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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 March 31, 2019

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
(State or other jurisdiction of incorporation or
organization)41-1458152
(I.R.S. Employer
Identification No.)350 Hills St., Suite 106, Richland, Washington
(Address of principal executive offices)99354
(Zip Code)(509) 375-1202

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period 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 every Interactive Data File required to be submitted electronically 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 May 08, 2019</u>
Common stock, \$0.001 par value	67,338,047

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	ISR	NYSE American

ISORAY, INC.

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

	March 31, 2019	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,059	\$ 2,600
Short-term investments (Note 3)	2,333	825
Accounts receivable, net	1,116	1,192
Inventory	533	494
Prepaid expenses and other current assets	390	335
Total current assets	8,431	5,446
Property and equipment, net	1,564	1,311
Restricted cash	181	181
Inventory, non-current	243	319
Other assets, net of accumulated amortization	160	198
Total assets	<u>\$ 10,579</u>	<u>\$ 7,455</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,001	\$ 1,391
Accrued protocol expense	117	77
Accrued radioactive waste disposal	65	37
Accrued payroll and related taxes	38	155
Accrued vacation	134	175
Total current liabilities	1,355	1,835
Long-term liabilities:		
Asset retirement obligation	613	590
Total liabilities	1,968	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; 67,338,047 and 56,331,147 shares issued and outstanding	67	56
Additional paid-in capital	91,941	84,322
Accumulated deficit	(83,397)	(79,348)
Total shareholders' equity	8,611	5,030
Total liabilities and shareholders' equity	<u>\$ 10,579</u>	<u>\$ 7,455</u>

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)

	Three months ended		Nine months ended	
	March 31,		March 31,	
	2019	2018	2019	2018
Sales, net	\$ 1,924	\$ 1,573	\$ 5,390	\$ 4,320
Cost of sales	1,045	964	3,222	2,915
Gross profit	<u>879</u>	<u>609</u>	<u>2,168</u>	<u>1,405</u>
Operating expenses:				
Research and development:				
Proprietary research and development	299	317	1,088	914
Collaboration arrangement, net of reimbursement (Note 8)	-	156	45	260
Total research and development	<u>299</u>	<u>473</u>	<u>1,133</u>	<u>1,174</u>
Sales and marketing	645	692	1,996	1,980
General and administrative	1,099	783	3,173	2,610
Gain on equipment disposal	(1)	-	(24)	-
Total operating expenses	<u>2,042</u>	<u>1,948</u>	<u>6,278</u>	<u>5,764</u>
Operating loss	(1,163)	(1,339)	(4,110)	(4,359)
Non-operating income:				
Interest income, net	34	7	59	17
Other income	2	-	2	-
Non-operating income, net	<u>36</u>	<u>7</u>	<u>61</u>	<u>17</u>
Net loss	(1,127)	(1,332)	(4,049)	(4,342)
Preferred stock dividends	(3)	(3)	(8)	(8)
Net loss applicable to common shareholders	<u>\$ (1,130)</u>	<u>\$ (1,335)</u>	<u>\$ (4,057)</u>	<u>\$ (4,350)</u>
Basic and diluted loss per share	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.06)</u>	<u>\$ (0.08)</u>
Weighted average shares used in computing net loss per share:				
Basic and diluted	<u>67,333</u>	<u>55,100</u>	<u>66,937</u>	<u>55,058</u>

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

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

	Nine months ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,049)	\$ (4,342)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation expense	100	56
Gain on equipment disposals	(24)	-
Amortization of other assets	37	37
Accretion of asset retirement obligation	23	22
Share-based compensation	269	317
Changes in operating assets and liabilities:		
Accounts receivable, net	76	(250)
Inventory	37	(16)
Prepaid expenses and other current assets	(53)	(58)
Accounts payable and accrued expenses	(390)	96
Accrued protocol expense	40	2
Accrued radioactive waste disposal	28	(97)
Accrued payroll and related taxes	(117)	(33)
Accrued vacation	(41)	2
Net cash used by operating activities	<u>(4,064)</u>	<u>(4,264)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(353)	(231)
Proceeds from sale of equipment	24	-
Proceeds from maturity of certificates of deposit	9,632	4,943
Purchases of and interest from certificates of deposit and U.S. Treasury Securities	(11,141)	(4,054)
Net cash (used) provided by investing activities	<u>(1,838)</u>	<u>658</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Preferred dividends paid	(11)	(11)
Proceeds from sales of common stock, pursuant to registered direct offering, net	7,370	-
Proceeds from sales of common stock, pursuant to exercise of options	2	50
Net cash provided by financing activities	<u>7,361</u>	<u>39</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	1,459	(3,567)
Cash, cash equivalents, and restricted cash beginning of period	2,781	6,113
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH END OF PERIOD	<u>\$ 4,240</u>	<u>\$ 2,546</u>
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets:		
Cash and cash equivalents	\$ 4,059	\$ 2,365
Restricted cash	\$ 181	\$ 181
Total cash, cash equivalents, and restricted cash	<u>\$ 4,240</u>	<u>\$ 2,546</u>
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.

