IsoRay, Inc.
Form S-1/A
December 10, 2018

Table of Contents

**As filed with the Securities and Exchange Commission on December 10, 2018**

**Registration No. 333-227909**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Amendment No.1**

**to**

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE**

**SECURITIES ACT OF 1933**

**ISORAY,
INC.**

(Exact
name of
registrant
as
specified
in its
charter)

| | | |
|---|---|---|
| **Minnesota** | **3841** | **41-1458152** |
| (State or other jurisdiction | (Primary Standard Industrial | (IRS Employer |

| of incorporation or organization) | Classification Code Number) | Identification No.) |
|---|---|---|

**350 Hills Street, Suite 106**

**Richland, Washington 99354**

**(509) 375-1202**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Stephen R. Boatwright**
**Gallagher & Kennedy, P.A.**
**2575 E. Camelback Road**
**Phoenix, Arizona 85016**
**(602) 530-8000**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement but in no event sooner than January 11, 2019.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 | Accelerated filer |
| Non-accelerated filer | Smaller reporting company |
| | 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.

Table of Contents

**CALCULATION OF REGISTRATION FEE**

| Title of each class of securities to be registered | Amount to be registered | Proposed maximum offering price per unit | Proposed maximum aggregate offering price | Amount of registration fee |
|---|---|---|---|---|
| Common Stock, $0.001 par value, issuable upon exercise of warrants to purchase Common Stock[1] | 5,830,000 | $0.48[2] | $2,798,400 | $339.17[3] |

[1] The shares registered are offered for resale by the selling stockholders named in the prospectus.

[2] Estimated for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, and based on the average of the high and the low prices of the Common Stock on October 15, 2018 as reported by the NYSE American stock exchange.

[3] Previously paid.

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of l933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

Table of Contents

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**PROSPECTUS**

**IsoRay, Inc.**

**5,830,000 Shares of Common Stock**

This prospectus relates to the sale or other disposition from time to time of up to 5,830,000 shares of our common stock underlying warrants to purchase shares of our common stock by the persons (the "selling stockholders") identified in the section entitled "Selling Stockholders" in this prospectus, or their transferees. This registration does not mean that the selling stockholders will actually offer or sell any of these shares.

We will not receive any proceeds from the sale or other disposition of the shares of common stock offered by the selling stockholders. However, we may receive up to $4,434,375 in gross proceeds, solely to the extent the warrants are exercised for cash. We will pay for the expenses of this offering which are estimated to be $15,000.

Our common stock is listed on the NYSE American stock exchange under the symbol "ISR." On December 7, 2018, the last reported sale price of our common stock on the NYSE American stock exchange was $0.42 per share.

**Investing in our securities involves a high degree of risk. Before buying any securities, you should read the discussion of material risks of investing in our securities referred to under the heading "Risk Factors" beginning on page 24 of our annual report on Form 10-K for the fiscal year ended June 30, 2018, and on page 17 of our quarterly report on Form 10-Q for the quarterly period ended September 30, 2018, which are incorporated by reference.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Subject to Completion, dated December 10, 2018.

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Table of Contents

**TABLE OF CONTENTS**


| | |
|---|---|
| **ABOUT THIS PROSPECTUS** | **1** |
| **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS** | **1** |
| **INDUSTRY AND MARKET DATA** | **2** |
| **TRADEMARKS** | **2** |
| **PROSPECTUS SUMMARY** | **2** |
| **PRIOR REGISTERED OFFERING AND PRIVATE PLACEMENT** | **6** |
| **THE OFFERING** | **7** |
| **RISK FACTORS** | **7** |
| **USE OF PROCEEDS** | **8** |
| **LEGAL MATTERS** | **8** |
| **EXPERTS** | **8** |
| **SELLING STOCKHOLDERS** | **8** |
| **PLAN OF DISTRIBUTION** | **9** |
| **INCORPORATION BY REFERENCE** | **10** |
| **WHERE YOU CAN FIND MORE INFORMATION** | **11** |
| **COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES** | **11** |
| **INFORMATION NOT REQUIRED IN PROSPECTUS** | **12** |
| **SIGNATURES** | **18** |

Table of Contents

## ABOUT THIS PROSPECTUS

As permitted under the rules of the Securities and Exchange Commission (the "SEC") this prospectus incorporates important business information about us that is contained in documents that we file with the SEC, but that are not included in or delivered with this prospectus. You may obtain copies of these documents, without charge, from the website maintained by the SEC at *www.sec.gov,* as well as other sources.

**You should rely only on the information contained in or incorporated by reference into this prospectus. We have not authorized anyone to provide you with information that is different. This prospectus is not an offer to sell or solicitation of an offer to buy these securities in any circumstances under which the offer or solicitation is unlawful. You should not assume that the information we have included in this prospectus is accurate as of any date other than the date of this prospectus or that any information we have incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or of any of our securities. It is important for you to read and consider all information contained in this prospectus, including the documents incorporated by reference herein, in making your investment decision. You should also read and consider the information in the documents we have referred you to in "Incorporation of Certain Documents by Reference" and "Where You Can Find More Information" in this prospectus.**

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

All statements contained in this prospectus and the documents incorporated by reference herein, other than statements of historical facts, that address future activities, events, or developments are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements often contain the words "may," "will," "believe," "expect," "anticipate," "intends," "estimate," "forecast," "project," and similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including statements relating but not limited to:

- projections of earnings, revenues or other financial items;
- plans and objectives of management for future operations;
- proposed new products or services;

future operations, plans, regulatory filings or approvals;

any statements regarding pending or future mergers or acquisitions; and

future economic conditions or performance, and any statement 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 that may cause actual results to differ materially.

