IsoRay, Inc.
Form 10-Q
May 10, 2016

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

**þ QUARTERLY Report PURSUANT TO Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended March 31, 2016

or

¨ Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from __________ to ____________

Commission File No. 001-33407

**ISORAY, INC.**

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: (509)
375-1202

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer”, “accelerated filer”, and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨

Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act):
Yes ¨ No x

Number of shares outstanding of each of the issuer's classes of
common equity as of the latest practicable date:

| Class | Outstanding as of May 6, 2016 |
| --- | --- |
| Common stock, $0.001 par value | 55,010,619 |

**ISORAY, INC.**

**Table of Contents**

**PART I – FINANCIAL INFORMATION**

**ITEM 1 – FINANCIAL STATEMENTS**

**IsoRay, Inc. and Subsidiaries**

**Consolidated Balance Sheets**

| | (Unaudited) March 31, 2016 | June 30, 2015 |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $5,694,339 | $5,226,740 |
| Certificates of deposit | 5,910,756 | 9,362,574 |
| Accounts receivable, net of allowance for doubtful accounts of $30,000 and $30,000, respectively | 883,702 | 1,049,041 |
| Inventory | 457,291 | 403,955 |
| Other receivables | 5,098 | 19,615 |
| Prepaid expenses and other current assets | 288,977 | 263,597 |
| Total current assets | 13,240,163 | 16,325,522 |
| Property and equipment, net | 415,675 | 574,840 |
| Certificates of deposit, non-current | 5,191,960 | 5,106,775 |
| Restricted cash | 181,368 | 181,262 |
| Inventory, non-current | 544,363 | 569,854 |
| Other assets, net of accumulated amortization | 222,529 | 245,031 |
| Total assets | $19,796,058 | $23,003,284 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $732,018 | $498,253 |
| Accrued protocol expense | 97,679 | 124,131 |
| Accrued radioactive waste disposal | 164,544 | 129,500 |
| Accrued payroll and related taxes | 119,165 | 212,795 |
| Accrued vacation | 98,874 | 127,515 |
| Total current liabilities | 1,212,280 | 1,092,194 |

| | | |
|---|---|---|
| Long-term liabilities: | | |
| Warrant derivative liability | 45,000 | 181,000 |
| Asset retirement obligation | 1,013,782 | 947,849 |
| Total liabilities | 2,271,062 | 2,221,043 |
| 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 | 59 | 59 |
| Series C: 1,000,000 shares allocated; no shares issued and outstanding | - | - |
| Series D: 1,671 shares allocated; no shares issued and outstanding | - | - |
| Common stock, $.001 par value; 192,998,329 shares authorized; | | |
| 55,010,619 and 54,967,559 shares issued and outstanding | 55,010 | 54,968 |
| Treasury stock, at cost, 0 and 13,200 shares, respectively | - | (8,390) |
| Additional paid-in capital | 82,727,429 | 82,467,111 |
| Accumulated deficit | (65,257,502) | (61,731,507) |
| Total shareholders' equity | 17,524,996 | 20,782,241 |
| Total liabilities and shareholders' equity | $19,796,058 | $23,003,284 |

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

1

**IsoRay, Inc. and Subsidiaries**

**Consolidated Statements of Operations**

**(Unaudited)**

| | Three months ended March 31, 2016 | Three months ended March 31, 2015 | Nine months ended March 31, 2016 | Nine months ended March 31, 2015 |
|---|---|---|---|---|
| Product sales | $ 1,198,701 | $ 1,158,109 | $ 3,649,031 | $ 3,265,795 |
| Cost of product sales | 1,132,397 | 1,102,912 | 3,472,357 | 3,303,364 |
| Gross profit (loss) | 66,304 | 55,197 | 176,674 | (37,569) |
| Operating expenses: | | | | |
| Research and development | 183,187 | 141,399 | 385,325 | 458,636 |
| Sales and marketing | 300,995 | 374,876 | 833,887 | 1,032,402 |
| General and administrative | 909,144 | 589,934 | 2,785,539 | 1,703,825 |
| Total operating expenses | 1,393,326 | 1,106,209 | 4,004,751 | 3,194,863 |
| Operating loss | (1,327,022) | (1,051,012) | (3,828,077) | (3,232,432) |
| Non-operating income (expense): | | | | |
| Interest income | 53,725 | 68,954 | 167,032 | 214,009 |
| Change in fair value of warrant derivative liability | 78,000 | 28,605 | 136,000 | 375,605 |
| Financing and interest expense | - | (100) | (950) | (3,551) |
| Non-operating income (expense), net | 131,725 | 97,459 | 302,082 | 586,063 |
| Net loss | (1,195,297) | (953,553) | (3,525,995) | (2,646,369) |
| Preferred stock dividends | (2,658) | (2,658) | (7,974) | (7,974) |
| Net loss applicable to common shareholders | $ (1,197,955) | $ (956,211) | $ (3,533,969) | $ (2,654,343) |
| Basic and diluted loss per share | $ (0.02) | $ (0.02) | $ (0.06) | $ (0.05) |
| Weighted average shares used in computing net loss per share: | | | | |
| Basic and diluted | 55,022,668 | 54,883,551 | 55,010,619 | 54,878,297 |

