IsoRay Announces First Quarter Fiscal 2019 Financial Results

Year Over Year First Quarter Revenues Increased 29%
Double Digit Revenue Increases Year Over Year for Sixth Consecutive Quarter

RICHLAND, WASHINGTON - November 8, 2018 -- IsoRay, Inc. (NYSE AMERICAN: ISR), a medical technology company and innovator in seed brachytherapy powering expanding treatment options throughout the body, today announced its financial results for the first quarter fiscal 2019 ended September 30, 2018.

Revenue for the first quarter fiscal 2019 grew 29% to $1.56 million versus $1.21 million in the prior year comparable period. The revenue increase was driven by continued sales execution in the company's core prostate brachytherapy markets as well as in brachytherapy sales for treatment of other cancers. Prostate brachytherapy represented 88% of total revenue for the first quarter of 2019 compared to 89% in the prior year comparable period. Additionally, year over year growth in non-prostate brachytherapy revenue was driven by growth in sales to treat brain, lung, and head and neck cancers.

Gross profit as a percentage of revenues increased to 33.5% for the three months ended September 30, 2018 versus 21.9% in the prior year comparable period. First quarter gross profit increased 98% to $0.52 million versus $0.27 million in the first quarter of fiscal 2018, largely attributed to increased sales and the company's continued improvement in utilization of the isotope.

IsoRay Interim CEO Lori Woods said, "We are pleased with the continued growth in revenues and the demonstrated strong sales momentum that has continued into fiscal 2019. We intend to build on this momentum with the incremental growth of revenues from our new product, Blu-Build™, and from our role as the manufacturer of GammaTile™ Therapy for GT Medical Technologies, Inc."

Woods concluded, "We have reached an important milestone with the successful completion of the first case involving the treatment of prostate cancer utilizing our customizable, intra-operative Cesium-131 Blu-Build delivery system. The case was completed on October 26 at the Medical University of South Carolina. We are confident that we have the right products at the right time that will allow us to execute our plans for future growth."

Total operating expenses in the first quarter were $2.04 million compared to $1.82 million in the prior year period. Total research and development expenses increased 16% versus the prior year comparable period. The increase in total research and development expenses was primarily the result of increases in

proprietary new product development expenses related to the Blu-Build delivery system, which was partially offset by the year-over-year decline in collaborative research and development expenses related to GT Medical Technologies and their pending launch of GammaTile Therapy. Sales and marketing expenses increased 6% versus the prior year comparable period. General and administrative expenses increased 16% versus the prior year comparable period, primarily the result of an increase in headcount and incentive compensation related to the increase in revenue.

The net loss for the three months ended September 30, 2018 was $1.51 million or ($0.02) per basic and diluted share versus a net loss of $1.55 million or ($0.03) per basic and diluted share in the comparable prior year period. Basic and diluted per share results are based on weighted average shares outstanding of approximately 66.1 million for the three months ended September 30, 2018 versus 55.0 million in the comparable prior year period.

During the quarter, the company closed a public offering of 11.0 million shares of its common stock at a price of $0.75 per share. Gross proceeds, before underwriting discounts, commissions and estimated offering costs, were approximately $8.25 million. Cash, cash equivalents, and short-term investments at the end of the first quarter of fiscal 2019 totaled $9.19 million and the company had no debt.

Conference Call Details

The Company will hold an earnings conference call today, November 8, at 4:30 p.m. ET/1:30 p.m. PT to discuss operating results. To listen to the conference call, please dial (877) 407-8031. For callers outside the U.S., please dial (201) 689-8031.

The conference call will be simultaneously webcast and can be accessed at http://www.investorcalendar.com/event/39638 by clicking on the link. The webcast will be available until February 8, 2019 following the conference call. A replay of the call will also be available by phone and can be accessed by dialing (877) 481-4010 and providing reference number 39638. For callers outside the U.S., please dial (919) 882-2331 and provide reference number 39638. The replay will be available beginning approximately one hour after the completion of the live event, ending at 4:30 p.m. Eastern Time on November 15, 2018.

Contacts

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About IsoRay, Inc.

IsoRay, Inc., through its subsidiary, IsoRay Medical, Inc. is the sole producer of Cesium-131 brachytherapy seeds, which are expanding brachytherapy options throughout the body. Learn more about this innovative Richland, Washington company and explore the many benefits and uses of Cesium-131 by visiting www.isoray.com. Join us on LinkedIn and Facebook/IsoRay. Follow us on Twitter @IsoRay.