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Isoray, Inc. and Subsidiaries
Consolidated Statement of Changes in Shareholders' Equity (unaudited)
(In thousands, except shares)

	Series B Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at June 30, 2018	59,065	\$ -	56,331,147	\$ 56	-	\$ -	\$ 84,322	\$ (79,348)	\$ 5,030
Issuance of common stock pursuant to registered direct offering, net			11,000,000	11			7,483		7,494
Share-based compensation							93		93
Net loss								(1,508)	(1,508)
Balances at September 30, 2018	59,065	\$ -	67,331,147	\$ 67	-	\$ -	\$ 91,898	\$ (80,856)	\$ 11,109
Offering costs pursuant to registered direct offering, net							(116)		(116)
Payment of dividend to preferred shareholders							(11)		(11)
Share-based compensation							97		97
Net loss								(1,414)	(1,414)
Balances at December 31, 2018	59,065	\$ -	67,331,147	\$ 67	-	\$ -	\$ 91,868	\$ (82,270)	\$ 9,665
Issuance of common stock pursuant to exercise of options			6,900	-			2		2
Offering costs pursuant to registered direct offering, net							(8)		(8)
Share-based compensation							79		79
Net loss								(1,127)	(1,127)
Balances at March 31, 2019	59,065	\$ -	67,338,047	\$ 67	-	\$ -	\$ 91,941	\$ (83,397)	\$ 8,611

	Series B Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at June 30, 2017	59,065	\$ -	55,017,419	\$ 55	-	\$ -	\$ 83,151	\$ (72,604)	\$ 10,602
Share-based compensation							90		90
Net loss								(1,546)	(1,546)
Balances at September 30, 2017	59,065	\$ -	55,017,419	\$ 55	-	\$ -	\$ 83,241	\$ (74,150)	\$ 9,146
Issuance of common stock pursuant to exercise of options			82,810				50		50
Payment of dividend to preferred shareholders							(11)		(11)
Share-based compensation							78		78
Share-based compensation for third party services							72		72
Net loss								(1,464)	(1,464)
Balances at December 31, 2017	59,065	\$ -	55,100,229	\$ 55	-	\$ -	\$ 83,430	\$ (75,614)	\$ 7,871
Share-based compensation							77		77

Net loss										(1,332)	(1,332)
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Balances at March 31, 2018	59,065	\$	-	55,100,229	\$	55	-	\$	-	\$	83,507	\$	(76,946)	\$	6,616
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The accompanying notes are an integral part of these consolidated financial statements.

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.

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In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is in the process of evaluating the impact the standard will have on its financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The Company has presented changes in stockholders' equity in its financial statements for the period ended March 31, 2019.

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 March 31, 2019 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 March 31, 2019 and June 30, 2018 are as follows (in thousands):

	As of March 31, 2019			
	Under 90 Days	91 days to six months	Six months to 1 year	Greater than 1 year
U.S. Treasury Securities	\$ 2,333	\$ -	\$ -	\$ -

	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 March 31, 2019 and 2018, 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.

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Securities not considered in the calculation of diluted weighted average shares, but that could be dilutive in the future as of March 31, 2019 and 2018, were as follows (in thousands):

	March 31,	
	2019	2018
Series B preferred stock	59	59
Common stock warrants	6,080	250
Common stock options	3,925	3,272
Total potential dilutive securities	10,064	3,581

5. Inventory

Inventory consisted of the following at March 31, 2019 and June 30, 2018 (in thousands):

	March 31,	June 30,
	2019	2018
Raw materials	\$ 383	\$ 371
Work in process	114	96
Finished goods	36	27
Total inventory, current	\$ 533	\$ 494

