# 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): March 24, 2016

## 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) 900-6833 (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))				

#### Item 7.01. Regulation FD Disclosure

On March 23, 2016, MRI Interventions, Inc. (the "Company") posted an updated investor presentation to its website at http://ir.stockpr.com/mriinterventions/investor-presentation. 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 information in Item 7.01 of this Form 8-K, as well as Exhibit 99.1 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 99.1 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 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 MRI Interventions, Inc. investor presentation dated March 23, 2016

#### **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: March 24, 2016 MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer

#### INDEX TO EXHIBITS

Exhibit Number	Description
Exhibit 99.1	MRI Interventions, Inc. investor presentation dated March 23, 2016



Ticker: MRIC

## Investor Presentation

March 23, 2016



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 its filings with the Securities and Exchange Commission. 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**



#### **Market Potential**

- · Market potential
  - · 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

#### Opportunity to **Attract 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 in neurosurgery; FDA/CE approved products
  - · Delivery platform for multiple therapies
  - · Established, proprietary IP 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; recent restructuring complete

Attractive razor/razorblade business model with strong potential margins

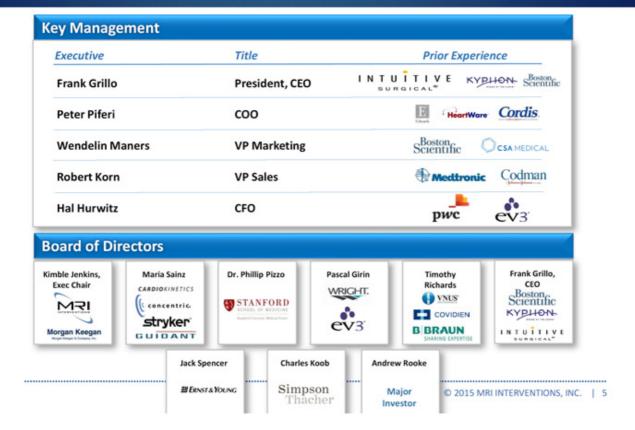
Compatible with all major MRI manufacturers; Interoperability w/ Medtronic, Monteris, neuro products

Established intellectual property portfolio

Professional management team with relevant medical device commercialization experience: Intuitive, Medtronic, Kyphon, Boston Scientific, ev3, Edwards Lifescience, Cordis

## Leadership – A History of 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

#### <u>Visualize</u>

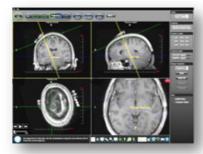
Identify target

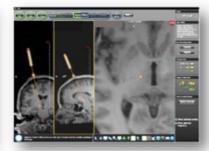
#### Verify

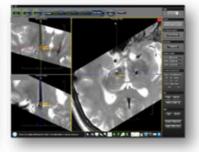
Observe progress to target

## Confirm

Confirm precise placement at target







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

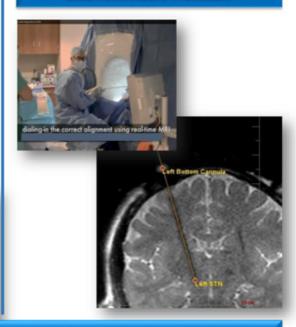


#### **Conventional Stereotactic Procedure**



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 O

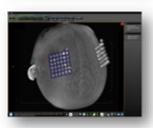
BrainSUITE

## **ClearPoint Procedure Overview**

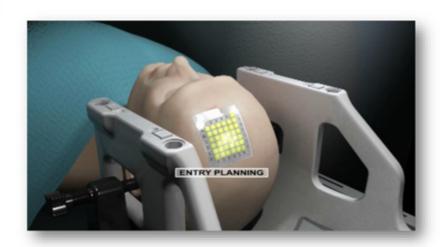








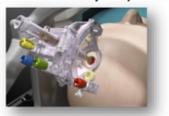




## **ClearPoint Procedure Overview**



SmartFrame® Trajectory Guide



SmartFrame® Hand Controller



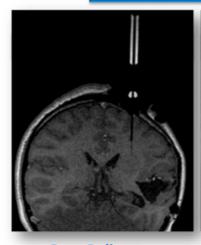
**Trajectory Alignment & Device Insertion** 

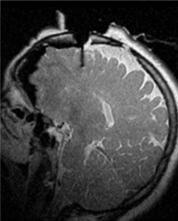


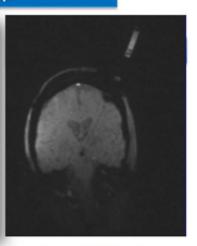
#### **ClearPoint Procedure Overview**



#### **Delivery of Neurological Therapy**







Drug Delivery<sup>1</sup>

**Electrode Placement** 

Laser Ablation<sup>2</sup>

- (1) Drug Delivery The SmartFlow\* cannula received \$10(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.
- (2) 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**

