# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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): October 17, 2018 (October 16, 2018)

# **MRI INTERVENTIONS, INC.**

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation) 001-34822 (Commission File Number) 58-2394628 (I.R.S. Employer Identification Number)

5 Musick

Irvine, Ca. 92618 (Address of principal executive offices, zip code)

(949) 900-6833

(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:

□ 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Company  $\Box$ 

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.  $\Box$ 

## Item 1.01. Entry into a Material Definitive Agreement.

On October 16, 2018, MRI Interventions, Inc. (the "Company") and Clinical Laserthermia Systems AB ("CLS") entered into a License and Collaboration Agreement (the "License Agreement") and a Distribution Agreement (the "Distribution Agreement").

Under the License Agreement, the Company and CLS have agreed to collaborate and share certain information and technology with one another to develop, evaluate, and commercialize products and technology integrating or incorporating laser treatment solutions based on immune stimulating interstitial laser thermotherapy (imILT®) methods, including laser applicators and CLS's TRANBERG® Thermal Therapy System (the "CLS System") or CLS's related intellectual property in the field of medical procedures, processes and therapies related to neuro applications, including intracranial and spine surgery (the "Field"). Under the terms of the License Agreement, the Company and CLS shall jointly own any new intellectual property developed as a result of the development and other collaboration activities conducted by the Company and CLS with respect to new products pursuant to the License Agreement. CLS has also agreed to grant the Company an exclusive right to sell, offer for sale, market, and distribute the CLS System and new products developed under this License Agreement in the Field.

Under the Distribution Agreement, CLS appoints Company during the term of the Distribution Agreement as the exclusive distributor in the United States and Canada for products developed by CLS related to minimally invasive methods for cancer treatment (the "Products"), excluding indications within the neuro (brain and spine) field. CLS grants Company an exclusive (as between Company and any third parties) license to use CLS's trademarks in the United States and Canada for marketing purposes for the Products.

The foregoing description of the terms and conditions of the License Agreement and the Distribution Agreement is only a summary and is qualified in its entirety by the full text of such agreements, copies of which will be filed with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and which are incorporated into this Item 1.01 by reference.

#### Item 7.01. Regulation FD Disclosure.

On October 17, 2018, the Company issued a press release announcing entry into the License Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information, including the press release, furnished under this Item 7.01 shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any other filing by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

<u>99.1</u>

Press Release dated October 17, 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: October 17, 2018

### MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz Harold A. Hurwitz Chief Financial Officer

# MRI Interventions and Clinical Laserthermia Systems (CLS) Announce Collaboration to Develop Next-Generation Navigation and Laser Ablation Platforms for Neurosurgery — UPDATE

# Under the terms of the agreement, MRIC acquires worldwide exclusive rights to the platform for use in Neurosurgery and Spine with CLS as manufacturer

Irvine, CA and Lund, Sweden – October 17, 2018 – MRI Interventions, Inc. (OTCQB:MRIC) and Clinical Laserthermia Systems AB (NASDAQ FIRST NORTH:CLS B), today entered into a collaborative license and co-development agreement to provide next-generation navigation and laser ablation platforms for use in Spine and Neurosurgery. Under the terms of the agreement, CLS will provide an exclusive, worldwide license to current and future products and IP to MRI Interventions and will act as the exclusive manufacturer of those products. CLS will retain the rights for all fields outside of Neuro and Spine.

"This agreement is a truly exciting step towards execution of our four-pillar growth strategy," commented Joe Burnett, President and CEO of MRI Interventions. "Historically we have been the company that helps deliver other company's therapeutic products to deep structures of the brain in the most precise manner possible. Now we have the opportunity to deliver our own therapies, which will improve efficiency, workflow and procedure times for our hospital customers, and expand revenue and per-procedure profitability for our investors. Now in partnership with CLS, we can truly be a leader in the movement toward minimally-invasive neurosurgery because we can offer both navigation and laser ablation therapy, all under the watchful eye of a single clinical specialist to help support the procedure."

