

IsoRay, Inc.
Form 8-K
January 08, 2018

**United States Securities And Exchange Commission
Washington, DC 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): January 3,
2018

ISORAY, INC.

(Exact name of registrant as specified in its charter)

Minnesota

001-33407

41-1458152

(State or other jurisdiction of incorporation) (Commission File Number) (IRS Employer Identification No.)

350 Hills Street, Suite 106, Richland, Washington 99354

(Address of principal executive offices) (Zip Code)

(509) 375-1202

(Registrant's telephone number)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

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Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement

On January 3, 2018, IsoRay Medical, Inc. (“Medical”), a wholly owned subsidiary of IsoRay, Inc. (the “Company”), and GT Medical Technologies, Inc., a Delaware corporation (“GT Tech”), entered into a Manufacturing and Supply Agreement (the “Supply Agreement”).

Pursuant to the Supply Agreement, Medical will manufacture and supply a brachytherapy product that incorporates Cesium-131 seeds within customizable carriers configured as squares or rectangles for the treatment of brain tumors (the “GammaTile™ Product”), developed pursuant to the Collaborative Development Agreement described below. Once regulatory clearance from the U.S. Food and Drug Administration permitting marketing of the GammaTile™ Product is received (the “510(k) Clearance”), , Medical will exclusively manufacture and supply the GammaTile™ Product for end users designated by GT Tech. Additionally, Medical will supply loose or braided Cesium-131 seeds for brachytherapy brain cancer treatment to GT Tech on a non-exclusive basis. The prices for the GammaTile™ Product and Cesium-131 seeds are set forth on Exhibit B of the Supply Agreement, subject to periodic adjustment, with an initial price per seed of between \$130 and \$150 depending on quantity ordered. As part of the Supply Agreement, Medical has agreed to transfer the 510(k) Clearance to GT Tech within 30 days of receipt. The term of the Supply Agreement is 10 years.

As a precursor to the Supply Agreement, on March 13, 2017, Medical entered into a Collaborative Development Agreement (the “Development Agreement”) with GammaTile, LLC, an Arizona limited liability company (“GammaTile”) and an affiliate of GT Tech.

Pursuant to the Development Agreement, the parties agreed to collaborate to (a) refine GammaTile’s manufacturing process to develop the GammaTile™ Product, (b) seek regulatory approval of the GammaTile™ Product and (c) gain a reimbursement code with Medicare (together, the “Collaboration Project”). The parties agreed to share costs associated with the Collaboration Project equally. While the initial budget of the services to be provided by Medical was \$429,514, with the need for additional animal testing as requested by the FDA, management believes the new budget will be closer to \$950,000 and the parties have spent over \$500,000 as of January 1, 2018. Intellectual property developed during the course of the Collaboration Project that does not relate to either prior existing intellectual property of a party or subsequent inventions related to such prior intellectual property of a party will be jointly owned by Medical and GammaTile. The Development Agreement terminates on March 13, 2018, but may be extended by mutual consent if necessary.

The foregoing summaries of the Supply Agreement and the Development Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of each agreement. Copies of both agreements are attached hereto as Exhibits 10.1 and 10.2 and are incorporated herein by reference.

Item 8.01 *Other Events.*

On January 8, 2018, the Company issued a press release announcing its entry into the Supply Agreement, the text of which is attached hereto as Exhibit 99.1.

Item 9.01 *Financial Statements and Exhibits*

(d) Exhibits

10.1 Manufacturing and Supply Agreement, dated January 3, 2018, between IsoRay Medical, Inc. and GT Medical Technologies, Inc.

10.2 Collaborative Development Agreement, dated effective as of March 13, 2017, between IsoRay Medical, Inc. and GammaTile, LLC.

99.1 Press release issued by IsoRay, Inc., dated January 8, 2018.

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 hereunto duly authorized.

Date: January 8, 2018

IsoRay, Inc., a Minnesota corporation

By: /s/ Thomas C. LaVoy

T Thomas C. LaVoy, CEO