You should not place undue reliance on our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties, and other unpredictable factors, many of which are beyond our control. Our forward-looking statements are based on the information currently available to us and speak only as of the date of this prospectus or, in the case of forward-looking statements incorporated by reference, as of the date of the filing that includes the statement. New risks and uncertainties arise from time to time, and it is impossible for us to predict these matters or how they may affect us. Over time, our actual results, performance or achievements will likely differ from the anticipated results, performance or achievements that are expressed or implied by our forward-looking statements, and such difference might be significant and materially adverse to our security holders. We do not undertake and specifically decline any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

Table of Contents

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in our most recent Annual Report on Form 10-K and quarterly report on Form 10-Q, which are incorporated by reference, including without limitation under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in other documents that we may file with the SEC, all of which you should review carefully. Please consider our forward-looking statements in light of those risks as you read this prospectus.

**INDUSTRY AND MARKET DATA**

This prospectus contains and incorporates by reference market data, industry statistics, and other data that have been obtained from, or compiled from, information made available by third parties. Although we believe these third-party sources are reliable, we have not independently verified the information. Except as may otherwise be noted, none of the sources cited in this prospectus has consented to the inclusion of any data from its reports, nor have we sought their consent. In addition, some data are based on our good faith estimates. Such estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as our own management’s experience in the industry, and are based on assumptions made by us based on such data and our knowledge of such industry and markets, which we believe to be reasonable. However, none of our estimates have been verified by any independent source. See “Special Note Regarding Forward-Looking Statements” above.

**TRADEMARKS**

The IsoRay logo, and IsoRay are our registered trademarks. These trademarks are important to our business. Although we may have omitted the “®” or “TM” trademark designation for such trademarks in this prospectus, all rights to such trademarks are nevertheless reserved. Unless otherwise noted, other trademarks used in this prospectus are the property of their respective holders.

**Prospectus Summary**

*This summary highlights selected information appearing elsewhere or incorporated by reference in this prospectus and may not contain all of the information that is important to you. This prospectus includes or incorporate by reference information about our common stock as well as information regarding our business and detailed financial data. After you read this summary, you should read this prospectus in its entirety, including the information incorporated by reference in this prospectus, especially the section entitled “Risk Factors.” If you invest in our securities, you are assuming a high degree of risk.*

*Unless the context requires otherwise, in this prospectus the terms "IsoRay," the "Company," "we," "us," "our," and similar terms refer to IsoRay, Inc. and its operating subsidiary IsoRay Medical, Inc., and, to the extent applicable, its non-operating subsidiary, IsoRay International LLC.*

**Business Overview**

In 2003, IsoRay obtained clearance from the Food and Drug Administration (FDA) for the use of Cesium-131 (Cesium-131) radioisotope in the treatment of all malignant tumors. As of the date of this Report, such applications include prostate cancer, brain cancer, breast cancer, colorectal cancer, gynecological cancer, lung cancer, liver cancer, ocular melanoma and pancreatic cancer. The brachytherapy seed form (a sealed source) of Cesium-131 may be used in surface, interstitial and intra-cavity applications for tumors with known radio-sensitivity. Management believes the combination of a short half-life and relatively high-energy of Cesium-131 will allow it to become a leader in the brachytherapy market, and Cesium-131 represents the first major advancement in brachytherapy technology in approximately 30 years with attributes that could make it the long-term "seed of choice" for internal radiation therapy procedures.

The Company's core product is its Cesium-131 sealed source brachytherapy "seed." These seeds can be inserted individually or in combination into various locations in the body until the physician is satisfied with the radiation dose delivered. The Company also sells seeds in strands to keep them from individually moving and to allow the physician to put multiple seeds in a row as desired. In addition, "pre-loaded" needles may have Cesium-131 brachytherapy seeds inserted in them, or a strand with seeds in the strand, inserted into the needle. Seeds can also be loaded into suture material, which can be sewn by IsoRay into a piece of bio-absorbable mesh which can be sewn or stapled into tissue by the physician for use in lung, pelvic floor and other cancer locations.

Table of Contents

Brachytherapy seeds are small devices containing a therapeutic dose of radiation used in an interstitial radiation procedure. The procedure has become one of the primary treatments for prostate cancer. The brachytherapy procedure places radioactive seeds as close as possible to (in or near) the cancerous tumor (the word “brachytherapy” is derived from Greek and means close therapy). A primary advantage of seed brachytherapy is the ability of the seeds to deliver therapeutic radiation thereby killing the cancerous tumor cells while minimizing exposure (damage) to adjacent healthy tissue. This procedure allows doctors to administer a higher dose of radiation directly to the tumor. A seed contains a radioisotope sealed within a titanium capsule. The number of seeds used varies based on the size of the cancerous area being treated, the isotope used and the activity level specified by the physician. When brachytherapy is combined with another treatment method (dual-therapy), fewer seeds are used in the procedure. The isotope decays over time (half-life) and eventually the seeds become inert (typically over 6 half-lives). The seeds may be used as a primary treatment (monotherapy) or as an adjunct therapy with other treatment modalities, or as treatment for residual disease after excision of primary tumors. The number of seeds for treatment sites vary widely (as few as 8 seeds to more than 100 seeds) depending on the type of cancer, the tumor location, the prescribed activity level and any additional type of therapy being utilized.

In the cases of lung and brain tumors (and other solid tumors), a surgeon will remove the tumor if it is medically prudent and this offers the patient some benefit in terms of controlling the growth of the cancer or its symptoms. In many cases, radiation therapy is added following the surgery; this is known as “adjuvant” radiation therapy. The Company believes that its form of adjuvant radiation therapy deployable in such cases offers advantages over external beam methods. However, external beam holds the vast majority of the market for adjuvant radiation therapy.

The FDA clearance granted in August 2009 to permit loading Cesium-131 seeds into bio-absorbable braided sutures or “braided strands” gives the Company the ability to treat brain, lung, head and neck, colorectal, and chest wall cancers. The Company has also received CE Mark clearance to commercially deliver Cesium-131 brachytherapy seeds that are pre-loaded into braided strands in Europe. This clearance permits the product to be commercially distributed in Europe for treatment of prostate, brain, lung, and head and neck tumors as well as tumors in other organs.

*Prostate Cancer*

IsoRay began the production and sales of Cesium-131 brachytherapy seeds in October 2004 for the treatment of prostate cancer after receiving clearance of its premarket notification (510(k)) by the Food and Drug Administration. Prostate cancer treatment represents over 85% of the business of IsoRay today.

