# 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 1, 2015

# MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE (State or other jurisdiction of incorporation) 000-54575 (Commission File Number) 58-2394628 (I.R.S. Employer Identification Number)

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

(949) 900-6300 (Registrant's telephone number, including area code)

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under 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 2.02. Results of Operations and Financial Condition.

On October 1, 2015, MRI Interventions, Inc. (the "Company") issued a press release announcing certain information regarding the Company's financial performance for the third fiscal quarter ended September 30, 2015. A copy of the press release is furnished herewith as Exhibit 99.1.

The information in Item 2.02 of this Form 8-K, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### Item 7.01. Regulation FD Disclosure

On October 1, 2015, the Company posted 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 99.2. The Company may use the investor presentation from time to time in conversations with analysts, investors and others.

The information in Item 7.01 of this Form 8-K, as well as Exhibit 99.2 attached hereto, shall not be deemed "filed" for the purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

The information contained in Exhibit 99.2 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 or other reports or documents with the SEC, through press releases or through other public disclosure.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit 99.1 Press Release dated October 1, 2015.

Exhibit 99.2 MRI Interventions, Inc. investor presentation dated October 1, 2015

#### **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 1, 2015 MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer

#### INDEX TO EXHIBITS

Exhibit

Number Exhibit 99.1 <u>Description</u>
Press Release dated October 1, 2015.

Exhibit 99.2 MRI Interventions, Inc. investor presentation dated October 1, 2015



Contact: Harold A. Hurwitz, Chief Financial Officer (949) 900-6833

#### For Immediate Release

#### MRI INTERVENTIONS, INC. ANNOUNCES 2015 THIRD QUARTER REVENUES

**IRVINE**, **CA**, October 1, 2015 – MRI Interventions, Inc. (OTCQB: MRIC) today announced its revenues for the third quarter and nine months ended September 30, 2015.

#### **Quarter Ended September 30, 2015**

Revenues were \$1.25 million for the three months ended September 30, 2015, and \$633,000 for the same period in 2014, an increase of \$613,000, or 97%, attributable to increases in the Company's ClearPoint® System reusable and disposable products.

ClearPoint disposable product sales for the three months ended September 30, 2015 were \$970,000, compared with \$577,000 for the same period in 2014, representing an increase of \$393,000, or 68%. This increase was due primarily to a greater number of procedures performed using the ClearPoint system within a larger installed base for ClearPoint, relative to the 2014 period.

ClearPoint reusable product sales for the three months ended September 30, 2015 were \$239,000, and \$11,000 for the same period in 2014. Reusable products consist primarily of computer hardware and software bearing sales prices that are appreciably higher than those for disposable products and historically have fluctuated from quarter to quarter.

#### Nine Months Ended September 30, 2015

Revenues were \$3.08 million for the nine months ended September 30, 2015, and \$2.64 million for the same period in 2014, an increase of \$437,000, or 17%, primarily attributable to growth in the Company's disposable products sales, driven by growth in ClearPoint enabled procedures.

ClearPoint disposable product sales for the nine months ended September 30, 2015 were \$2.49 million, compared with \$1.91 million for the same period in 2014, representing an increase of \$580,000, or 30%. This increase is due primarily to the aforementioned growth in procedures and the size of the ClearPoint system installed base.

ClearPoint reusable product sales for the nine months ended September 30, 2015 were \$469,000, compared with \$492,000 for the same period in 2014, representing a decrease of \$23,000, or 4%.

The Company plans a full release of its results for the three and nine months ended September 30, 2015 on or about the end of October 2015.

5 Musick, Irvine, California 92618 949.900.6833

#### **Management's Comments**

"We had a strong third quarter, and are pleased to see significant growth in disposable product sales, driven by an increase in ClearPoint enabled procedures," said Frank Grillo, Chief Executive Officer. "With 2015 third quarter revenues nearly double those of the same quarter in 2014, and more than 50% greater than the 2015 second quarter revenues, we are pleased to share this news with our investors. We had several significant accomplishments this quarter, including record high disposable product sales, record high quarterly revenue, the award of a Phase II grant from the National Institutes of Health, completion of our corporate restructuring, and continued growth in the adoption of our technology. This week, we attended the Congress of Neurological Surgeons in New Orleans, where interest in our technology and its use with laser ablation, electrode placement, drug delivery and biopsy continues to grow. We look forward to reporting our full results of operations later this month, and providing further updates on the progress we are making in our business."

