(2,947)	(85)	(3,020)	(111)	(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 continued the ongoing positive sales growth in the second quarter of fiscal 2019 when compared to fiscal 2018 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.

Three months ended December 31, 2018 and 2017 (in thousands):

	Three months ended December 31,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Prostate brachytherapy	$1,695	89	$1,315	86	29

Other brachytherapy	209	11	221	14	(5)
Product sales, net	1,904	100	1,536	100	24

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

Six months ended December 31, 2018 and 2017 (in thousands):

	Six months ended December 31,				
	2018		2017		2018 - 2017
	Amount	% (a)	Amount	% (a)	% Change
Prostate brachytherapy	$3,071	89	$2,399	87	28
Other brachytherapy	395	11	348	13	14
Product sales, net	3,466	100	2,747	100	26

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

Table of Contents

Prostate Brachytherapy

Prostate brachytherapy sales were impacted by growing sales to existing customers and adding new customers, including the limited market release of Blu Build real-time Cesium-131 brachytherapy delivery system at the end of October, 2018. 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 improved the Company’s prostate revenues, in the quarter ended December 31, 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 variability in the three and six months ended December 31, 2018 compared to 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 three and six months ended December 31, 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.

The Company terminated its Irradiation Services Agreement with MURR in December, 2018. If purchases of isotope remain at a constant level, management believes that by obtaining these services elsewhere, it will save approximately $450,000 per year but there is no assurance these savings will be obtained.

Gross Profit

Gross profit as a percentage of revenues for the second quarter of fiscal 2019 increased to 40.2% for the first time in the Company's history compared to 34.6% for the second quarter of fiscal 2018. The gross margin increase was primarily driven by higher sales and continued operating efficiencies from better leverage of our facilities, personnel, and isotope.

Total Operating Expenses

Total operating expenses, consisting of sales and marketing, general and administrative, and research and development increased by 10% and were $2.2 million in the second quarter of fiscal 2019 versus $2.0 million in the second quarter of fiscal 2018.

Research and development

Total research and development expenses increased 22% to $424,000 in the second quarter of fiscal 2019 compared to the second quarter of fiscal 2018, due to increases in proprietary product development expenses primarily related to the development of the recently launched Blu Build delivery system that is now contributing revenue.

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 and six months ended December 31, 2018 and 2017 proprietary research and development comparison were increases associated with participation in new protocols, device development activities, legal fees relating to patents and trademarks, as well as increased consulting costs which were partially offset by reduced payroll costs due to headcount reduction and reduced travel costs.

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.

Table of Contents

Contributing to the three and six months ended December 31, 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. Since the collaborative agreement with GammaTile, LLC terminated during March 2018, the Company and GT Medical Technologies have worked collaboratively to obtain 510(k) clearance and on the design transfer to production without a formal agreement. As such, the costs are no longer shared equally and during the three and six months ended December 31, 2018 GT Medical Technologies was responsible for more than 50% of the costs.

Sales and marketing expenses

Sales and marketing expenses were $702,000 in the second quarter of fiscal 2019, representing a 4% increase versus second quarter of fiscal 2018.

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, 2018 and 2017 as headcount increased in periods prior to the quarter ended December 31, 2018 which increased salaries and increased travel costs. Also, due to increased sales, there were increases in commission and bonus expense.

Contributing to the six months ended December 31, 2018 and 2017 comparison were increased public relations costs as part of the revitalized marketing plan. Staffing differences are a major factor in the cost comparison as headcount increased in periods prior to the quarter ended December 31, 2018 which increased salaries. Also, due to increased sales, there were increases in commission and bonus expense.

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.

General and administrative expenses grew 12% to $1.1 million in the second quarter of fiscal 2019 compared to the second quarter of fiscal 2018. Contributing to the three months ended December 31, 2018 and 2017 comparison were cost increases associated with payroll due to increased headcount, insurance premiums, renewal fees of our CE Mark, legal fees, and proxy solicitation fees associated with redomiciling the Company to Delaware. These cost increases were partially offset in the three months ended December 31, 2018 by a decrease in state use tax expense.

Contributing to the six months ended December 31, 2018 and 2017 comparison were cost increases associated with payroll due to increased headcount, insurance premiums, renewal fees of our CE Mark, legal fees, and proxy solicitation fees associated with redomiciling the Company to Delaware. These costs were partially offset in the six months ended December 31, 2018 by decreases associated with employee hiring expense, state sales tax, and public company related expenses as a result of changing some key vendors which resulted in significant savings.