When brachytherapy is the only treatment (monotherapy) used in the prostate, approximately 70 to 120 seeds are permanently implanted in the prostate during an outpatient procedure. Typically, physicians use loose seeds in needles or in a cartridge or seeds loaded into strands which can also be loaded into needles from the treatment of prostate cancer. Seeds may be combined with another treatment method (dual therapy) when treating prostate cancer.

In late 2017, the first report with long-term follow-up clinical outcomes for patients treated with Cesium-131 brachytherapy for low-risk patients was presented at the annual meeting of the American Society for Therapeutic Radiation Oncology. Moran, B. J. and M. H. Braccioforte (2017). *Long-term PSA outcomes in a single institution, prospective randomized 131-Cs/125-I permanent prostate brachytherapy trial.* Int J Radiat Oncol Biol Phys **99**(2 (Suppl)): E255. In this randomized study of 140 patients no statistically significant difference in biochemical failure was seen with long-term follow-up between the Cesium-131 group and the group implanted with I-125.

In addition to the long-term cancer control data mentioned above, a report from 2017 describes favorable long-term quality of life outcomes following Cesium-131 brachytherapy in the treatment of prostate cancer (S.M. Glaser, et al., *Long-Term Quality of Life in Prostate Cancer Patients Treated With Cesium-131,* Int J Radiat Oncol Biol Phys. 98(5):1053-1058 (2017)).

The Company continues to identify and support work that seeks to employ and study Cesium-131 brachytherapy seeds in combination with external beam radiation therapy ("EBRT"). Compelling evidence is emerging supporting the use of such combination brachytherapy and EBRT in intermediate and high-risk prostate cancer cases. (Kwok, Y., et al. (2018). *Recent advances in radiation oncology: multimodal targeting of high risk and recurrent prostate cancer.* Curr Opin Oncol **30**(3): 165-171).

Table of Contents

For low-risk prostate cancer, studies are ongoing to evaluate the use of Cesium-131 in "focal," or sub-total brachytherapy of the prostate. It is hypothesized that low-risk patients using focal brachytherapy may achieve rates of prostate cancer control comparable to that of full gland treatment while significantly reducing side effects. (M.H. Mendez, et al., *Current trends and new frontiers in focal therapy for localized prostate cancer,* Current Urology Report 16, 35 (June 2015)).

Early results from a series of men treated with Cesium-131 focal therapy were presented at the 2018 Annual Meeting of the American Brachytherapy Society, Kalash, R., et al., (2018), *Focal brachytherapy using Cesium-131 in low-risk prostate cancer.* Brachytherapy 17 (Suppl):S89. The authors conclude that, while too early to estimate disease specific outcomes, serum PSAs in these men have declined in the short term and there was no residual effect on urinary, bowel or erectile symptoms.

*Gynecologic Cancer*

Individual seeds can also be placed via needle into the female reproductive tract for the treatment of various gynecologic cancers. This effort has been led by Dr. Jonathan Feddock, formerly of the University of Kentucky, and currently of Baptist Health Lexington. In June 2016, Dr. Feddock conducted two presentations on gynecological cancer patients who underwent treatment with permanent implantation of Cesium-131 brachytherapy seeds. In the first presentation, it was noted that 21 out of 26 recurrent cancer patients remained visually free of cancer at a median of 14 months after implantation which equates to 80.7% local control (J. Feddock, et al., *Permanent interstitial re-irradiation with cesium-131: a highly successful second chance for cure in recurrent pelvic malignancies,* Brachytherapy 15 (S1)S78-9 (2016)). In the second presentation, a series of 22 women with pelvic cancer underwent Cesium-131 brachytherapy seed implantation with other forms of radiation therapy treating patients who were recently diagnosed and had not yet undergone any treatment. All these cancers were successfully controlled at a median follow-up of 16 months. Side effects using the Cesium-131 brachytherapy seeds were minor and all treatments were performed as outpatient procedures. (J. Feddock, et al., *Outpatient interstitial implants - integrating cesium-131 permanent interstitial brachytherapy into definitive treatment for gynecologic malignancies,* Brachytherapy 15 (S1):S93-4 (2016)). Dr. Feddock and his team are continuing ongoing research.

*Brain and Head and Neck Cancer*

Starting in 2012, multiple institutions began utilizing Cesium-131 brachytherapy seeds loaded in braided strands for treatment of brain and head and neck cancers. The application of Cesium-131 brachytherapy seeds loaded in braided strands to date has been primarily in salvage cases as a treatment of last resort for brain and head cancers where aggressive tumors had reoccurred multiple times following standard of care treatment. From 2014 to 2016 there have been numerous published abstracts and society presentations which have been presented and support the effectiveness of treating very difficult and aggressive cancers with Cesium-131 in multiple body sites. Dr. Gabriella Wernicke's group, at Weill Cornell Medical College at the NY Presbyterian Hospital, published four papers on the efficacy,

favorable side-effect profile and cost-effectiveness of Cesium-131 brachytherapy seeds in the treatment of metastatic brain cancer. (A. Pham, et al., *Neurocognitive function and quality of life in patients with newly diagnosed brain metastasis after treatment with intra-operative cesium-131 brachytherapy: a prospective trial*, J Neurooncol 127(1):63-71 (2016); A.G. Wernicke, et al., *Surgical technique and clinically relevant resection cavity dynamics following implantation of cesium-131 brachytherapy in patients with brain metastases,* Operative Neurosurgery 12(1):49-60 (2016); A.G. Wernicke, et al., *Cesium-131 brachytherapy for recurrent brain metastases: durable salvage treatment for previously irradiated metastatic disease,* J Neurosurg DOI: 10.3171/2016.3.JNS152836 (Published online June 3, 2016); A.G. Wernicke, et al., *The cost-effectiveness of surgical resection and cesium-131 intraoperative brachytherapy versus surgical resection and stereotactic radiosurgery in the treatment of metastatic brain tumors,* J Neurooncol 127(1):145-53 (2016)). At the same institution, Dr. Bhupesh Parashar has published two journal articles on the effectiveness of Cesium-131 brachytherapy seeds in the treatment of both head and neck and lung cancer. (B. Parashar, et al., *Analysis of stereotactic radiation vs. wedge resection vs. wedge resection plus Cesium-131 brachytherapy in early stage lung cancer*, Brachytherapy 14(5):648-54 (2015); A. Pham, et al., *Cesium-131 brachytherapy in high risk and recurrent head and neck cancers: first report of long-term outcomes*, J Contemp Brachytherapy 7(6):445-52 (2015).) In 2017, Dr. Wernicke's group published favorable results on a series of patients with large brain metastases treated with Cesium-131 in braided strands. A. G. Wernicke, et al., *Clinical Outcomes of Large Brain Metastases Treated With Neurosurgical Resection and Intraoperative Cesium-131 Brachytherapy: Results of a Prospective Trial,* Int J Radiat Oncol Biol Phys. 98 (5):1059-1068 (2017)).