	March 31,	June 30,
	2019	2018
Enriched barium, non-current	\$ 193	\$ 276
Raw materials, non-current	50	43
Total inventory, non-current	\$ 243	\$ 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 March 31, 2019, the Company estimates that the remaining enriched barium will result in at least 1,678 curies: approximately 303 of which we believe will be obtained within the next 12 months, and 1,375 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 March 31, 2019 and June 30, 2018 (in thousands):

	March 31,	June 30,
	2019	2018
Land	\$ 366	\$ 366
Equipment	3,802	4,152
Leasehold improvements	4,143	4,136
Other ¹	587	328
Property and equipment	8,898	8,982
Less accumulated depreciation	(7,334)	(7,671)
Property and equipment, net	\$ 1,564	\$ 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 March 31, 2019 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 March 31, 2019 and 2018 (in thousands):

	Three Months ended March 31,	
	2019	2018
Cost of sales	\$ 9	\$ 10
Research and development expenses	18	20
Sales and marketing expenses	22	17
General and administrative expenses	30	30
Total share-based compensation	\$ 79	\$ 77

The following table presents the share-based compensation expense recognized for stock-based options during the nine months ended March 31, 2019 and 2018 (in thousands):

	Nine Months ended March 31,	
	2019	2018
Cost of sales	\$ 30	\$ 40
Research and development expenses	54	58
Sales and marketing expenses	65	50
General and administrative expenses	120	97
Total share-based compensation	\$ 269	\$ 245

As of March 31, 2019, total unrecognized compensation expense related to stock-based options was approximately \$494,000 and the related weighted-average period over which it is expected to be recognized is approximately .95 years.

During the nine months ended March 31, 2018, there was approximately \$72,000 of share based compensation related to warrants granted in connection with the services performed by AI & J Media Inc.

A summary of stock options within the Company's share-based compensation plans as of March 31, 2019 was as follows (in thousands except for exercise prices and terms):

As of March 31, 2019	Number of Options	Weighted Exercise Price	Weighted Average Contractual Term (Years)	Intrinsic Value
Outstanding	3,925	\$.67	7.18	\$ 10
Vested and expected to vest	3,925	\$.67	7.18	\$ 10
Vested and exercisable	2,163	\$.79	5.85	\$ 10

There were 6,900 and no stock options exercised, with approximately \$1,000 and \$0 of intrinsic value associated with these exercises during the three months ended March 31, 2019 and 2018, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 25,000 and 15,000 option awards granted with a fair value of approximately \$7,000 and \$5,000 during the three months ended March 31, 2019 and 2018, respectively.

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There were 10,000 and no stock option awards which expired during the three months ended March 31, 2019 and 2018, respectively.

There were no and 37,500 stock option awards forfeited during the three months ended March 31, 2019 and 2018, respectively.

There were 6,900 and 82,810 stock options exercised, with approximately \$1,000 and \$0 of intrinsic value associated with these exercises during the nine months ended March 31, 2019 and 2018, respectively. The Company's current policy is to issue new shares to satisfy stock option exercises.

There were 262,500 and 90,000 option awards granted with a fair value of approximately \$94,000 and \$38,000 during the nine months ended March 31, 2019 and 2018, respectively.

There were 20,000 and no stock option awards which expired during the nine months ended March 31, 2019 and 2018, respectively.

There were 70,750 and 114,041 stock option awards forfeited during the nine months ended March 31, 2019 and 2018, 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 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. Purchases beyond that date will be renegotiated.

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 nine months ended March 31, 2019, 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 statement of operations. These costs are reported on the statement of operations under "Research and development: Collaboration arrangements, net of reimbursement." During the three months ended March 31, 2019, IsoRay did not incur any expenses net of reimbursement from GT Medical Technologies.

During the three months ended March 31, 2019 and 2018, gross costs incurred before reimbursement from GT Medical Technologies in connection with the collaboration agreement were \$31,000 and \$304,000, respectively.

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During the nine months ended March 31, 2019 and 2018, gross costs incurred in connection with the collaboration agreement were \$235,000 and \$509,000, respectively.

As of March 31, 2019 and June 30, 2018, the Company had outstanding receivables from GT Medical Technologies in connection with the collaboration agreement of \$30,000 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 March 31, 2019			
	Total	Level 1	Level 2	Level 3
Cash and cash equivalents	\$ 4,059	\$ 4,059	\$ -	\$ -

	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. 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 sales:

Facility	Nine months ended	
	March 31, 2019	March 31, 2018
El Camino Hospital of Los Gatos & other facilities ¹	20.97%	24.23%

¹ – This group of facilities individually each comprise less than 10% of total Company 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").

