# 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: August 20, 2012 (Date of earliest event reported)

#### MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

**Delaware** 000-54575 58-2394628 (I.R.S. Employer (State or other jurisdiction (Commission File of incorporation or organization) Identification No.) Number) One Commerce Square, Suite 2550 38103 Memphis, Tennessee (Address of principal executive offices) (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 7.01. Regulation FD Disclosure.

The Company is posting an updated investor presentation to its website at http://ir.stockpr.com/mriinterventions/presentations. A copy of the investor presentation is being furnished herewith as Exhibit 99.1. The Company may use the investor presentation from time to time in conversations with investors, analysts and others.

The Company is furnishing the information contained in Exhibit 99.1 pursuant to Regulation FD. Such information is furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission ("SEC") and other public announcements that the Company may make from time to time, by press release or otherwise. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

#### 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: <u>/s/ Oscar Thomas</u> Oscar Thomas Vice President, Business Affairs

Date: August 20, 2012

#### EXHIBIT INDEX

Exhibit No. Description

99.1 MRI Interventions, Inc. investor presentation dated August 2012



Ticker: MRIC

# Investor Presentation

August 2012



### **Forward-Looking Statements**

Certain matters in this presentation 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. Forwardlooking 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. For MRI Interventions, particular uncertainties and risks include, among others: demand and market acceptance of its products; its ability to successfully complete the development of, and to obtain regulatory clearance or approval for, future products, including its current product candidates; availability of third party reimbursement; the sufficiency of its 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; its ability to protect and enforce its intellectual property rights; its dependence on collaboration partners; the retention of its sales representatives and independent distributor; the impact of competitive products and pricing; and the impact of the commercial and credit environment on it and its 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 for the quarterly period ended June 30, 2012. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements contained in this presentation to reflect any change in MRI Interventions' expectations or any change in events, conditions or circumstances on which any such statements are based.

MRI Interventions Investor Presentation

# MRI Interventions, Inc. (MRIC)

Creating MRI-based interventional platforms for the next generation of minimally invasive surgical procedures.

#### OPPORTUNITY HIGHLIGHTS

- ClearPoint® Neuro Intervention System, first-to-market platform, allows neurosurgeons to see inside the patient's brain during a procedure.
- Targeting 2.2 million late-stage neuro disease patients.
- ClearPoint is now installed in 15 prominent U.S. neurosurgery centers,
   2 in Europe, and growing.
- ClearPoint has generated \$1.8M since commercial roll-out, and growing.
- MRIC is developing a second platform, ClearTrace<sup>™</sup> System, for MRI-guided minimally invasive surgical procedures in the heart.

MRI Interventions Investor Presentation

# Min. Inv. Procedures: A Revolution Driven by Imaging

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# Visualization is the Fundamental Building Block

Keystone for min. inv. procedures is <u>intra-procedural visualization</u>. This capability wasn't available for neurosurgery until ClearPoint.

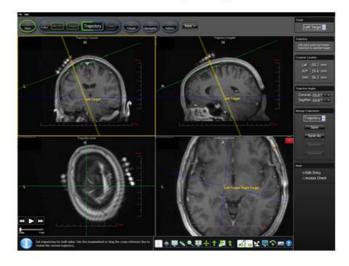
#### **Conventional Procedure**

Surgeon sees the outside of the head during the procedure



#### **ClearPoint Procedure**

Provides detailed visualization, inside the brain, during the procedure



MRI Interventions **Investor Presentatior** 

### Support from Clinicians, Industry, and Academics

Leading industry partners, academic institutions, and clinicians support MRIC technology and its application across multiple specialties.

#### **INDUSTRY PARTNERS**

#### SIEMENS & BrainLAB

Scientific

#### UNIVERSITY RESEARCH





JOHNS HOPKINS

#### SYSTEM COMPATABILITY

**PHILIPS** SIEMENS

BrainSUITE IMRIS O

**GE Healthcare** 

#### **CLINICIAN ADVISORS**



Dr. Philip Starr UCSF



Dr. Paul Larson UCSF & VA



Dr. Ali Rezai Ohio State Univ



Dr. Russ Lonser Nat Inst. of Health



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



Dr. Nassir Marrouche Univ of Utah

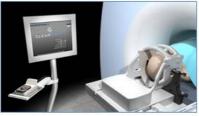
MRI Interventions Investor Presentation

#### **Standard MRI Suite**

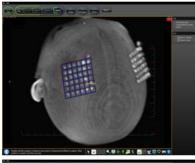


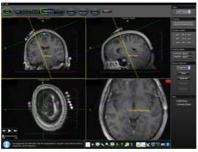
ClearPoint Workstation Monitor Standard Diagnostic MRI Scanner ClearPoint Imaging Coil and Fixation Frame