Table of Contents

During fiscal 2013, the Company began providing technical assistance and selling Cesium-131 brachytherapy seeds for embedding in collagen tiles by physicians at Barrow Neurological Institute (Barrow) to treat malignant meningioma, primary brain cancers and metastases of cancers to the brain. From this a company was formed, GammaTile LLC, now GT Medical Technologies, Inc. ("GT Med Tech"), and further refined this technology which integrates Cesium-131 brachytherapy seeds and has resulted in the issuance of multiple patents to GT Med Tech for the treatment of brain cancers. In December 2014 and June 2016, physicians representing Barrow presented their findings at two society conferences for neuro-oncologists. Highlights of the presentation included a new treatment delivery system of Cesium-131 brachytherapy seeds to the brain while embedded in collagen tiles by applying directly to brain tissue after tumor removal. The trial presented included 16 patients with 20 tumors. The patients in the study had multiple reoccurrences of tumors following previous surgeries in conjunction with treatments with external beam radiation and had an increased risk for additional reoccurrences. Following treatment with Cesium-131, 95% of the treated tumors had no evidence of regrowth at the operative site (local control). The incidence of radiation side effects to the brain from Cesium-131 brachytherapy seeds (a common side effect) occurred in only 2 of the 20 treatments. (D. Brachman, *Prospective trial of surgery and permanent intraoperative brachytherapy (S+BT) using a modular, biocompatible radiation implant for recurrent aggressive meningiomas*, Society of Neuro-Oncology Conference on Meningioma, Toronto, Canada (June 18, 2016)).

In November of 2016, Dr. Emad Youssef of the Barrow Neurological Institute presented a study conducted on 13 patients with recurrent high grade gliomas (primary brain cancer) at the annual meeting of the Society for Neuro-Oncology meeting. (E. Youssef, et al; *Rthp-23. Cs131 Implants For Salvage Therapy Of Recurrent High Grade Gliomas (Hgg)*, Neuro-Oncology Volume 18, Issue suppl_6, 1 November 2016, Pages vi179). These patients were reported to have achieved a 92% rate of local control of their cancers during the follow-up interval. Due to the fact that the GammaTile™ treatment has displayed promising results in difficult to control recurrent brain cancers, the Company has collaborated with GT Med Tech, in filing applications to: the U.S. Food and Drug Administration (FDA) to clear GammaTile™ for clinical use; and a New Technology Add-on Payment to the Center for Medicare and Medicaid Services (CMS) seeking re-imbursement for the GammaTile™ treatment in the in-patient setting. The application with the FDA was cleared on July 6, 2018, however, the NTAP referenced herein is not currently under consideration. GT Med Tech re-filed the NTAP in October 2018 for the Federal Fiscal Year 2020, which begins October 1, 2019. In the meantime, CMS has allowed properly licensed medical centers to apply for re-imbursement under an existing Diagnostic Related Groups (DRG) code that allows partial recovery of the GammaTile™ treatment cost. The Company continues to work with GT Med Tech in preparation of a commercial launch of GammaTile™ by GT Med Tech, who is the sole commercial agent of the GammaTile™ Therapy.

**Our Corporate Information**

Our principal executive offices are located at 350 Hills Street, Suite 106, Richland, Washington 99354, and our telephone number is (509) 375-1202. We maintain a website at *www.isoray.com*. Information on or accessible through our website does not constitute part of this prospectus and should not be relied upon in connection with making any investment decision with respect to the securities offered by this prospectus.

Although our predecessor operating company was organized in 1998, IsoRay, Inc. was incorporated in 1983 in Minnesota and operated under the name Century Park Pictures Corporation until the merger with IsoRay Medical, Inc. on July 28, 2005.

On July 6, 2018, the Company received clearance for its 510(k) application required to commercialize the GammaTile™ system. The Company continues to work with GT Med Tech in preparation of a commercial launch of GammaTile™ by GT Med Tech, who is the sole commercial agent of the GammaTile™ Therapy.

Table of Contents

**PRIOR REGISTERED OFFERING AND PRIVATE PLACEMENT**

On July 9, 2018, the Company terminated the continuous offering pursuant to our Sales Agreement with H.C. Wainwright & Co., LLC to sell common stock at the market prices prevailing at the time of sale. As of July 6, 2018, the Company had raised gross proceeds of $487,353 through the sale of an aggregate of 980,918 shares of common stock, pursuant to an at the market transaction that began in early May, 2018.

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.

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 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").

The aggregate number of shares of our common stock issuable upon the exercise of the Warrants is 5,830,000 shares. The offer and sale of the Warrants was made without registration in reliance on the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506 promulgated thereunder. We will receive gross proceeds from this offering solely to the extent any Warrants are exercised for cash.

This prospectus relates to the sale or other disposition by the selling stockholders of the shares of common stock underlying the Warrants.

