#### 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: September 25, 2015 (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) 58-2394628 (I.R.S. Employer Identification No.)

5 Musick Irvine, California (Address of principal executive offices)

92618

(Zip Code)

(949) 900-6833

(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.

MRI Interventions, Inc. (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 analysts, investors and others.

The presentation is furnished by the Company pursuant to Item 7.01 of Form 8-K and will not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor will it be deemed to be incorporated by reference in any filing under the Securities Act 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: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer

Date: September 25, 2015

### EXHIBIT INDEX

Exhibit No.Description99.1MRI Interventions, Inc. investor presentation dated September 2015



Transforming minimally invasive neurosurgery by enabling real-time visualization with MRI

### **Forward Looking Statements**



Certain statements 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. Particular uncertainties and risks include, among others: demand and market acceptance of our products; our ability to successfully expand, and achieve full productivity from, our sales, clinical support and marketing capabilities; availability and adequacy of 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 our intellectual property rights; our dependence on collaboration partners; the impact of competitive products and pricing; the impact of the commercial and credit environment on us and our customers and suppliers; and our ability to successfully complete the development of, and to obtain regulatory clearance or approval for, our ClearTrace system. More detailed information on these and additional factors that could affect MRI Interventions' actual results and the timing of events are described in our filings with the Securities and Exchange Commission, including, without limitation, the quarterly report on Form 10-Q filed on August 10, 2015. Except as required by law, MRI Interventions undertakes no obligation to publicly update or revise any forward-looking statements made 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                                   | Opportunity   |  |  |  |
|---|---|--|--|--|
| Large<br>Market                                     | <ul> <li>Market is large and growing</li> <li>55,000 potential ClearPoint procedures across multiple therapies</li> </ul>   |  |  |  |
| Navigation System<br>for Multiple<br>Therapies      | <ul> <li><i>Electrode placement</i> for Deep Brain Stimulation</li> <li><i>Laser Ablation</i> for ablation of epileptic foci or Brain Tumors</li> <li><i>Brain Tumor Biopsy</i> for deep seated tumors</li> <li><i>Precise Drug Delivery</i> to target lesions</li> </ul> |  |  |  |
| Large Opportunity<br>Attracting<br>Multiple Players | <ul> <li>Area of interest to large medical device companies</li> <li>Medtronic, St. Jude and Boston Scientific investing in neuro market</li> <li>MRI Scanner Companies embracing MRI-guided therapies</li> <li>Drug Companies pursuing direct delivery</li> </ul>        |  |  |  |
| Uniquely<br>Positioned                              | <ul> <li>Focused commercial effort; FDA/CE approved products</li> <li>Delivery platform for multiple therapies</li> <li>Strong, proprietary position</li> <li>Recent restructuring complete</li> </ul>  |  |  |  |

### MRI Interventions: Real Time MRI Guided Surgery

MRI

First-to-market technology platform enabling real-time MRI guided surgery; FDA-cleared, CE-marked and 40+ ClearPoint sites

Focused commercialization of neuro platform underway, gaining traction; recent restructuring complete

Attractive razor/razorblade business model with strong margins

Compatible with all major MRI manufacturers; Interoperability w/ Medtronic, Monteris, neuro products

Strong intellectual property portfolio

Strong management team with extensive medical device commercialization experience: Intuitive, Medtronic, Kyphon, Boston Scientific, Edwards Lifescience, Cordis

# Leadership – Significant Med Device Experience



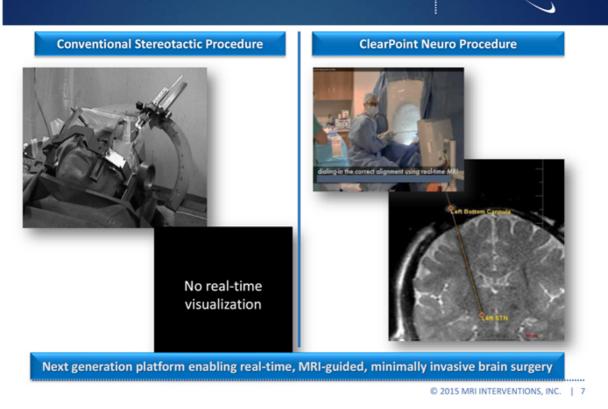
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### Technology: ClearPoint<sup>®</sup> Neuro Navigation System

Navigation System consisting of Integrated Devices and Software for Real-Time, MRI Guided, Minimally Invasive Neurosurgical Procedures