#### **About MRI Interventions, Inc.:**

Building on the imaging power of MRI, MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain and heart. The Company's ClearPoint® 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. In partnership with Siemens Healthcare, MRI Interventions is developing the ClearTrace® System to enable MRI-guided catheter ablations to treat cardiac arrhythmias. For more information, please visit www.mriinterventions.com.

#### **Forward-Looking Statements**

Statements herein concerning the Company'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. The Company's actual results may differ materially from those suggested as a result of various factors. Particular uncertainties and risks include those relating to: future revenues from sales of the Company's ClearPoint system products; the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint system products; estimates regarding the sufficiency of the Company's cash resources; and the Company's ability to obtain additional financing. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" sections of the Company's Form 10-K for the year ended December 31, 2014 and the Company's Form 10-Q for the quarter ended June 30, 2015, both of which have been filed with the Securities and Exchange Commission.



Ticker: MRIC

Investor Presentation

October 1, 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 Market

- · Market is large and growing
  - 55,000 potential ClearPoint procedures across multiple therapies

## **Navigation System** for Multiple **Therapies**

- · Electrode placement for Deep Brain Stimulation
- · Laser Ablation for ablation of epileptic foci or Brain Tumors
- · Brain Tumor Biopsy for deep seated tumors
- · Precise Drug Delivery to target lesions

## **Large Opportunity Attracting Multiple Players**

- · Area of interest to large medical device companies
  - · Medtronic, St. Jude and Boston Scientific investing in neuro market
  - · MRI Scanner Companies embracing MRI-guided therapies
  - · Drug Companies pursuing direct delivery

### Uniquely **Positioned**

- · Focused commercial effort; FDA/CE approved products
  - · Delivery platform for multiple therapies
  - · Strong, proprietary position
  - · Recent restructuring complete

# **MRI Interventions:** Real Time MRI Guided Surgery



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**





# Technology: ClearPoint® Neuro Navigation System



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

### Visualize

Identify target

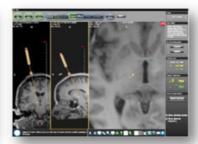
### Verify

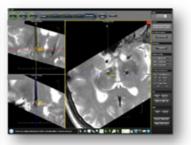
Observe progress to target

### Confirm

Confirm precise placement at target







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

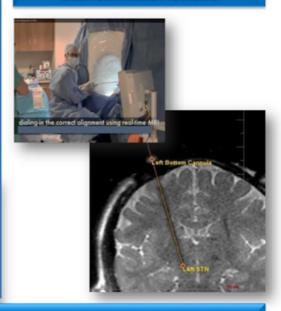






No real-time visualization

#### **ClearPoint Neuro Procedure**



Next generation platform enabling real-time, MRI-guided, minimally invasive brain surgery

# ClearPoint® Neuro Navigation System 1.5T or 3T MR Scanners, also works in intraop MRI Suites





#### MRI Safe Disposable Components:

SmartGrid® and SmartFrame® – Integrated ClearPoint Targeting and Trajectory Precision

ClearPoint® Drape provides sterile procedural field in any diagnostic or intraoperative MRI scanner