Table of Contents

**THE OFFERING**

*The following is a brief summary of some of the terms of the offering and is qualified in its entirety by reference to the more detailed information appearing elsewhere in this prospectus and the documents incorporated by reference.*

| | |
|---|---|
| Common stock offered for sale by the selling stockholders: | 5,830,000 shares of common stock, par value $0.001 per share. |
| Common stock outstanding before this offering | 67,331,147 shares. |
| Common stock to be outstanding after this offering | 67,331,147 shares assuming no other shares of common stock are issued.[1] |
| Use of proceeds | We will not receive any proceeds from the sale or other disposition of the 5,830,000 shares of common stock offered by the selling stockholders under this prospectus. However, we may receive up to $4,434,375 in gross proceeds solely to the extent the Warrants held by the selling stockholders are exercised for cash. |
| Risk Factors | Our business is subject to substantial risk. See “Risk Factors” and other information included or incorporated by reference in this prospectus for a discussion of certain factors that you should carefully consider before investing in our common stock. |
| NYSE American Symbol | ISR |

[1] The number of shares of our common stock to be outstanding immediately after this offering is based on 67,331,147 shares of our common stock outstanding as of December 5, 2018, and excludes as of such date:

- 250,000 shares of common stock issuable upon the exercise of warrants with a weighted average exercise price of $0.54;
- 59,065 shares of common stock issuable upon the conversion of preferred stock;
- 3,916,590 shares of common stock issuable upon the exercise of options with a weighted average exercise price of $0.68; and
- 5,830,000 shares of common stock issuable upon the exercise of the Warrants.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, does not assume or give effect to the exercise of options or warrants outstanding as of December 5, 2018.

**RISK FACTORS**

Investing in shares of our Common Stock involves a high degree of risk. You should carefully consider the risks described under “Risk Factors” in any applicable prospectus supplement and in our annual report on Form 10-K for the fiscal year ended June 30, 2018, or any updates in our quarterly reports on Form 10-Q, which are incorporated by reference, together with all of the other information appearing in or incorporated by reference into this prospectus and any applicable prospectus supplement, before deciding whether to purchase any of the common stock being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. You should be able to bear a complete loss of your investment.

Table of Contents

## USE OF PROCEEDS

We will not receive any proceeds from the sale or other disposition of the 5,830,000 shares of common stock offered by the selling stockholders under this prospectus. However, we may receive up to $4,434,375 in gross proceeds solely to the extent the Warrants held by the selling stockholders are exercised for cash.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby has been passed upon for us by Gallagher & Kennedy, P.A., Phoenix, Arizona.

## EXPERTS

The consolidated financial statements of IsoRay and its subsidiaries included in our Annual Report on Form 10-K for the year ended as of June 30, 2018 and our Quarterly Report on Form 10-Q for the quarter ended as of September 30, 2018 have been incorporated by reference herein in reliance on the report of DeCoria, Maichel & Teague, P.S., an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## SELLING STOCKHOLDERS

The common stock being offered by the selling stockholders consists of 5,830,000 shares of common stock underlying the Warrants. For additional information regarding the issuance of the Warrants, see “Prior Registered Offering and Private Placement” above. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of selling stockholder. The second column lists the number of shares of common stock beneficially owned by each selling stockholder, based on its ownership of the shares of common stock and warrants as of December 4, 2018. The third column lists the total number of shares of common stock being offered by this prospectus by the selling stockholder. The fourth and fifth columns assume the sale of all of the shares offered by the selling stockholders pursuant to this prospectus.

Under the terms of the Warrants, a selling stockholder may not exercise the warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% of our then outstanding common stock following such exercise (or 9.99% in the case of Hudson Bay Master Fund Ltd.), provided that the selling stockholder may, upon notice to the Company, increase or decrease this beneficial ownership limitation up to 9.99% of our then outstanding common stock following exercise. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

| **Name of selling stockholder** | **Number of shares of common stock owned prior to offering** | **Maximum number of shares of common stock to be sold pursuant to this prospectus** | **Number of shares of common stock owned after offering** | **Percent of shares of common stock owned after offering** |
|---|---|---|---|---|
| Anson Investments Master Fund LP[1] | 1,375,000[3] | 1,375,000[3] | - | - |
| Armistice Capital Master Fund, Ltd. [1] | 1,375,000[3] | 1,375,000[3] | - | - |
| Hudson Bay Master Fund Ltd. [1] | 1,375,000[3] | 1,375,000[3] | - | - |
| Sabby Volatility Warrant Master Fund, Ltd. [1] | 3,505,268[4] | 1,375,000[3] | 2,130,268 | 3.16% |
| Michael Vasinkevich[2] | 229,350[3] | 229,350[3] | - | - |
| Noam Rubinstein[2] | 57,750[3] | 57,750[3] | - | - |
| Mark Viklund[2] | 26,400[3] | 26,400[3] | - | - |
| Charles Worthman[2] | 16,500[3] | 16,500[3] | - | - |

[1] Investor Warrant holder. Except for the ownership of shares of common stock or warrants, the selling stockholder has not had any material relationship with us within the past three years.

[2] Placement Agent Warrant holder, issued to person affiliated with Wainwright as part of its compensation for acting as placement agent for the registered direct offering.

[3] Represents shares issuable upon exercise of the Warrants to purchase Common Stock.

(4) Represents 1,375,000 shares issuable upon exercise of the Warrants to purchase Common Stock and 2,130,268 shares of Common Stock.

Table of Contents

The controlling persons of the non-individual selling stockholders are:

| Name of selling stockholder | Controlling Person(s) |
|---|---|
| Anson Investments Master Fund LP | Bruce Winson, Moez Kassam, Amin Nathoo |
| Armistice Capital Master Fund, Ltd. | Steven Boyd |
| Hudson Bay Master Fund, Ltd. | Sander Gerber[1] |
| Sabby Volatility Warrant Master Fund, Ltd. | Hal Mintz |

[1] Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.

To our knowledge:

- the holders of Investor Warrants are not affiliated with a securities broker; and
- the holders of Placement Agent Warrants are affiliated with Wainwright, a securities broker.