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 six months ended December 31, 2018 and 2017, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

	Six months ended December 31,	
	2018	2017
Net cash used by operating activities	$(2,726)	$(3,184)
Net cash (used) provided by investing activities	(4,043)	164
Net cash provided by financing activities	7,370	39
Net increase (decrease) in cash and cash equivalents	$601	$(2,981)

Table of Contents

	As of December 31, 2018	June 30, 2018
Working capital	$8,180	$3,611
Current ratio	5.99	2.97

Cash flows from operating activities

Net cash used by operating activities in the six months ended December 31, 2018 was primarily due to a net loss of approximately $2.92 million, net of approximately $273,000 in adjustments for non-cash activity such as depreciation and amortization expense, gain on equipment disposal, ARO accretion, and share-based compensation. Changes in operating assets and liabilities used approximately $77,000 to fund operating activities; decreases in accounts payable and accrued expenses, accrued payroll and related taxes, accrued vacation and an increase in prepaid expenses and other current assets were partially offset by decreases in accounts receivable and inventory and increases in accrued protocol expense and accrued radioactive waste disposal.

Cash flows from investing activities

Investing activities consisted of transactions related to the purchase and sale of fixed assets, including automation of production processes, as well as the purchase and subsequent maturity of U.S. Treasury Bills. Management will continue to invest in technology and machinery that improves and streamlines production processes and to invest maturing U.S. Treasury Bills 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 six months ended December 31, 2018 included payment of preferred dividends and proceeds from sale of common stock, pursuant to registered direct offering, net (see note 11 to the financial statements).

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 six months ended December 31, 2018. 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 six months ended December 31, 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 six months ended December 31, 2018, the Company invested approximately $149,000 in the automation of thirteen production processes, four of which have been placed into service. Through December 31, 2018, the Company has invested approximately $697,000 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 Cesium-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.

Table of Contents

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, 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 19, 2015, and the SEC file number assigned to the registration statement is 333-206559 and expired on November 19, 2018.

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.

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 the registered direct offering completed on July 11, 2018. The Company may receive up to $4,434,375 in gross proceeds solely to the extent the warrants are exercised for cash. The registration statement became effective on December 14, 2018, and the SEC file number assigned to the registration statement is 333-207909.

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 December 31, 2018 other than those previously disclosed in Note 8 of 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.

Table of Contents

During the quarter ended December 31, 2018, 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, 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.

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, 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.

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 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 six months ended December 31, 2018 approximately 45% of the Company’s revenues were dependent on five customers with approximately 22% 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.

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

None.

Table of Contents

ITEM 3 – DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4 - MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5 – OTHER INFORMATION

None

ITEM 6. EXHIBITS

(Except as otherwise indicated (a) all exhibits were previously filed, (b) all omitted exhibits are intentionally omitted, and (c) all documents referenced below were filed under SEC file number 001-33407.)

Exhibits:

3(i)	Certificate of Incorporation, incorporated by reference to Exhibit A of the Form Def 14A filed on November 9, 2018.
3(ii)	Bylaws, incorporated by reference to Exhibit C of the Form Def 14A filed on November 9, 2018.
4.1	Amendment and Termination of Rights Agreement, dated November 7, 2018, by and between IsoRay, Inc. and Computershare Trust Company, N.A., as Rights Agent, incorporated by reference to the Form 8-K filed on November 8, 2018.
10.1	Form of Employment Agreement, incorporated by reference to the Form 8-K filed on October 12, 2018.
10.2	Employment Agreement, dated effective December 3, 2018, between Jonathan Hunt and IsoRay, Inc., incorporated by reference to the Form 8-K filed on December 3, 2018.

10.3	Employment Agreement between IsoRay, Inc. and Lori A. Woods, dated effective January 1, 2019, incorporated by reference to the Form 8-K filed on December 17, 2018.
10.4*	Addendum #8 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, signed December 24, 2018 (confidential treatment requested for redacted portions).
10.5*	Amendment to Exhibit B of Manufacturing and Supply Agreement between IsoRay Medical, Inc. and GT Medical Technologies, Inc., dated December 28, 2018 (confidential treatment requested for redacted portions).
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 Co-Principal Financial Officer
31.3*	Rule 13a-14(a)/15d-14(a) Certification of Co-Principal Financial Officer
32.1**	Section 1350 Certifications
99.1*	Addendum #3 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, dated November 30, 2017 (confidential treatment requested for redacted portions).
99.2*	Addendum #4 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, dated March 19, 2018 (confidential treatment requested for redacted portions).

Table of Contents

99.3*	Addendum #5 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, dated April 17, 2018 (confidential treatment requested for redacted portions).
99.4*	Addendum #6 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, dated May 3, 2018 (confidential treatment requested for redacted portions).
99.5*	Addendum #7 to Contract between IsoRay Medical, Inc. and Joint Stock Company <<Isotope>>, dated May 4, 2018 (confidential treatment requested for redacted portions).
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

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 12, 2019

ISORAY, INC., a Delaware corporation

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

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

/s/ *Jonathan Hunt*
Chief Financial Officer

(Co-Principal Financial Officer)