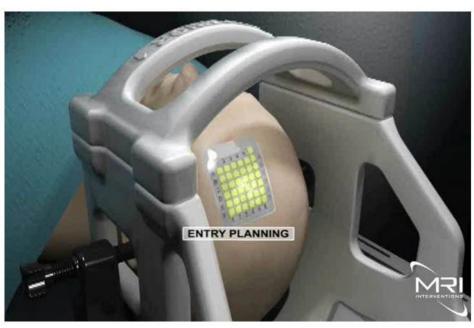
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ARI Interventions **Investor Presentatior** 

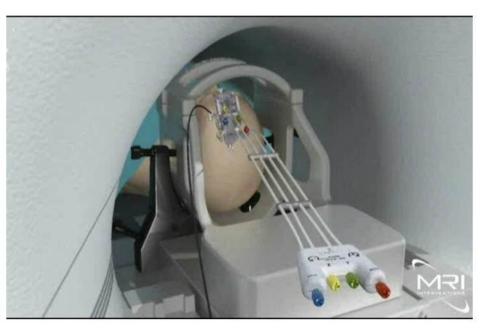
SmartFrame® Trajectory Guide



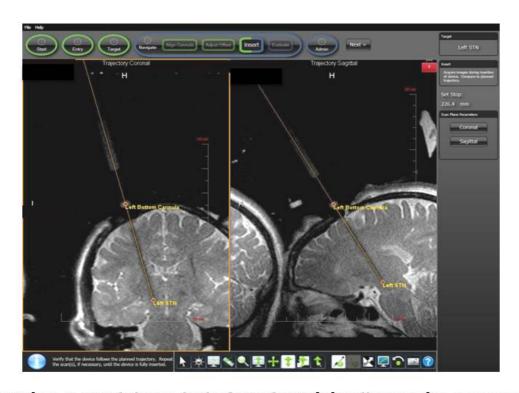
SmartFrame® Hand Controller



Trajectory Alignment & Device Insertion



MRI Interventions Investor Presentation



ClearPoint: A Breakthrough Platform for Minimally Invasive Neurosurgery
...Now the Neurosurgeon can See

MRI Interventions Investor Presentation

# **The ClearPoint Difference**

Conventional Procedure	Clear Point Procedure
No direct visualization, Performed in an operating room	Direct, high resolution visualization, Performed in an MRI Suite
Patient often must be awake for their own brain surgery	Patient under general anesthesia
Long procedures – up to 8 hours	Short procedures – 3 hours or less
Complex procedure, requires extensive training	Simple procedure, brief training
Requires specialized neurosurgeon - 300 in US	Not limited to specialized neurosurgeons - 3500 neurosurgeons in US
Poor economics for hospital and physician	Attractive economics for hospital and physician

MRI Interventions Investor Presentation

### **ClearPoint Economics**

#### BUSINESS MODEL - RAZOR / RAZORBLADE

- ClearPoint Hardware/Software: \$180,000 ASP (paid upfront or over time).
- ClearPoint Disposables: \$7,300 ASP per procedure with strong margins.
- Generate recurring revenue from the sale of disposables.
- Procedures covered by existing reimbursement codes.
- Platform system for minimally invasive neurosurgery.

#### ATTRACTIVE ECONOMICS

- For Hospitals: increases revenue, improves efficiency, and utilizes existing infrastructure.
- For Surgeons: decreases procedure time and increases revenues generated per hour.