**PLAN OF DISTRIBUTION**

Each selling stockholder of the securities and any of their pledgees, assignees, and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the principal Trading Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;

- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Table of Contents

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each Selling Stockholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

**INCORPORATION BY REFERENCE**

This prospectus is part of a registration statement filed with the SEC. The SEC allows us to "incorporate by reference" into this prospectus the information that we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. We incorporate by reference the documents listed below, as well as any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act from the date of the initial registration statement and prior to the effectiveness of this registration statement, and any filings made after the date of this prospectus and prior to the termination of this offering. The information that we file later with the SEC will automatically update and supersede this information. The following documents were filed with the SEC pursuant to the Exchange Act and are incorporated by reference and made a part of this prospectus:

- our Annual Report on Form 10-K for the fiscal year ended June 30, 2018, filed on September 26, 2018 (File No. 001-333407);
- our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, filed on November 9, 2018 (File No. 001-333407);
- our Periodic Reports on Form 8-K filed on October 12, 2018, November 8, 2018, and December 3, 2018 (File No. 001-333407);
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on April 12, 2007 (File No. 001-333407), including any amendments or reports filed for the purpose of updating such description;
- the description of our rights contained in our Registration Statement on Form 8-A filed on February 7, 2007 (File No. 001-14247), including any amendments or reports filed for the purpose of updating such description; and
- all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act (i) after the date on which this registration statement that includes this prospectus was initially filed with the SEC and prior to the effectiveness of such registration statement, and (ii) after the date of this prospectus and prior to the termination of this offering, unless otherwise stated therein.

Notwithstanding the foregoing, information furnished under Items 2.02 and 7.01 of any Current Report on Form 8-K, including the related exhibits, is not incorporated by reference in this prospectus.

Any statement contained herein or made in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein, or in any other subsequently filed document which also is incorporated or deemed to be incorporated by reference herein, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon oral or written request, a copy of any or all of the foregoing documents incorporated herein by reference (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into the information that this prospectus incorporates). Written or telephone requests should be directed to: IsoRay, Inc., 350 Hills Street, Suite 106, Richland, Washington 99354, telephone number (509) 375-1202, Attn: Corporate Secretary. A copy of any or all of the documents which we incorporate by reference in this prospectus may be accessed on our corporate website at *http://www.isoray.com*.

You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized anyone else to provide you with different or additional information. We will not make an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date of this document.

Table of Contents

**Where You Can Find More Information**

We file annual, quarterly and special reports, and other information with the SEC (Commission File Number 001-33407). You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Our SEC filings are also available on the SEC website at *www.sec.gov*, which contains reports, proxy and information statements, and other information regarding issuers that file electronically.

**COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

The Company's Articles of Incorporation provide to directors and officers indemnification to the full extent provided by law, and provide that, to the extent permitted by Minnesota law, a director will not be personally liable for monetary damages to the Company or its shareholders for breach of his or her fiduciary duty as a director, except for liability for certain actions that may not be limited under Minnesota law. On July 1, 2006, the Company entered into Indemnification Agreements with each of its directors and executive officers, and has entered into Indemnification Agreements with each officer and director who took office subsequent to July 1, 2006, and the Company intends to enter into substantially identical agreements with any officers and directors who take office in the future. The purpose of the Indemnification Agreements is to provide all officers and directors with indemnification to the fullest extent permitted under the Minnesota Business Corporations Act.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

Table of Contents

**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the estimated costs and expenses payable by us in connection with the offering of the securities being registered. All the amounts shown are estimates, except for the registration fee.

| | |
|---|---|
| SEC registration fee | $339 |
| Legal fees and expenses | $15,000 |
| Accounting fees and expenses | $5,000 |
| Miscellaneous | $500 |
| Total | $20,839 |

**Item 14. Indemnification of Directors and Officers.**

The Company's Articles of Incorporation provide to directors and officers indemnification to the full extent provided by law, and provide that, to the extent permitted by Minnesota law, a director will not be personally liable for monetary damages to the Company or its shareholders for breach of his or her fiduciary duty as a director, except for liability for certain actions that may not be limited under Minnesota law. The Company has entered into Indemnification Agreements with each of its directors and executive officers, and the Company intends to enter into substantially identical agreements with any officers and directors who take office in the future. The purpose of the Indemnification Agreements is to provide all officers and directors with indemnification to the fullest extent permitted under the Minnesota Business Corporations Act. The Registrant maintains a directors' and officers' insurance policy. The policy insures directors and other officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses the Registrant for those losses for which the Registrant has lawfully indemnified its directors and officers. The policy contains various exclusions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

**Item 15. Recent Sales of Unregistered Securities.**

On October 3, 2017, the Company issued warrants to purchase 250,000 shares of common stock to Al & J Media Inc. ("Al & J") in accordance with a Media Advertising Agreement entered into by Al & J and the Company, which vested immediately, entitling Al & J to purchase shares of Company common stock, exercisable on or before October 3, 2020, at an exercise price of $0.54 per share. The warrants were issued as partial consideration for Al & J's services under the Media Advertising Agreement, which was subsequently terminated by the Company. Al & J's services included introducing the Company to potential sources of media, marketing agreements, and/or strategic alliances. The warrants were issued in reliance on Section 4(a)(2) of the Securities Act. This exemption was available due to Al & J being a sophisticated party and the limited nature of the issuance.

On May 20, 2018, the Company issued warrants to purchase 250,000 shares of common stock to World Wide Holdings, LLC DBA Invictus Resources ("Invictus") in accordance with a Master Service Agreement entered into by Invictus and the Company, which vested immediately, entitling Invictus to purchase shares of Company common stock, exercisable on or before May 20, 2020, at an exercise price of $0.01 per share. The warrants were issued as partial consideration for Invictus' services under the Master Service Agreement. Invictus' services included advising and assisting the Company in developing and implementing plans and materials for presenting the Company and its business to the general public. This contract was terminated on July 9, 2018 but the warrants vested immediately. The warrants were exercised in June 2018. The warrants and underlying shares were issued in reliance on Section 4(a)(2) of the Securities Act. This exemption was available due to Invictus being a sophisticated party and the limited nature of the issuance.