# Without ClearPoint, minimally invasive neuro procedures are performed "blind"





# **ClearPoint Procedure Overview**





# **ClearPoint Procedure Overview**



### SmartFrame® Trajectory Guide



SmartFrame® Hand Controller



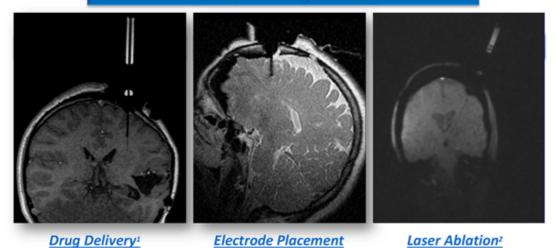
### Trajectory Alignment & Device Insertion



## **ClearPoint Procedure Overview**



### **Delivery of Neurological Therapy**



Drug Delivery - The SmartFlow\* cannula received 510(k) clearance for injection of cytarabine, a chemotherapy drug, to the ventricles or removal of CSF from the ventricles during intracranial procedures. Delivery of other therapeutic agents, and delivery of agents to other areas of the brain, using the SmartFlow cannula is investigational.
 Laser Ablation - 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. The ClearPoint system enables MRI-guided procedures and allows physicians to use this inherent MR capability during a procedure.

# **ClearPoint Hospital Economics**

#### **Increase Patients**

- Better patient experience provides hospitals the opportunity to reach additional patient
  populations that may otherwise forego surgery
- 65% of eligible DBS patients refuse treatment, due to fear of surgery<sup>(1)</sup>

#### **Established, Attractive Reimbursement**

 Move procedures from the more expensive OR to the less expensive MR suite, with equivalent reimbursement

#### Improved Utilization of Existing MRI's

- 1 hour of MR Scanner time used for diagnostic imaging could generate \$1,200<sup>(2)</sup>
- 1 hour of MR scanner time used for a ClearPoint procedure could generate \$5,275<sup>(3)</sup>
- · Utilizes existing MRI's already in hospital

(2) Estimated average US hospital-based MRI suite revenue per hour for outpatient diagnostic scans, based on data gathered by MRI Interventions. Excludes professional fees. Actual revenues will vary by hospital, procedure and payor.





<sup>(1)</sup> Medtronic Investor Presentation, June, 2014

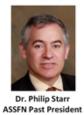
<sup>(3)</sup> Based on a weighted average payment to MRI Interventions' customers (as of September 2014) for an electrode placement procedure for Medicare and private insurance patients, calculated by MRI Interventions using a payor mix weighted 67% to average Medicare reimbursement and 33% to average private insurance reimbursement. Average Medicare reimbursement calculated as the weighted average Medicare payment for MRI Interventions' customers (as of September 2014) for an electrode placement procedure under MS-DRGs 025, 026 and 027. Average private insurance reimbursement calculated as 1.5x Medicare reimbursement, based on published data. Hourly amount assumes 4.5 hour procedure duration. Excludes professional fees. Actual revenues will vary by hospital, procedure and payor.

# Multi-Therapy MRI-Guided Navigational System



Leading Neurosurgeon Supporters

Strong Peer-Reviewed Journal Support









Dr. Robert Gross Emory University



Dr. Robert Wharen, Jr. Mayo Clinic -Jacksonville



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



OSU - NIH



### Strong Intellectual Property Close to 100 issued patents around the world



| 50+ U.S. Pater | nts 45+ (  | OUS Patents | 40+ U.S.<br>Patent Applicat | 50+ OUS<br>t Applications |
|----------------|--|-------------|-----------------------------|---------------------------|
|                |  |             |                             |                           |
| C. A.          | Not the second s | ilitze      | Sie                         |                           |

- Issued patents cover areas such as: MRI-guided surgical systems that include software and devices; the SmartFrame® trajectory guide; other ClearPoint® disposable components; active intracranial probes; MRI-compatible catheters; MRIsafety technology
- Key ClearPoint-related patents do not begin to expire until 2027