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

2

**IsoRay, Inc. and Subsidiaries**

**Consolidated Statements of Cash Flows**

**(Unaudited)**

| | Nine months ended March 31, 2016 | 2015 |
|---|---|---|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | $ (3,525,995) | $ (2,646,369) |
| Adjustments to reconcile net loss to net cash used by operating activities: | | |
| Allowance for doubtful accounts | - | (8,607) |
| Depreciation expense | 412,170 | 439,223 |
| Loss on equipment disposals | 6,512 | - |
| Writeoff of inventory associated with discontinued product | 72,200 | - |
| Amortization of other assets | 25,494 | 34,923 |
| Change in fair value of derivative warrant liability | (136,000) | (375,605) |
| Accretion of asset retirement obligation | 65,933 | 60,278 |
| Share-based compensation | 229,442 | 64,360 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, gross | 165,339 | (116,817) |
| Inventory | (125,536) | (104,818) |
| Other receivables | 14,517 | 43,154 |
| Prepaid expenses and other current assets | 111 | (9,171) |
| Accounts payable and accrued expenses | 233,765 | (135,198) |
| Accrued protocol expense | (26,452) | 38,031 |
| Accrued radioactive waste disposal | 35,044 | (23,469) |
| Accrued payroll and related taxes | (93,630) | (146,746) |
| Accrued vacation | (28,641) | (5,633) |
| Net cash used by operating activities | (2,675,727) | (2,892,464) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | |
| Payments for property and equipment | (259,517) | (77,963) |
| Additions to licenses and other assets | (2,992) | (14,016) |
| Proceeds from maturity of certificates of deposit | 9,558,812 | 10,031,758 |
| Purchases of certificates of deposit | (6,106,994) | (9,110,673) |
| Purchases of certificates of deposit, non-current | (85,185) | (4,744,580) |
| Change in restricted cash | (106) | (40) |
| Net cash provided (used) by investing activities | 3,104,018 | (3,915,514) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Preferred dividends paid | (10,632) | (10,632) |

| | | |
|---|---|---|
| Proceeds from sales of common stock, pursuant to exercise of warrants, net | - | 70,789 |
| Proceeds from sales of common stock, pursuant to exercise of options | 49,940 | 145,274 |
| | | |
| Net cash provided by financing activities | 39,308 | 205,431 |
| | | |
| Net increase (decrease) in cash and cash equivalents | 467,599 | (6,602,547) |
| Cash and cash equivalents, beginning of period | 5,226,740 | 7,680,073 |
| | | |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | $ 5,694,339 | $ 1,077,526 |
| | | |
| Non-cash investing and financing activities: | | |
| Retirement of treasury stock | $ 8,390 | $ - |
| Reclassification of derivative warrant liability to equity upon exercise | $ - | $ 17,395 |

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

3

**IsoRay, Inc.**

**Notes to the Unaudited Consolidated Financial Statements**

**For the three and nine months ended March 31, 2016 and 2015**

## 1. Basis of Presentation

The accompanying unaudited interim consolidated financial statements are those of IsoRay, Inc., and its wholly-owned subsidiaries (“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, 2015.

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 2016 will be 0%.

## 2. New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes the revenue recognition requirements in FASB Accounting Standards Codification (ASC) Topic 605, Revenue Recognition. The guidance requires that an entity recognize revenue in a way that depicts the transfer of promised goods or services to customers in the amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods and services. The guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, and is to be applied retrospectively, with early application not permitted. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11 – Inventory. The guidance requires an entity's management to measure inventory within the scope of this ASU at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early application is permitted.  The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01 – Financial Instruments – Overall. The guidance requires an entity's management to measure equity investments except those accounted for under the equity method of accounting or those that result in consolidation of the investee to be measured at fair value; simplifies the impairment assessment of equity investments; eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for non-public entities: eliminates the requirement for a public entity to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset (that is, securities or loans and receivables) on the balance sheet or the accompanying notes to the financial statements; and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017. Early application is not permitted except as contained in the early adoption guidance. The Company is currently evaluating the new standard and its impact on the Company's consolidated financial statements.

**3. Certificates of deposit**

The Company has maintained all excess cash in certificates of deposit at certain banks in certificates of deposit and through the Certificate of Deposit Account Registry Service (CDARS), which 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). The Company ensures that principal amounts of certificates of deposit are fully insured. There may from time to time be short periods following maturity that amounts held in the money market account at the CDARS host bank will exceed FDIC coverage. In cases where the period that uninsured amounts will be held beyond ten banking days, the funds will be transferred to the primary operating account of the Company's operating subsidiary, IsoRay Medical, Inc. (Medical), that incorporates a sweep function that keeps the funds FDIC insured during that time.

| | As of March 31, 2016 | | | |
|---|---|---|---|---|
| | Under 90 | 91 days to | Six months to | Greater |
| | Days | six months | 1 year | than 1 year |
| CDARS | $5,910,756 | $ - | $ - | $5,191,960 |

| | As of June 30, 2015 | | | |
|---|---|---|---|---|
| | Under 90 | 91 days to | Six months to | Greater |

| | Days | six months | 1 year | than 1 year |
|---|---|---|---|---|
| CDARS | $3,523,167 | $ 500,064 | $ 5,339,343 | $5,106,775 |

**4. Loss per Share**

Basic and diluted earnings 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, 2016 and 2015, 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 March 31, 2016 and 2015, were as follows:

| | March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Series B preferred stock | 59,065 | 59,065 |
| Common stock warrants | 360,800 | 396,174 |
| Common stock options | 2,355,060 | 2,057,620 |
| Total potential dilutive securities | 2,774,925 | 2,512,859 |

5

**5. Inventory**

Inventory consisted of the following at March 31, 2016 and June 30, 2015:

| March 31, | June 30, |
|---|---|