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. 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, 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 Wainwright, the placement agent for the registered direct offering, as part of its compensation. The aggregate number of shares of our common stock issuable upon the exercise of the Warrants is 5,830,000 shares. The Warrants were offered and sold in reliance upon the exemption from registration provided by Section 4(a)(2) under the Securities Act. The Warrants contain representations to support the Company's reasonable belief that each of the recipients of such securities had access to information concerning the Company's operations and financial condition, that each such recipient is acquiring the securities for its own account and not with a view to the distribution thereof, and that each such recipient is an "accredited investor" as defined by Rule 501 promulgated under Securities Act.

Table of Contents

**Item 16. Exhibits and Financial Statement Schedules.**

**Exhibit Index**

(Except as otherwise indicated (a) all exhibits were previously filed, (b) all omitted exhibits are intentionally omitted, and (c) all Reports referenced below were filed under SEC file number 001-33407.)

| Exhibit Number | Description |
|---|---|
| 3.2 | Certificate of Designation of Rights, Preferences and Privileges of Series A and B Convertible Preferred Stock, filed with the Minnesota Secretary of State on June 29, 2005, incorporated by reference to Exhibit 3.1 of the Form 8-K filed on August 3, 2005 (File No. 000-14247). |
| 3.3 | Restated and Amended Articles of Incorporation, incorporated by reference to Exhibit 3.3 of the Form 10-KSB filed on October 11, 2005 (File No. 000-14247). |
| 3.4 | Certificate of Designation of Rights, Preferences and Privileges of Series C Junior Participating Preferred Stock, incorporated by reference to Exhibit 2 of the Company's Registration Statement on Form 8-A filed on February 7, 2007 (File No. 000-14247). |
| 3.5 | Amended and Restated By-Laws of the Company dated as of January 8, 2008, incorporated by reference to Exhibit 3.5 of the Form 8-K filed on January 14, 2008. |
| 3.6 | Certificate of Designation and Preferences, Rights and Limitations of Series D Convertible Preferred Stock dated August 29, 2013 of IsoRay, Inc., incorporated by reference to Exhibit 3.1 of the Form 8-K filed on August 29, 2013. |
| 4.16 | Amended and Restated 2006 Director Stock Option Plan, incorporated by reference to Exhibit 4.13 of the Form S-8/A1 filed on December 18, 2006 (Reg. No. 333-136728). |
| 4.19 | Rights Agreement, dated as of February 1, 2007, between the Computershare Trust Company N.A., as Rights Agent, incorporated by reference to Exhibit 1 of the Company's Registration Statement on Form 8-A filed on February 7, 2007 (File No. 000-14247). |
| 4.20 | Certificate of Designation of Rights, Preferences and Privileges of Series C Junior Participating Preferred Stock, incorporated by reference to Exhibit 1 to Exhibit 2 of the Company's Registration Statement on Form 8-A filed on February 7, 2007 (File No. 000-14247). |
| 4.26 | Form of Common Stock Purchase Warrant, incorporated by reference to Exhibit 4.26 of the Form 8-K filed on October 13, 2011. |
| 4.27 | Amendment, dated July 9, 2018, to the Share Rights Agreement, dated as of February 1, 2007, between IsoRay, Inc. and Computershare Trust Company, N.A., as Rights Agent, incorporated by reference to Exhibit 4.1 of the form 8-K filed on July 12, 2018. |
| 4.28 | Amendment and Termination of Rights Agreement, dated November 7, 2018, by and between IsoRay, Inc. and Computershare Trust Company, N.A., as Rights Agent, incorporated by reference to Exhibit 4.1 of the form 8-K filed on November 8, 2018. |
| 5.1* | Opinion of Gallagher & Kennedy, P.A. |
| 10.3 | Royalty Agreement of Invention and Patent Application, dated July 12, 1999 between Lane A. Bray and IsoRay LLC, incorporated by reference to Exhibit 10.3 of the Form SB-2 filed on November 10, 2005 (Reg. No. 333-129646). |

13

Table of Contents

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| 10.5 | Section 510(k) Clearance from the Food and Drug Administration to market Lawrence CSERION Model CS-1, dated March 28, 2003, incorporated by reference to Exhibit 10.5 of the Form SB-2 filed on November 10, 2005 (Reg. No. 333-129646). |
| 10.10 | Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source, dated September 17, 2004, incorporated by reference to Exhibit 10.10 of the Form SB-2/A2 filed on April 27, 2006 (Reg. No. 333-129646). |
| 10.18 | State of Washington Radioactive Materials License dated October 6, 2005, incorporated by reference to Exhibit 10.18 of the Form SB-2 filed on November 10, 2005 (Reg. No. 333-129646). |
| 10.35 | Form of Officer and Director Indemnification Agreement, incorporated by reference to Exhibit 10.35 of the Form SB-2 Post-Effective Amendment No. 2 filed on October 13, 2006 (Reg. No. 333-129646). |
| 10.85 | Contract, dated December 15, 2015 and effective as of December 7, 2015, by and between IsoRay Medical, Inc. and The Open Joint Stock Company ‹‹ Isotope ›› (confidential treatment granted for redacted portions), incorporated by reference to Exhibit 10.85 of the Form 8-K filed on December 21, 2015. |
| 10.93 | Employment Agreement by and between Michael Krachon and IsoRay, Inc. dated effective March 7, 2016, incorporated by references to Exhibit 10.93 of the Form 10-K filed on September 9, 2016. |
| 10.94 | Stipulation of Settlement, dated September 23, 2016, by and between IsoRay, Inc., Dwight Babcock, and the settlement class, incorporated by reference to Exhibit 10.1 of the Form 10-Q filed on November 9, 2016. |
| 10.95 | Addendum No. 1 to contract with The Open Joint Stock Company ‹‹ Isotope ››, dated December 22, 2016 and effective as of December 9, 2016, by and between IsoRay Medical, Inc. and The Open Joint Stock Company ‹‹ Isotope ›› (confidential treatment granted for redacted portions), incorporated by reference to Exhibit 10.1 of the Form 8-K filed on December 28, 2016. |
| 10.96 | Amendment to Share Rights Agreement by and between Computershare Trust Company, N.A. and IsoRay, Inc., incorporated by reference to Exhibit 4.1 of the Form 8-K filed on February 3, 2017. |
| 10.97 | Irradiation Services Agreement, dated November 29, 2016, between The Curators of the University of Missouri and IsoRay Medical, Inc. (confidential treatment requested for redacted portions), incorporated by reference to Exhibit 10. 1 of the Form 10-Q filed on February 9, 2017. |
| 10.98 | Contract Modification, entered into on November 15, 2016 with an effective date of November 1, 2016, to Contract No. X-40403 between Energy Northwest and IsoRay Medical, Inc., incorporated by reference to Exhibit 10.2 of the Form 10-Q filed on February 9, 2017. |
| 10.99 | Separation Agreement, dated February 28, 2017, between Brien Ragle and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on March 3, 2017. |
| 10.100 | IsoRay, Inc. 2017 Equity Incentive Plan (incorporated by reference to Appendix B to IsoRay, Inc.'s Definitive Proxy Statement on Schedule 14A, filed on May 17, 2017). |
| 10.101 | Rescission and Release Agreement, dated May 2, 2017, between IsoRay Medical, Inc., and the Port of Benton, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 8, 2017. |
| 10.102 | Separation Agreement, dated May 1, 2017, between Matthew Branson and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 23, 2017. |
| 10.103 | Form of IsoRay, Inc. Stock Option Agreement and Notice of Grant of Stock Option, by and between each grantee thereunder and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 30, 2017. |
| 10.104 | Employment Agreement, dated June 30, 2017, between Mark Austin and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on July 7, 2017. |
| 10.105 | Consignment Agreement, dated August 25, 2017, between IsoRay Medical, Inc. and MedikorPharma-Ural LLC, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on August 31, 2017. |