Patient Impact



# Martin's Story ClearPoint-Enabled Electrode Placement



# Patient Benefit – Minimally Invasive Procedure



7 days after ClearPoint procedure – Arrow Indicates Surgery Site

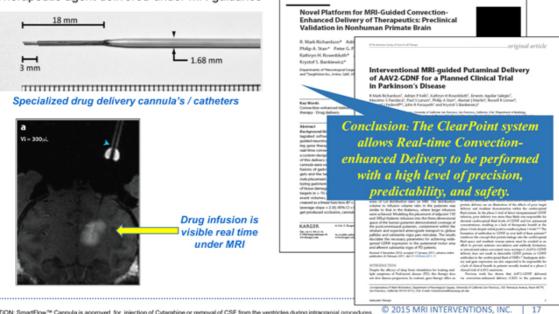


### **ClearPoint Drug Delivery**



Residual Separatar 16, 2010 Assigned physical and Texas Public Assignments and Texas

- · MR visualization of neuro target
- · MR-guided placement of catheter
- Therapeutic agent delivered under MR-guidance\*



Stampotactic -- Functional Neurosurgery

Doc 10

\* CAUTION: SmartFlow <sup>TM</sup> Cannula is approved for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. © 2015 MRI INTERVENTIONS, INC. | 17 Uses other than the approved indication are limited by Federal law to investigational use.

### **MRIC's Unique Opportunity in Drug Delivery**



## Provides MRIC with "biotech-like upside" without "all or nothing downside"

### Major Challenges in Delivering Drugs to the Brain

- Blood brain barrier blocks systemic delivery of almost all drugs 98% of small molecules
- Direct injection without ClearPoint is blind, so target is frequently missed
  - Neopharm Trial 51% of 572 catheters failed to meet all positioning criteria

### Major Benefits of Drug Delivery with ClearPoint

- Neurosurgeon sees that target is reached
- Eliminates the blood brain barrier issue; Reduces/eliminates unwanted systemic side effects; Reduces dosage levels (as little as 1/300th of systemic volumes)

### Business Model - MRIC Partners with Drug Companies and Researchers

- MRIC provides ClearPoint; Drug company provides drug candidate
- Drug company/sponsor pays for trial
- If drug is approved, MRIC gets device revs (~\$7000/case); Drug co gets drug revs



## The ClearPoint Difference



| Without ClearPoint (Stereotactic)                          | With ClearPoint  |  |  |
|--|--|--|--|
| No direct visualization; Performed in an operating room    | Direct, high resolution visualization; Performed ir an MRI Suite |  |  |
| Patient may be awake for own brain surgery <sup>(1)</sup>  | Patient may be under general anesthesia <sup>(1)</sup>           |  |  |
| Long procedures – Can be up to 8 hours                     | Shorter procedures – Can be 3 hours or less                      |  |  |
| Accuracy to target based on prior images                   | Highly accurate, based on real time images                       |  |  |
| May require OR and MRI for same procedure (laser ablation) | One procedure, one place   |  |  |
| Poor economics for hospital and physician                  | Attractive economics for hospital and physician                  |  |  |

**Better for Patients** 

**Better for Surgeons** 

Better for Hospitals

(1) Microelectrode recording and macrostim are processes that involve listening to neuronal firings (i.e., physiological recordings) and observing physiological responses to stimuli during brain surgery. In connection with our \$10(k) clearance in 2010, the FDA requested a warming within ClearPoint's instructions for Use based on the lack of data with respect to deep brain stimulation (DBS) procedures. The warning states that the ClearPoint system, alone, should not be used to guide a DBS lead to a specific brain target and that final placement of DBS leads requires physiological recordings to confirm that they are located in the correct brain target and functioning as intended.

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## **ClearPoint Revenue Model**



# BUSINESS MODEL - RAZOR / RAZORBLADE

- ClearPoint Hardware/Software: \$100,000 \$150,000 ASP
- ClearPoint Disposables: \$7,500 (average) ASP per procedure with strong margins
- Recurring revenue from the sale of disposables
- Procedures covered by existing inpatient DRG reimbursement codes



# Growing the ClearPoint Footprint Installed Base of 39 sites in the US



June, 2015

# **ClearPoint US Market Opportunity**



|   | <u>Parkinson's</u>           | <u>Epilepsy</u>                    | <u>Brain Tumors</u>                               |
|---|------------------------------|------------------------------------|---|
| Total Prevalence (US)                                     | 1,500,000                    | 2,200,000                          | 80,000 (annual diagnosis)                         |
| Prevalence – Drug Treatment<br>Resistant (DTR)            | 125,000                      | 264,000                            |   |
| Incidence – DTR   | 7,500                        | 18,000                             | Resections: 80,000<br>Stereotactic Biopsy: 10,000 |
| ClearPoint Enabled Therapy                                | Electrode<br>Placement (DBS) | Laser Ablation<br>RNS <sup>1</sup> | Biopsy / Laser Ablation /<br>Drug Delivery        |
| Potential ClearPoint<br>Procedures, Annually <sup>2</sup> | 12,500                       | 28,000                             | 14,500  |

# 55,000+ Potential Procedures Per Year

Note: Prevalence and Incidence based on either market research conducted by a third party on behalf of MRI Interventions or research conducted by MRI Interventions of publicly available sources. (1) Responsive neurostimulation device (RNS) (2) Potential Annual ClearPoint Procedures for brain tumors based on market research conducted by a third party on behalf of MRI Interventions.