**UCSF Medical Center** 



University of Pittsburgh Medical Center



Brigham and Women's Hospital\*

\* Image courtesy of IMRIS

**Integrates with All Major Scanner Platforms** 

**SIEMENS** 

**PHILIPS** 

GE Healthcare

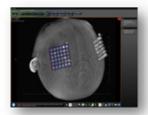
IMRIS 🔾

BrainSUITE

# **ClearPoint Procedure Overview**

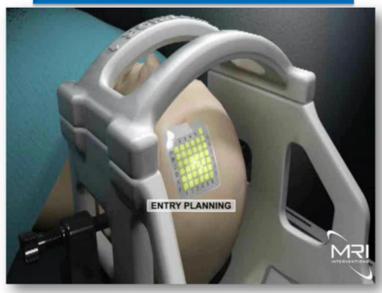








## Target Selection & Entry Planning



# **ClearPoint Procedure Overview**



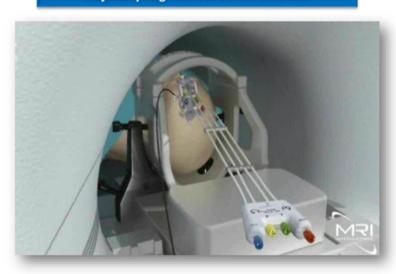
SmartFrame® Trajectory Guide



SmartFrame® Hand Controller



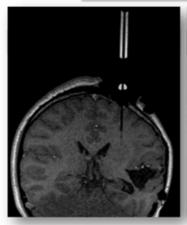
# **Trajectory Alignment & Device Insertion**

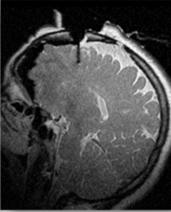


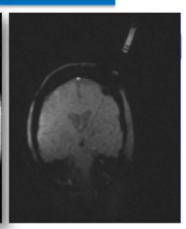
# **ClearPoint Procedure Overview**



# **Delivery of Neurological Therapy**







Drug Delivery1

**Electrode Placement** 

Laser Ablation<sup>2</sup>

- 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(2)
- 1 hour of MR scanner time used for a ClearPoint procedure could generate \$5,275(3)
- Utilizes existing MRI's already in hospital



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

<sup>(2)</sup> 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>(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 MRI Interventions using a payor mix weighted 67% to average Medicare reimbursement and 33% to average private insurance reimbursement. Average Medicare reimbursement calculated 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. Howly 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**







Dr. Paul Larson UCSF & VA



Dr. Robert Gross Emory University



Dr. Robert Wharen, Jr. Mayo Clinic -Jacksonville



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



Dr. Russ Lonse OSU - NIH

### Strong Peer-Reviewed Journal Support











### Compatible With Multiple Therapies





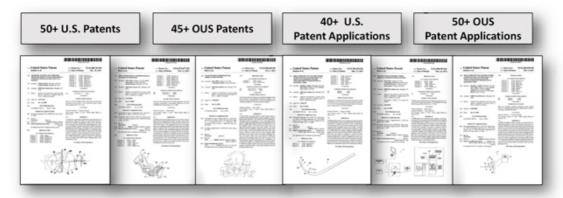






### **Strong Intellectual Property** Close to 100 issued patents around the world





- 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



# Martin's Story ClearPoint-Enabled Electrode Placement



# Patient Benefit – Minimally Invasive Procedure

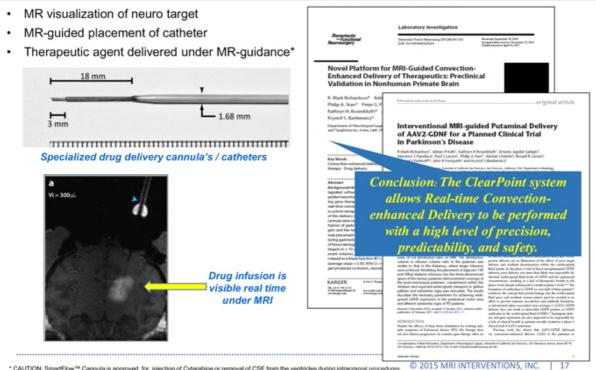


# 7 days after ClearPoint procedure – Arrow Indicates Surgery Site



# **ClearPoint Drug Delivery**





\* CAUTION: SmartFlow™ Cannula is approved for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. 

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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 in an MRI Suite
Patient may be awake for own brain surgery(1)	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 warning within ClearaPoint'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.

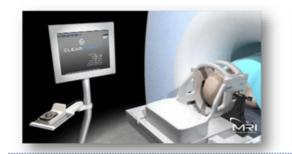
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# **ClearPoint Revenue Model**



# 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





# **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 Resistant (DTR)	125,000	264,000	
Incidence – DTR	7,500	18,000	Resections: 80,000 Stereotactic Biopsy: 10,000
ClearPoint Enabled Therapy	Electrode Placement (DBS)	Laser Ablation RNS <sup>1</sup>	Biopsy / Laser Ablation / Drug Delivery
Potential ClearPoint 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 based upon 5% of prevalence and 85% of incidence; Potential Annual ClearPoint Procedures for brain tumors based on market research conducted by a third party on behalf of MRI interventions.