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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, Preferred Stock Series A, C and D designations were terminated. There were no shares issued under these Series. Series B is the remaining Series authorized at March 31, 2019 and had 59,065 issued and outstanding shares at March 31, 2019.

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*.

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 – direct sales of products and services.
2. International – direct sales of products and services.

For the three months ended March 31, 2019 and 2018 the Company had no international revenue. During the nine months ended March 31, 2019 and 2018 the Company had revenue from both sources. International revenues in all periods was immaterial. For the three months ended March 31, 2019, prostate brachytherapy comprised 88% of our revenue while other revenue comprised 12% compared to 83% and 17%, respectively, in the three months ended March 31, 2018. For the nine months ended March 31, 2019, prostate brachytherapy comprised 88% of our revenue while other revenue comprised 12% compared to 86% and 14%, respectively, in the nine months ended March 31, 2018.

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.

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 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 standard 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 20 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 March 31, 2019 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.

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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, the Russian Federation, and Peru with a nominal amount of reported revenues in these locations during the nine months ended March 31, 2019.

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 in the second half of calendar 2019 into 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

Three months ended March 31, 2019 and 2018 (in thousands):

	Three months ended March 31,					
	2019		2018		2019 - 2018	
	Amount	% (a)	Amount	% (a)	% Change	
Sales, net	\$ 1,924	100	\$ 1,573	100	22	
Cost of sales	1,045	54	964	61	8	
Gross profit	879	46	609	39	44	
Operating expenses:						
Research and development expenses - proprietary	299	16	317	20	(6)	
Research and development expenses – collaboration agreement, net of reimbursement	-	-	156	10	(100)	
Sales and marketing expenses	645	34	692	44	(7)	
General and administrative expenses	1,099	57	783	50	40	
Gain on Equipment Disposal	(1)	(0)	-	-	-	
Total operating expenses	2,042	106	1,948	124	5	
Operating loss	(1,163)	(60)	(1,339)	(85)	(13)	

(a) Expressed as a percentage of sales, net

Nine months ended March 31, 2019 and 2018 (in thousands):

	Nine months ended March 31,					
	2019		2018		2019 - 2018	
	Amount	% (a)	Amount	% (a)	% Change	
Sales, net	\$ 5,390	100	\$ 4,320	100	25	
Cost of sales	3,222	60	2,915	67	11	
Gross profit	2,168	40	1,405	33	54	
Operating expenses:						
Research and development expenses - proprietary	1,088	20	914	21	19	
Research and development expenses – collaboration agreement, net of reimbursement	45	1	260	6	(83)	
Sales and marketing expenses	1,996	37	1,980	46	1	
General and administrative expenses	3,173	59	2,610	60	22	
Gain on Equipment Disposal	(24)	(0)	-	-	-	
Total operating expenses	6,278	116	5,764	133	9	
Operating loss	(4,110)	(76)	(4,359)	(101)	(6)	

(a) Expressed as a percentage of sales, net

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 third quarter of fiscal 2019 when compared to fiscal 2018 third quarter. Ongoing training and support of new sales personnel has led to not only new customers but also reconnecting with and receiving orders from prior customers.

Three months ended March 31, 2019 and 2018 (in thousands):

	Three months ended March 31,					
	2019		2018		2019 - 2018	
	Amount	% (a)	Amount	% (a)	% Change	
Prostate brachytherapy	\$ 1,690	88	\$ 1,304	83	30	
Other sales	234	12	269	17	(13)	
Sales, net	1,924	100	1,573	100	22	

(a) Expressed as a percentage of sales, net

Nine months ended March 31, 2019 and 2018 (in thousands):

	Nine months ended March 31,					
	2019		2018		2019 - 2018	
	Amount	% (a)	Amount	% (a)	% Change	
Prostate brachytherapy	\$ 4,761	88	\$ 3,703	86	29	
Other sales	629	12	617	14	2	
Sales, net	5,390	100	4,320	100	25	

(a) Expressed as a percentage of sales, net

Prostate Brachytherapy

Prostate brachytherapy sales were impacted by growing sales to existing and new customers. 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 March 31, 2019.

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Other Sales

Other sales includes, but is not limited to, brain, lung, head/neck, gynecological treatments, and services. 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 nine months ended March 31, 2019 compared to the prior year.

Cost of sales

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

Contributing to the three and nine months ended March 31, 2019 and 2018 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.