Safe Harbor Statement

Statements in this news release about IsoRay's future expectations, including: the advantages of our products and their delivery systems, whether interest in and use of our products will increase or continue, whether our new marketing strategy will continue to increase sales, whether use of Cesium-131 in non-prostate applications will continue to increase revenue, whether further manufacturing and production process improvements will be completed or will result in lower costs, whether our market presence and growth will continue, the timing of ongoing commercialization of Blu-Build™ and GammaTile™ Therapy, the positive industry data fueling renewed interest in brachytherapy, and all other statements in this release, other than historical facts, are "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. It is important to note that actual results and ultimate corporate actions could differ materially from those in such forward-looking statements based on such factors as physician acceptance, training and use of our products, our ability to successfully manufacture, market and sell our products, our ability to manufacture our products in sufficient quantities to meet demand within required delivery time periods while meeting our quality control standards, our ability to enforce our intellectual property rights, whether additional studies are released that support the conclusions of past studies, whether ongoing patient results with our products are favorable and in line with the conclusions of clinical studies and initial patient results, patient results achieved when our products are used for the treatment of cancers and malignant diseases, successful completion of future research and development activities, whether we, our distributors and our customers will successfully obtain and maintain all required regulatory approvals and licenses to market, sell and use our products in its various forms, continued compliance with ISO standards, the success of our sales and marketing efforts, changes in reimbursement rates, the procedures and regulatory requirements mandated by the FDA for 510(k) approval and reimbursement codes, changes in laws and regulations applicable to our products, the scheduling of physicians who either delay or do not schedule patients in periods anticipated, the use of competitors' products in lieu of our products, less favorable reimbursement rates than anticipated for each of our products, and other risks detailed from time to time in IsoRay's reports filed with the SEC. Unless required to do so by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

IsoRay, Inc. and Subsidiaries
Consolidated Balance Sheets (unaudited)
(In thousands, except shares)

	September 30, 2018	June 30, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,193	$ 2,600
Short-term investments	7,000	825
Accounts receivable, net of allowance for doubtful accounts of $26 and $26, respectively	1,071	1,192
Inventory	487	494
Prepaid expenses and other current assets	517	335
Total current assets	11,268	5,446
Property and equipment, net	1,394	1,311
Restricted cash	181	181
Inventory, non-current	316	319
Other assets, net of accumulated amortization	185	198
Total assets	$ 13,344	$ 7,455
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,167	$ 1,391
Accrued protocol expense	125	77
Accrued radioactive waste disposal	45	37
Accrued payroll and related taxes	125	155
Accrued vacation	175	175
Total current liabilities	1,637	1,835
Long-term liabilities:		
Asset retirement obligation	598	590
Total liabilities	2,235	2,425
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, $.001 par value; 7,001,671 shares authorized:		
Series A: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series B: 5,000,000 shares allocated; 59,065 shares issued and outstanding	-	-
Series C: 1,000,000 shares allocated; no shares issued and outstanding	-	-
Series D: 1,671 shares allocated; no shares issued and outstanding	-	-
Common stock, $.001 par value; 192,998,329 shares authorized; 67,311,147 and 56,331,147 shares issued and outstanding	67	56
Additional paid-in capital	91,898	84,322
Accumulated deficit	(80,856)	(79,348)
Total shareholders' equity	11,109	5,030
Total liabilities and shareholders' equity	$ 13,344	$ 7,455

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

	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017
	Q1 2019	Q1 2018
Product sales, net	$ 1,562	$ 1,211
Cost of product sales	1,038	946
Gross profit	524	265
Operating expenses:		
Research and development		
Proprietary research and development	394	287
Collaboration arrangement, net of reimbursement (Note 15)	26	75
Total research and development	420	362
Sales and marketing	649	614
General and administrative	973	841
Change in estimate of asset retirement obligation (Note 9)	-	-
Total operating expenses	2,042	1,817
Operating loss	(1,518)	(1,552)
Non-operating income:		
Interest income	10	6
Change in fair value of warrant derivative liability	-	-
Financing and interest expense	-	-
Non-operating income, net	10	6
Net loss	(1,508)	(1,546)
Preferred stock dividends	(3)	(3)
Net loss applicable to common shareholders	$ (1,511)	$ (1,549)
Basic and diluted loss per share	$ (0.02)	$ (0.03)
Weighted average shares used in computing net loss per share:		
Basic and diluted	66,147	55,017