"We are delighted to find a partner to bring our advanced laser ablation platform to the neurosurgery space," added Lars-Erik Eriksson, President and CEO of CLS. "The neurosurgery market is an incredibly challenging market to enter and build from the ground up. We are thrilled to be able to find a partner in MRI that already has years of experience in the space, a large and growing installed base at some of the most prestigious neurosurgery centers in the U.S., and a team of clinical specialists already participating in the guidance of these laser surgeries today. This allows us to leave our technology in MRI's experienced hands in neuro, while maintaining control of high precision laser ablation elsewhere in the body including Prostate, Urology and more."

TRANBERG<sup>®</sup> | Thermal Therapy System is a laser system with USFDA 510 (k) clearance for soft tissue ablation and in Europe (CE mark) for soft tissue ablation and immunostimulatory interstitial laser thermotherapy (imILT<sup>®</sup>).

"Our number one priority will always be our patients", continued Mr. Burnett. "We will innovate and develop new products and workflows in collaboration with CLS until we have a platform that provides accuracy and workflow advantages to our customers and meets our requirements of being able to do multiple procedures in the same day. We estimate a formal launch of this combined platform sometime in 2020. Given the advanced development and regulatory status of the Tranberg system, we see the development costs in 2019 as more of a re-prioritization of existing resources than a large operating investment. Moreover, we expect this partnership to improve profitability in 2020 given the added therapy revenue MRI will see on the top line with minimal added distribution costs through our existing sales channel and support network. In no way will this agreement impact our commitment to support hospitals using laser ablation technology from other providers as we strongly believe these technologies are essential to making minimally-invasive neurosurgery the new standard, and the preferred pathway for patients."

## **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast discussion of the Company's announcement on Friday, October 19, 2018, at 9:00 a.m. Eastern time (6:00 a.m. Pacific time) that may be accessed by visiting the Company's website at <u>www.mriinterventions.com</u> and selecting "Investors" / "News" / "IR Calendar." Investors and analysts who would like to participate in the conference call may do so via telephone at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until November 2, 2018 by calling (877) 660-6853, or (201) 612-7415 if calling from outside the U.S. or Canada, and then entering conference I.D. number 413671. An online archive of the broadcast will be available on the Company's website at www.mriinterventions.com, on the "Investor Relations" page.

# About MRI Interventions, Inc.

Building on the power of magnetic resonance imaging ("MRI"), MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain. The ClearPoint Neuro Navigation System, which has received 510(k) clearance and is CE marked, utilizes a hospital's existing diagnostic or intraoperative MRI suite to enable a range of minimally invasive procedures in the brain. For more information, please visit www.mriinterventions.com.

# About Clinical Laserthermia Systems AB

The company is developing TRANBERG<sup>®</sup> | Thermal Therapy System for precise, safe and effective minimally invasive ablation of soft tissues including immune stimulating thermal therapy (imILT<sup>®</sup>) of solid cancerous tumors. The products have received 510(k) clearance and are CE marked. The company, which is headquartered in Lund Sweden, has subsidiaries in Germany and USA. For more information, please visit <u>www.clinicallaser.com</u>.

## **Forward-Looking Statements**

Statements herein concerning MRI Interventions, Inc.'s plans, growth and strategies may include forward-looking statements within the context of the federal securities laws. Statements regarding the company's future events, developments and future performance, as well as management's expectations, beliefs, plans, estimates or projections relating to the future, are forward-looking statements within the meaning of these laws. Uncertainties and risks may cause the company's actual results to differ materially from those expressed in or implied by forward-looking statements. Particular uncertainties and risks include those relating to: the Company's ability to obtain additional financing; estimates regarding the sufficiency of the Company's cash resources; future revenues from sales of the company's ClearPoint Neuro Navigation System products; and the company's ability to market, commercialize and achieve broader market acceptance for the company's ClearPoint Neuro Navigation System products. More detailed information on these and additional factors that could affect the company's actual results are described in the "Risk Factors" section of the company's Annual Report on Form 10-K for the year ended December 31, 2017, and its Quarterly Report on Form 10-Q for the three months ended June 30, 2018, both of which have been filed with the Securities and Exchange Commission.

# **Contact Information MRI Interventions Inc:**

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