Research and development

Research and development – proprietary

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

Contributing to the three and nine months ended March 31, 2019 and 2018 proprietary research and development comparison were increases associated with participation in new protocols, device development activities, legal fees relating to patents and trademarks, reallocation of employee costs for employees working on research and development projects, as well as increased consulting costs which were partially offset by reduced software and 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.

Contributing to the three and nine months ended March 31, 2019 and 2018 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 nine months ended March 31, 2019 GT Medical Technologies was responsible for more than 50% of the costs.

Sales and marketing expenses

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

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Decreased tradeshow and travel costs are a major factor in the cost comparison for the three months ended March 31, 2019 and 2018 as the Company attended fewer tradeshows in the three months ending March 31, 2019 compared to 2018. Expenses for the nine months ended March 31, 2019 and 2018 did not change materially.

General and administrative expenses

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

Contributing to the three months ended March 31, 2019 and 2018 comparison were cost increases associated with payroll due to increased headcount, employee hiring expenses, investor relations, tax audit expense, legal fees, and insurance premiums. During the three months ended March 31, 2019, we accrued approximately \$80,000 of expenses relating to the State of Washington Hazardous Substance Tax resulting from a state tax audit, \$50,000 accrued based on negotiations with a former consultant, and related professional service fees.

Contributing to the nine months ended March 31, 2019 and 2018 comparison were cost increases associated with payroll due to increased headcount and employee hiring expense, insurance premiums, renewal fees of our CE Mark, legal fees, tax audit expense, and proxy solicitation fees associated with redomiciling the Company to Delaware. These costs were partially offset in the nine months ended March 31, 2019 by decreases associated with 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 nine months ended March 31, 2019 and 2018, the Company used existing cash reserves to fund its operations and capital expenditures (in thousands except current ratio):

	Nine months ended March 31,	
	2019	2018
Net cash used by operating activities	\$ (4,064)	\$ (4,264)
Net cash (used) provided by investing activities	(1,838)	658
Net cash provided by financing activities	7,361	39
Net increase (decrease) in cash and cash equivalents	<u>\$ 1,459</u>	<u>\$ (3,567)</u>

	As of	
	March 31, 2019	June 30, 2018
Working capital	\$ 7,096	\$ 3,611
Current ratio	6.24	2.97

Cash flows from operating activities

Net cash used by operating activities in the nine months ended March 31, 2019 was primarily due to a net loss of approximately \$4.05 million, net of approximately \$405,000 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 \$420,000 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.

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Cash flows from financing activities

Financing activities in the nine months ended March 31, 2019 included payment of preferred dividends and proceeds from sale of common stock, pursuant to a registered direct offering, net (see note 11 to the financial statements), and proceeds from sales of common stock, pursuant to the exercise of options.

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 met that target of twenty-five percent increased revenue in the nine months ended March 31, 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 nine months ended March 31, 2019 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 sales.

During the nine months ended March 31, 2019, the Company invested approximately \$219,000 in the automation of thirteen production processes, four of which have been placed into service. Through March 31, 2019, the Company has invested approximately \$768,000 in these automation projects, and management is expecting to invest approximately \$200,000 more over the next 7 months in 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.

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 March 31, 2019, 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 was 333-206559 and it 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 described above. There was no material change in the use of proceeds from our public offering as described in our prospectus supplement filed with the SEC pursuant to Rule 424(b) on July 11, 2018. Through March 31, 2019, the Company had used the net proceeds raised through the July 11 offering as described in the prospectus supplement. 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.

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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.

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 March 31, 2019 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.

During the quarter ended March 31, 2019, 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 co-principal financial officers, 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 March 31, 2019. Based on that evaluation, our principal executive officer and our co-principal financial officers have 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

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings, and our management believes there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our operations, financial condition, or cash flows. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

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 nine months ended March 31, 2019 approximately 45% of the Company’s revenues were dependent on five customers with approximately 21% 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.

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.
10.1	Employment Agreement between Isoray, Inc. and Michael Krachon, dated effective February 6, 2019, incorporated by reference to the Form 8-K filed on February 12, 2019.
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
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: May 10, 2019

ISORAY, INC., a Delaware corporation

/s/ Lori A. Woods

Lori A. Woods
Chief Executive Officer
(Principal Executive Officer)

/s/ Jonathan Hunt

Jonathan Hunt
Chief Financial Officer
(Co-Principal Financial Officer)

/s/ Mark J. Austin

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