# 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: February 21, 2014 (Date of earliest event reported)

MRI INTERVENTIONS, INC. (Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction

of incorporation or organization)

000-54575 (Commission File Number)

One Commerce Square, Suite 2550 Memphis, Tennessee

(Address of principal executive offices)

58-2394628 (I.R.S. Employer Identification No.)

> **38103** (Zip Code)

(901) 522-9300

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if changed since last report)

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))

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

On February 21, 2014, MRI Interventions, Inc. (the "Company") and Siemens Medical Solutions USA, Inc. ("Siemens Medical"), entered into a Development Agreement (the "Development Agreement"). This new Development Agreement replaces and supersedes the original Cooperation and Development Agreement entered into between the Company and Siemens Aktiengesellschaft, Healthcare Sector ("Siemens AG") in May 2009 (the "Original Agreement"). Therefore, upon execution of the new Development Agreement, on February 21, 2014, the Company and Siemens AG terminated the Original Agreement. References below to "Siemens" will mean Siemens Medical or Siemens AG, as applicable.

Under the Original Agreement, Siemens and the Company performed initial work related to the development of hardware and software needed for MRI-guided, catheter-based ablation procedures to treat cardiac arrhythmias, such as atrial fibrillation. Pursuant to the terms of the Original Agreement, the Company generally was responsible for developing catheters and other hardware, and Siemens was responsible for developing software, to the Company's specifications. The Company was responsible for paying Siemens for its software development work, but, under the Original Agreement, Siemens owned the software. Working closely with the Company, Siemens created a research version of the software platform specifically for use in MRI-guided cardiac ablation procedures with the Company's catheters, but a commercial version was not developed under the Original Agreement.

Under the new Development Agreement, Siemens and the Company are furthering their collaboration. The Company, with cooperation, assistance and technical support from Siemens, will develop the commercial version of the research software platform created by Siemens under the Original Agreement. Once the development work is completed, subject to appropriate regulatory clearance or approval, the Company will sell the software as its own product. The software will serve as the software component of the Company's ClearTrace system. The full ClearTrace system, which is in development, is an integrated system of software, reusable hardware and disposable catheters designed to enable catheter-based procedures to be performed under MRI guidance instead of fluoroscopic guidance. Both Siemens and the Company believe a shift to MRI-guidance is significant because MRI provides superior visualization of soft tissue, MRI provides continuous 3-D visualization, and MRI eliminates all radiation exposure for the patient and physician.

Pursuant to the Development Agreement, Siemens will develop certain software features for a planned software release (the "Host Features") for certain Siemens MAGNETOM MRI systems ("MAGNETOM Systems"). The Host Features will enable the connection of the Company's software and catheters to MAGNETOM Systems, and the Company will pay Siemens to perform development work for the Host Features. The Host Features, which will be owned by Siemens, will run within the MRI scanner system. The Host Features will then connect to the Company's software, which will operate on a separate computer workstation, and enable the performance of MRI-guided cardiac ablation procedures. Siemens expects to commercially release the Host Features in Europe first, followed by release in the United States. Once the Host Features are commercially released, Siemens will thereafter maintain the Host Features for the MAGNETOM Systems. In addition, for the term of the Development Agreement, Siemens will maintain technical compatibility of the Host Features with the Company's software.

The Development Agreement provides for certain commercial exclusivity, generally extending for a period of four years following the European product release date of the Host Features, in the field of MRI-guided catheter-based cardiac electrophysiology using catheters that are actively tracked by the MRI scanner. During that period and within that field, the parties intend for the Company to have the exclusive opportunity to commercialize MRI-guided catheter-based cardiac electrophysiology with active catheter tracking with Siemens MRI systems, and accordingly, Siemens agreed that it will not engage in certain actions and activities. Likewise, during that period and within that field, the Company agreed that it will not sell or otherwise provide to any third party actively tracked catheters for commercial use, within the meaning of the Development Agreement, that are intended to be used with a non-Siemens MRI system.

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The Development Agreement contains a cross-licensing arrangement between Siemens and the Company. Under that arrangement, each party granted the other party a non-exclusive license to use certain intellectual property rights owned by the granting party and realized in the research software platform developed under the Original Agreement. Under its license from Siemens, the Company may use the licensed intellectual property rights to develop, manufacture and sell software, provided that during the parties' exclusivity period and within the exclusivity field, any such software must be solely for use with Siemens MRI systems. Under its license from the Company, Siemens may also use the licensed intellectual property rights to develop, manufacture and sell software, provided that during the parties' exclusivity period and within the exclusivity field, any such software must be solely for use with the Company's catheters.