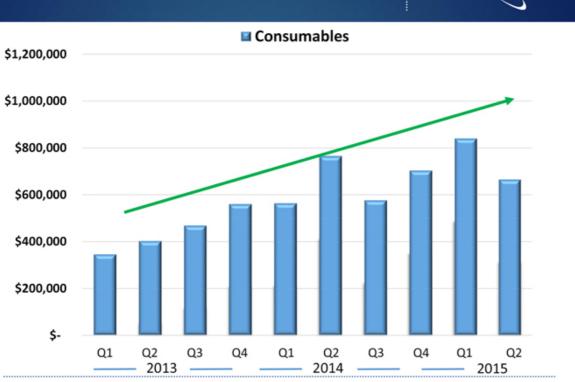
# ClearPoint Future Opportunities

Multiple Therapies for Future Growth

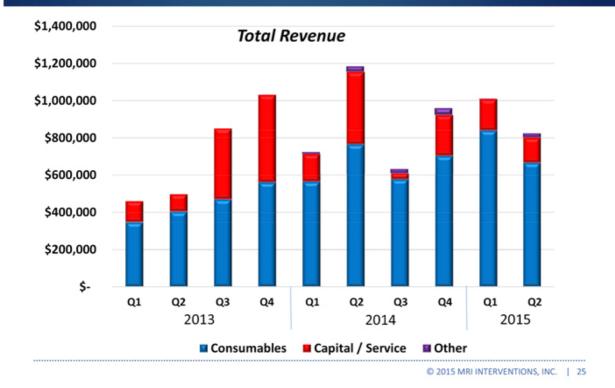


| <u>Neuro Disorder</u>  | <u>Patient</u><br><u>Population</u> | <u>Treatment Resistant</u><br><u>Patient Population</u> | <u>ClearPoint Enabled</u><br><u>Therapy</u> | <u>Current Status</u>     |
|------------------------|-------------------------------------|---|---|---------------------------|
| Dystonia               | 250,000                             | 25,000  | DBS   | Active Use, HDE           |
| OCD                    | 3,300,300                           | 100,000   | DBS   | Active Use, HDE           |
| Severe Depression      | 6,000,000                           | 1,200,000   | DBS   | IDE Trials (DBS)          |
| Parkinson's<br>Disease | 1,500,000                           | 125,000   | Drug Delivery                               | Clinical Trials – Phase 1 |
| Brain Tumors<br>(GBM)  | 11,000                              | 11,000  | Drug Delivery                               | Clinical Trials – Phase 1 |
| Huntington's           | 30,000                              | 30,000  | Drug Delivery                               | Pre-Clinical              |
| ALS                    | 30,000                              | 30,000  | Drug Delivery                               | Pre-Clinical              |
| Alzheimer's            | 5,400,000                           | 500,000   | DBS   | Research                  |

**ClearPoint Consumable Revenues** 



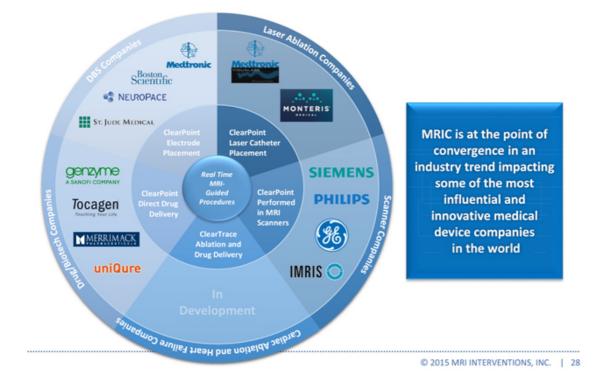
# Total Revenue, 2013 - 2015







# At the Center of an Emerging Industry Trend





### Ticker: MRIC

MRI Interventions, Inc. Irvine, CA

949.900.6833

mriinterventions.com



Transforming minimally invasive neurosurgery by enabling real-time visualization with MRI