Table of Contents

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|---|---|
| 10.106 | Service Agreement, dated August 25, 2017, between IsoRay Medical, Inc. and MedikorPharma-Ural LLC, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on August 31, 2017. |
| 10.107 | Media Advertising Agreement, dated October 3, 2017, between IsoRay, Inc. and Al & J Media Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on October 10, 2017. |
| 10.108 | Warrant to Purchase Common Stock, dated October 3, 2017, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on October 10, 2017. |
| 10.109 | Addendum No. 2 to supply contract by and between IsoRay Medical, Inc. and The Open Joint Stock Company «Isotope» (confidential treatment requested for redacted portions), incorporated by reference to Exhibit 10.1 of the Form 8-K filed on October 27, 2017. |
| 10.110 | Manufacturing and Supply Agreement, dated January 3, 2018, between IsoRay Medical, Inc. and GT Medical Technologies, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on January 8, 2018. |
| 10.111 | Collaborative Development Agreement, dated effective as of March 13, 2017, between IsoRay Medical, Inc. and GammaTile, LLC, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on January 8, 2018. |
| 10.112 | Sales Agreement between IsoRay, Inc. and H.C. Wainwright & Co., LLC, dated May 8, 2018, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on May 8, 2018. |
| 10.113 | Master Service Agreement, dated May 20, 2018, between IsoRay, Inc. and World Wide Holdings, LLC dba Invictus Resources, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on May 21, 2018. |
| 10.114 | Warrant to Purchase Common Stock, dated May 20, 2018, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on May 21, 2018. |
| 10.115 | Employment Agreement, dated effective June 13, 2018, between Lori A. Woods and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 19, 2018. |
| 10.116 | IsoRay, Inc. Stock Option Agreement and Notice of Grant of Stock Option to Lori A. Woods, dated June 13, 2018, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on June 19, 2018. |
| 10.117 | Separation Agreement, dated June 25, 2018, between Thomas C. LaVoy and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on June 29, 2018. |
| 10.118 | Letter Agreement, dated July 9, 2018, between H.C. Wainwright & Co. LLC and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on July 11, 2018. |
| 10.119 | Form of Securities Purchase Agreement, dated July 9, 2018, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on July 11, 2018. |
| 10.120 | Form of Warrant, dated July 11, 2018, incorporated by reference to Exhibit 10.3 of the Form 8-K filed on July 11, 2018. |
| 10.121 | Services Agreement, dated August 15, 2018, between IsoRay Medical, Inc. and J. Squared Partners, Inc., DBA Global IR Group, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on September 25, 2018. |
| 10.122 | Services Agreement, dated August 13, 2018, between IsoRay Medical, Inc. and Schultz Public Relations, LLC, incorporated by reference to Exhibit 10.2 of the Form 8-K filed on September 25, 2018. |
| 10.123 | Form of Employment Agreement, incorporated by reference to Exhibit 10.1 of the Form 8-K filed on October 12, 2018. |
| 10.124 | Employment Agreement, dated effective December 3, 2018, between Jonathan Hunt and IsoRay, Inc., incorporated by reference to Exhibit 10.1 of the Form 8-K filed on December 3, 2018. |
| 21.1 | Subsidiaries of the Company, incorporated by reference to Exhibit 21.1 of the Form 10-K filed on September 26, 2018. |
| 23.1* | Consent of Gallagher & Kennedy, P.A. (included in Exhibit 5.1) |
| 23.2** | Consent of DeCoria, Maichel & Teague, P.S. |

*Previously filed.

**Filed herewith.

15

Table of Contents

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or

Table of Contents

(ii) If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

**(6)** That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Table of Contents

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Richland, State of Washington, on December 10, 2018.

IsoRay, Inc., a Minnesota corporation

By: /s/ Lori A. Woods

Lori A. Woods, Interim CEO

Pursuant to the requirements of the Securities Exchange of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ Lori A. Woods<br>Lori A. Woods | Interim CEO and Director | December 10, 2018 |
| /s/ Jonathan Hunt<br>Jonathan Hunt | Chief Financial Officer | December 10, 2018 |
| /s/ Mark J. Austin<br>Mark J. Austin | Controller, Principal Financial and Accounting Officer | December 10, 2018 |
| /s/ Michael McCormick<br>Michael McCormick | Chairman on the Board | December 10, 2018 |
| /s/ Alan Hoffmann<br>Alan Hoffmann | Director | December 10, 2018 |
| /s/ Philip Vitale<br>Philip Vitale | Director | December 10, 2018 |

18