Under the Development Agreement, Siemens designated the Company as Siemens' Therapy Partner of Choice in the field of MRIguided catheter-based cardiac electrophysiology using actively tracked catheters. The Development Agreement contemplates that the Company and Siemens may enter into a separate co-marketing agreement pursuant to which parties would cooperate and work together on marketing initiatives.

The term of the Development Agreement will expire four years following the European product release date of the Host Features for MAGNETOM Systems.

The foregoing disclosure includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements often can be identified by words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," or the negative of these words or other words of similar meaning. Forward-looking statements by their nature address matters that, to different degrees, are uncertain and involve risk. Uncertainties and risks may cause the Company's actual results and the timing of events to differ materially from those expressed in or implied by the Company's forward-looking statements. Particular uncertainties and risks include, among others: the Company's ability to successfully complete the development of, and to obtain regulatory clearance or approval for, its ClearTrace system; demand and market acceptance of the Company's products; availability of third party reimbursement from third party payors for procedures utilizing the Company's products; the sufficiency of the COmpany's cash resources to maintain planned research and development programs and commercialization efforts; future actions of the FDA or any other regulatory body that could impact product development, manufacturing or sale; the Company's ability to protect and enforce its intellectual property rights; the Company's dependence on collaboration partners; and the impact of competitive products and pricing. More detailed information on these and additional factors that could affect the Company's actual results and the timing of events are described in the Company's quarterly report on Form 10-Q filed on November 13, 2013.

### Item 1.02. Termination of a Material Definitive Agreement.

The information set forth under Item 1.01 above regarding the Original Agreement is incorporated herein by reference.

# Item 7.01. Regulation FD Disclosure.

On February 24, 2014, the Company issued a press release announcing the Development Agreement. A copy of the press release is furnished herewith as Exhibit 99.1.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

See Exhibit Index immediately following signature page.

# SIGNATURE

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.

# MRI INTERVENTIONS, INC.

By: /s/ Oscar L. Thomas

Oscar L. Thomas Vice President, Business Affairs

Date: February 24, 2014

# EXHIBIT INDEX

# Exhibit No.

99.1

Description

Press release issued by MRI Interventions, Inc. dated February 24, 2014

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## MRI Interventions and Siemens Enter Into Agreement to Commercialize Next Generation Software Platform to Enable MRI-Guided, Catheter-Based Procedures

IRVINE, CA, February 24, 2014 – MRI Interventions, Inc. (OTCQB: MRIC) and Siemens Healthcare announced today an agreement to codevelop and commercialize a next generation software platform that will enable minimally invasive catheter-based procedures to be performed under real-time magnetic resonance imaging (MRI) guidance. Today, virtually all catheter-based interventions are performed using fluoroscopy, an X-ray based imaging technique. The software platform, to be used in combination with companion MRI-guided catheters, will enable procedures to be performed under MRI guidance instead of fluoroscopic guidance. This shift to MRI-guided procedures is significant because MRI provides superior visualization of soft tissue, MRI provides continuous 3-D visualization, and MRI eliminates all radiation exposure for the patient and physician.

The new software platform will serve as the software component of MRI Interventions' ClearTrace® system. The full ClearTrace system, which is in development, is an integrated platform of software, reusable hardware and disposable catheters designed to enable real-time, MRI-guided catheter interventions. MRI Interventions' software will be a commercial successor to an innovative research software platform created by Siemens. Under a 2009 agreement between the parties, MRI Interventions and Siemens worked together closely on the development of the research platform, specifically for use in MRI-guided cardiac ablation procedures with MRI Interventions' catheters. Under this new agreement, MRI Interventions, with cooperation and assistance from Siemens, will develop a commercial version of the research platform, for cardiac applications. Once the development work is completed, MRI Interventions will sell the software as its own product.

"We are pleased to continue our strong working relationship with MRI Interventions, a company that is helping to lead the industry into the emerging field of real-time MRI-guided procedures," said Robert Krieg, VP MR Product Innovation & Definition at Siemens Healthcare. "We see tremendous potential to improve patient care by further expanding the therapeutic uses of MRI."

MRI Interventions is a pioneer in the field of real-time, MRI-guided therapeutic interventions. The company's first product, the ClearPoint® Neuro Intervention System, is used commercially in the United States and Europe to enable MRI-guided, minimally invasive brain surgery. Similar to ClearTrace, the ClearPoint system is an integrated platform of software, reusable hardware and disposable devices. The end result for the neurosurgeon is real-time, 3-D visualization of the target neuro anatomy and surgical instruments with no radiation exposure for the patient or physician. MRI Interventions seeks to bring these same breakthrough capabilities to catheter-based procedures outside of the brain through its development of the ClearTrace system, with an initial focus on cardiac ablation procedures to treat arrhythmias.

