

Isoray, Inc.
Form 8-K
May 02, 2019
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): April 26, 2019

Isoray, Inc.

(Exact Name of Registrant as Specified in Charter)

| | | |
|---|-----------------------------|--------------------------------------|
| <u>Delaware</u> | <u>001-33407</u> | <u>41-1458152</u> |
| (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, including area code)

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:

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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)

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.

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 |

Item 1.01 Entry into a Material Definitive Agreement.

On April 26, 2019, IsoRay Medical, Inc. (“Medical”), a wholly owned subsidiary of Isoray, Inc., entered into an Amended and Restated Manufacturing and Supply Agreement (the “Agreement”) with GT Medical Technologies, Inc., a Delaware corporation (“GT Tech”). The Agreement amends and replaces in its entirety the Manufacturing and Supply Agreement dated January 3, 2018, as amended on December 28, 2018 (the “Prior Agreement”).

Pursuant to the Agreement, Medical manufactures and supplies a brachytherapy product that incorporates Cesium-131 seeds within customizable carriers for the treatment of brain tumors (the “GammaTile™ Product”) for end users designated by GT Tech. Additionally, Medical supplies 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, Cesium-131 seeds, and additional services are set forth on Exhibit B of the Agreement. The Agreement has a 10-year term, which extends the term of the Prior Agreement by approximately 16 months.

Also under the Agreement, GT Tech must provide, on a monthly basis, 12-month rolling forecasts setting forth the quantity of GammaTile™ Product it expects to purchase. This forecast establishes a binding purchase order for the first calendar month and a non-binding forecast for the remaining eleven calendar months. Unlike the Prior Agreement, the Agreement provides GT Tech the ability to move the loading of the GammaTile™ Product to another, non-Medical facility upon 6 months’ notice, provided GT Tech continues to purchase Cesium-131 exclusively from Medical.

The Agreement also governs GammaTile™ Product process improvement projects for which GT Tech may request Medical’s assistance, including how process improvement projects will be scoped and billed.

The foregoing summary of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement. A copy of the Agreement is attached hereto as Exhibit 10.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

- 10.1 Amended and Restated Manufacturing and Supply Agreement, dated April 26, 2019, between IsoRay Medical, Inc. and GT Medical Technologies, Inc. (confidential treatment requested for redacted portions).
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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 hereunto duly authorized.

Dated: May 2, 2019

Isoray, Inc., a Delaware corporation

By: /s/ Lori A. Woods

Lori A. Woods, CEO