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# **Market Opportunity for Minimally Invasive Neurosurgery**

#### Addressable Patient Population

#### **Therapeutic Approaches**

Indications	Patient Population	Treatment Resistant Addressable Market	Deep Brain Stimulation	Direct Drug Delivery	Focal Ablation
Parkinson's Disease	1,500,000	150,000	Today	In trials	Today
Epilepsy	2,300,000	250,000	In trials	In trials	Today
Brain Tumor	200,000	10,000	N/A	In trials	Today
OCD	3,300,000	100,000	Today	In trials	Today
Major Depression	6,000,000	1,200,000	In trials	Future	Today
Dystonia	250,000	25,000	Today	N/A	Today
Alzheimer's	5,400,000	500,000	Early trials	Early trials	N/A
Huntington's	30,000	30,000	N/A	Early trials	N/A

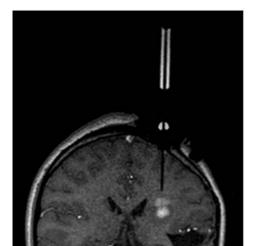
2.2 million, and growing...

All can be delivered in a minimally invasive procedure

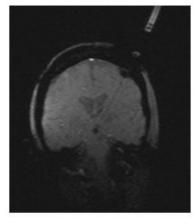
MRI Interventions **Investor Presentation** 

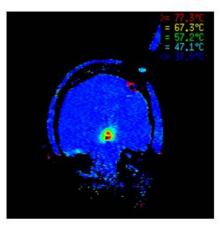
### **Additional Benefits of MRI-based Procedures**

MRI enables visualization of fluids as they are injected into the brain



MRI enables visualization of changes in tissue temperature in the brain





MR Thermometry is an MRI-based functionality available on most MR scanner platforms and it is a feature built into products from several third party vendors. ClearPoint enables MRI-guided procedures and allows physicians to use this inherent MR capability during a procedure.

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# **Neurosurgeon Comments on ClearPoint**

The ClearPoint System "represents a major step forward in our ability to treat complex neurological diseases."

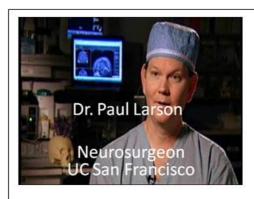
Dr. Karl Sillay, Director of Adult Functional and Stereotactic Neurological Surgery at the University of Wisconsin, quoted in UW Health News, May 24, 2011

"Yesterday's [ClearPoint case] was 2 hours and 45 minutes, compared to about 6 hours for the standard approach," ...some can take 12 hours...

"...the interventional MR approach allows the surgery to be done with a single brain penetration per side, so it's less invasive."

"They want a simple, accurate and fast solution and the new system makes that possible."

Dr. Philip Starr, Professor of Neurological Surgery, Dolores Cakebread Endowed Chair in Neurological Surgery, UCSan Francisco, quoted in UCSF News Feb 3, 2011



Dr. Paul Larson, Neurosurgeon, UCSF Comments on ClearPoint

Drs. Sillay, Starr and Larson have <u>no</u> equity interest in the Company and they are not consultants to the Company

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# **ClearPoint Adoption**

#### **CURRENT INSTALLED BASE**



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# **ClearPoint Market Opportunity**

#### HIGHLIGHTS

- First-to-market in U.S. and Europe
- Strong support from leading clinicians
- Growing ClearPoint market awareness
- 5,000 MRI scanners in U.S. hospitals
- 3,500 neurosurgeons in U.S.
- 2.2 million late stage neuro patients
- Strong IP position in MRI-guided interventions with 60+ issued patents and 110+ patent applications



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# **Our Next Platform in Development**



 $ClearTrace^{ ext{T}}$  Cardiac Intervention System for minimally invasive surgical procedures in the heart.

Intra-procedural Visualization: Current Procedurevs. ClearTrace

#### **Current Procedure**



#### ClearTrace System



CAUTION: Investigational device. Limited by federal law to investigational use.

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### **Personnel and Infrastructure**

Research, development, manufacturing, and fulfillment take place in the Company's facility in Irvine, California

#### **PERSONNEL**

- 20 Employees
- 15+ years average med device experience

#### INFRASTRUCTURE

- Product development and prototyping performed in-house
- Product assembly in-house
- Full quality system; ISO 13485 certified
- Sales, order processing, and distribution in-house





MRI Interventions Investor Presentation

# **Financial Highlights**

#### **BALANCE SHEET HIGHLIGHTS**

- Cash at July 31 \$5.0M
- Shares Outstanding (as of July 31) 47,402,420 (all common, no pref)
- \$70M has been invested in MRIC since inception in 1998, primarily R&D