"Effective evaluation and catheter-based treatment of patients suffering from complex cardiac arrhythmias have been impeded by poor visualization of patients' cardiac tissue. Leading Electrophysiology centers around the world are increasingly using MRI as the visualization platform to more accurately evaluate and stage their arrhythmia patients," said Dr. Nassir Marrouche, Associate Professor of Medicine and Director of the Electrophysiology Lab at the University of Utah, and the Executive Director of the Comprehensive Arrhythmia Research & Management Center (CARMA). "As this trend gathers momentum, the next step is to move the cardiac ablation procedure into the MRI suite, with a system like ClearTrace. The CARMA team at the University of Utah has performed a large number of successful experimental studies using the ClearTrace system. Our experience with the system has been very good, and we are pleased this technology is moving forward to commercialization."



"Interventional radiologists who have done research utilizing MRI guidance for catheter-based procedures are well aware of the many enticing benefits of moving from the fluoroscopic cath lab to the MRI suite," said Dr. Aravind Arepally, Section Chief, Vascular and Interventional Radiology, Piedmont Hospital. "It is exciting to hear that this capability is heading to a commercially-available product. This may not only provide an opportunity to improve certain current catheter-based fluoroscopic procedures but also may enable new procedures that are not currently feasible."

"Siemens is the global market leader in MRI scanners. We have enjoyed an excellent working relationship with Siemens over the last few years and we are delighted to be taking this next step with them," said Kimble Jenkins, CEO of MRI Interventions. "Extending the power of real-time MRI-guidance into catheter-based procedures represents another major opportunity in medicine. We believe that our ClearPoint system is transforming the way minimally invasive procedures are performed in the brain, and we hope to replicate this transformation for procedures in the body with our ClearTrace platform."

The ClearTrace system is currently limited to investigational use only and is not available for sale. MRI Interventions has not made any filings seeking regulatory approval or clearance of its ClearTrace system.

### About Cardiac Arrhythmias and Atrial Fibrillation

Atrial Fibrillation (AF) is the most common cardiac arrhythmia and is characterized by a rapid and uncontrolled beating of the upper chambers of the heart. AF affects approximately 3 million patients in the US, and over 6.7 million in the US and Europe combined. AF is a leading cause of stroke in patients 65 years and older. Each year there are between 200,000 and 400,000 new AF cases diagnosed in the U.S., and the rate of incidence is increasing. Researchers have estimated that AF prevalence in the US will exceed 10 million patients by 2050. The therapeutic aim of catheter-based cardiac ablation is to restore a patient's normal cardiac rhythm by delivering ablative energy to the cardiac tissue involved in the initiation or propagation of the arrhythmias.

## About MRI Interventions, Inc.

Founded in 1998, MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain and heart. Utilizing a hospital's existing MRI suite, the company's FDA-cleared ClearPoint® system is designed to enable a range of minimally invasive procedures in the brain. In partnership with Siemens Healthcare, MRI Interventions is developing the ClearTrace® system to enable MRI-guided catheter interventions. Building on the imaging power of MRI, the company's interventional platforms strive to improve patient care while reducing procedure costs and times. MRI Interventions is also working with Boston Scientific Corporation to incorporate its MRI-safety technologies into Boston Scientific's implantable leads for cardiac and neurological applications. For more information, please visit <u>www.MRI interventions.com</u>.



## Forward-Looking Statements

Certain matters in this press release may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements often can be identified by words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," or the negative of these words or other words of similar meaning. Forward-looking statements by their nature address matters that, to different degrees, are uncertain and involve risk. Uncertainties and risks may cause MRI Interventions' actual results and the timing of events to differ materially from those expressed in or implied by MRI Interventions' forward-looking statements. Particular uncertainties and risks include, among others: our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, our ClearTrace system; demand and market acceptance of our products; availability of third party reimbursement from third party payors for procedures utilizing our products; the sufficiency of our cash resources to maintain planned commercialization efforts and research and development programs; future actions of the FDA or any other regulatory body that could impact product development, manufacturing or sale; our ability to protect and enforce its intellectual property rights; our dependence on collaboration partners; the impact of competitive products and pricing; and the impact of the commercial and credit environment on us and our customers and suppliers. More detailed information on these and additional factors that could affect MRI Interventions' actual results are described in MRI Interventions' filings with the Securities and Exchange Commission, including, without limitation, the quarterly report on Form 10-Q filed on November 13, 2013. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements contained in this press release to reflect any change in MRI Interventions' expectations or any change in events, conditions or circumstances on which any such statements are based.

## **Contact Information:**

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