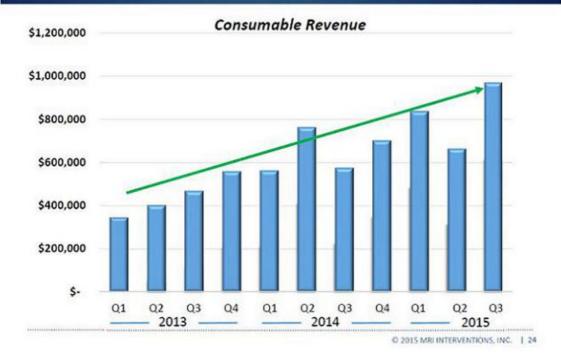
# ClearPoint Future Opportunities Multiple Therapies for Future Growth



<u>Neuro Disorder</u>	<u>Patient</u> <u>Population</u>	Treatment Resistant Patient Population	<u>ClearPoint Enabled</u> <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 Disease	1,500,000	125,000	Drug Delivery	Clinical Trials – Phase 1
Brain Tumors (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



## **Commercial Priorities**



#### Increase Utilization

- Focus on adding surgeons at existing accounts
- Target high volume sites, including epilepsy and tumor neurosurgeons within each account; gain greater share of their procedures
- Add Clinical Specialists and sales reps to commercial team; compensate for utilization growth

#### Enhance Communication

- Increase peer-to-peer events, presence at trade shows
- Highlight existing data on ClearPoint applications to neurologists and neurosurgeons
- Communicate value proposition across procedures:
  - Accuracy
  - Real time visualization
  - Improved workflow
  - Increase patient volume

#### **Expand Account** Base

- Identify highest volume potential accounts across multiple procedures
- Support local hospital marketing efforts
- Capitalize on interest in drug delivery to expand in oncology accounts
- Add sales reps

#### Achieve Cash **Breakeven**

- Tightly control working capital, consumption of cash
- Hire additional personnel only in key functions commercial team; engineering

## **R&D Priorities**



Software 2.0

- Significant upgrade to existing software; includes real time fusion, enhanced graphic and User Interface
- Technology licenses near complete with three additional software companies for this effort





**OR SmartFrame** 

Through partnership(s), expand our products and brand into the operating room for CT based neuro procedures





**Drug Delivery** 

- Establish additional drug delivery partnerships, and participate in additional clinical trials
- Become the neuro drug delivery device partner of choice



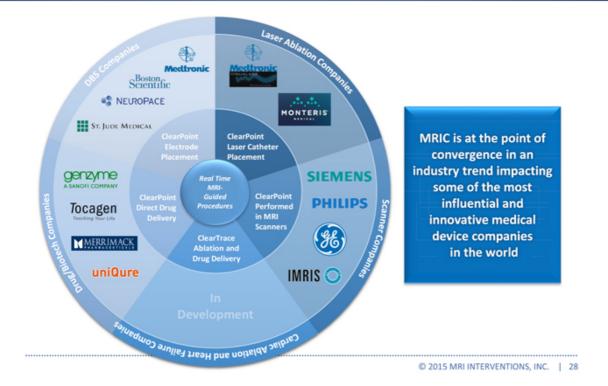
**Procedure Enhancements**  Continue to enhance product line with a focus on procedure simplification and consistency



**Bolt Driver** for Laser Ablation

# At the Center of an Emerging Industry Trend





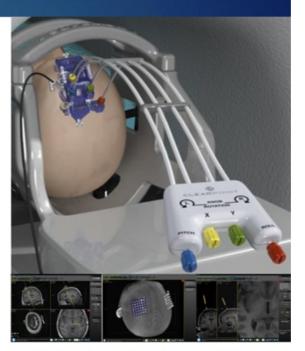


Ticker: MRIC

MRI Interventions, Inc. Irvine, CA

949.900.6833

mriinterventions.com



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