#### INCOME STATEMENT HIGHLIGHTS

	Six Months Ended 6/30 (in 000s)			
Revenues	2012		2011	
License	\$	1,300	\$	1,300
Service	\$	251	\$	** **
Product	\$	513	\$	199
Total Revenues	\$	2,064	\$	1,499
Operating Loss*	\$	(2,513)	\$	(3,179)

<sup>\*</sup>Reflects adding back \$882 reversal of R&D Obligation

MRI Interventions **Investor Presentation** 

# **Financial Highlights**

#### **PUBLIC TRADING COMMENCES**

- Symbol MRIC (OTCBB)
- \$0.75 Opening Trade May 21, 2012
- \$2.50 Closing Trade on August 17, 2012
- Average Daily Volume approx. 37,000 (as of Aug 17)

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# **Executing a Simple Growth Strategy**

#### **GROW SITES**

- Currently 15 Sites in U.S.; 2 Sites in Europe
- Strong and Growing Pipeline

#### **GROW UTILIZATION**

- Utilization Goal: 1 ClearPoint Case/Week
- 2 Sites Already at Goal (current run rate)
- Example: 15 Sites @ 1 Case/Week = 180 Cases/Qtr

#### HOW WE IMPLEMENT

- Hire Sales/Field Support Personnel
- Foster Broad Platform Utilization: electrodes / catheters / probes / biopsy

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MRI Interventions Investor Presentation



Ticker: MRIC

MRI Interventions, Inc.

One Commerce Square, Suite 2550

Memphis, TN 38103

(901) 522-9300 info@mriinterventions.com

# **Descriptions of the Videos Included in this Presentation**

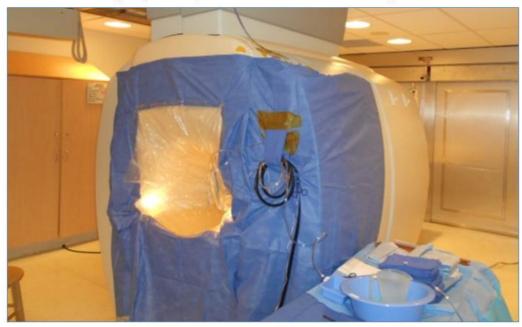
This presentation includes five embedded videos. The following table provides the location of each video in the presentation and a description of each video:

Slide No.	Description
8 (right side)	This video depicts the target selection and entry planning portion of a ClearPoint procedure. The video shows an animation of a patient and the ClearPoint system in use, along with images from the ClearPoint software that show MRI scans used to select a target site, trajectory to target and entry point on the MRIC SmartGrid® matrix.  This video is an excerpt of the ClearPoint system demonstration video available on MRI Interventions' website at www.mriinterventions.com/clearpoint/demonstration-video.
9 (right side)	This video depicts the trajectory alignment and device insertion portion of a ClearPoint procedure. The video shows an animation of a patient and the ClearPoint system in use, along with images from the ClearPoint software that show MRI scans used to align the MRIC SmartFrame® trajectory guide along a planned trajectory and then depicts the insertion of a device into the target neuro anatomy.  This video is an excerpt of the ClearPoint system demonstration video available on MRI Interventions' website at www.mriinterventions.com/clearpoint/demonstration-video.
14	The video on the far left depicts a series of MRI images that show the infusion of fluid into the brain. The video on the far right depicts a series of MRI images that show changes in brain tissue temperature, color-coded to correspond with the temperatures shown in the legend contained within the image window.
15	In this video, Dr. Paul Larson, a neurosurgeon at UCSF Medical Center, speaks about his experience with the ClearPoint system. The following is a transcript of Dr. Larson's remarks in the video:  "It was tremendous. The system performed exactly to our expectations. The patient was as leep. The targeting in the software worked flawlessly. We were able to place electrodes with one penetration of the brain as opposed to two or three or four that we would have done in that patient with the traditional implantation."  "It changes things pretty substantially. The scanner allows us to see where we're going, in real time. For surgeons, the procedure time gets cut down by a half or a third. And you have this immediate feedback. Is the electrode going to the right spot? From a patient standpoint there are tremendous advantages. You know, who would want to have an awake brain operation if you could be as leep for it?"

MRI Interventions Investor Presentation

# **ClearPoint Neuro Intervention System**

ClearPoint Draping in Preparation for a Case in a Diagnostic MRI Suite



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# **ClearPoint Neuro Intervention System**

### Selected ClearPoint Disposable Components



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