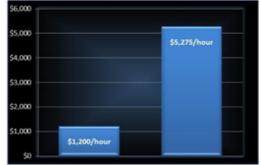
- Better potential patient experience provides hospitals the opportunity to reach additional patient populations that may otherwise forego surgery
- 65% of eligible DBS patients refuse treatment, due to fear of surgery(1)

#### **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



- (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.
- (3) 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% or average private insurance reimbursement. Average Medicare reimbursement calculated a 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**



#### **Notable Neurosurgeon Supporters**



Dr. Philip Starr ASSFN Past President



Dr. Paul Larson UCSF & VA



Dr. Robert Gross Emory University



Dr. Robert Wharen, Jr. Mayo Clinic -Jacksonville



Bankiewicz Lab, UCSF



OSU - NIH

#### Published Peer-Reviewed Journal Support













Compatible With Multiple Therapies





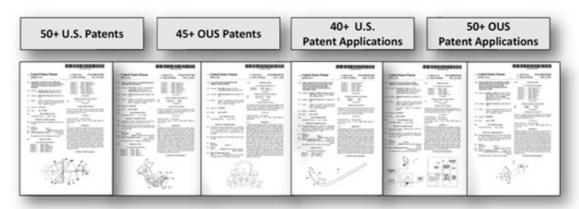






#### **Patented Intellectual Property** Close to 100 issued patents around the world

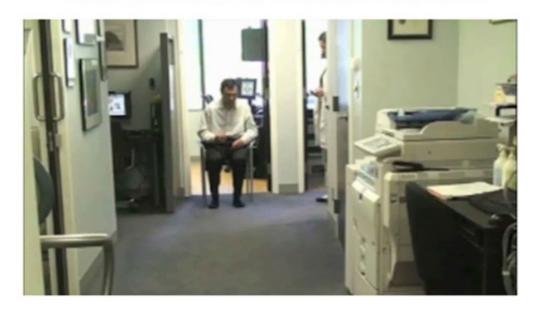




- Issued patents cover areas such as: MRI-guided surgical systems that include software and devices; the SmartFrame® trajectory guide; other ClearPoint® disposable components; active intracranial probes; MRI-compatible catheters and Hand Drill; MRI-safety technology; Scalp Mount Base
- Key ClearPoint-related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



## Martin's Story ClearPoint-Enabled Electrode Placement



## Patient Benefit - Minimally Invasive Procedure

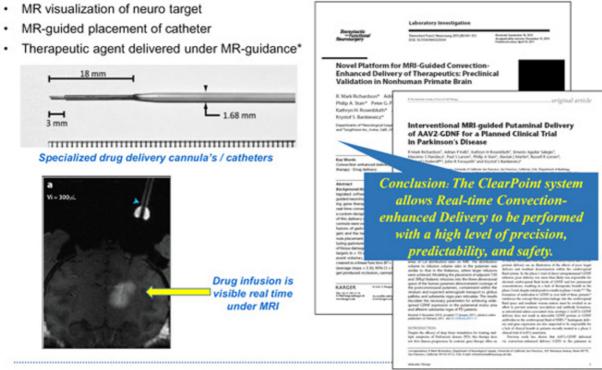


#### 7 days after ClearPoint procedure - Arrow Indicates Surgery Site



#### **ClearPoint Drug Delivery**





\* CAUTION: SmartFlow™ Cannula is approved for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures.
Uses other than the approved indication are limited by Federal law to investigational use.

#### MRIC's Unique Opportunity for Drug Delivery



#### Major Challenges in Delivering Drugs to the Brain

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

#### Major Benefits of Drug Delivery with ClearPoint

- Neurosurgeon can see 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	
Accuracy to target based on prior images	Highly accurate, based on real time images	
Patient may be awake for own brain surgery(1)	Patient may be under general anesthesia(1)	
Long OR time for the patient – Can be up to 8 hours	Shorter procedures – Can be 3 hours or less	
May require OR and MRI for same procedure (laser ablation)	MRI only procedure - 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** 

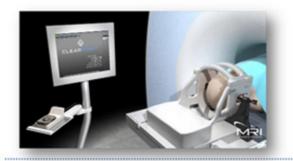
(1) Microelectrode recording and macrostim are processes that involve listening to neuronal firings (i.e., physiological recordings) and observing physiological responses to stimuli during brain surgery. In connection with our \$10(k) clearance in 2010, the FDA requested a warning within ClearPoint's 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.

#### **ClearPoint Revenue Model**



#### **BUSINESS MODEL - RAZOR / RAZORBLADE**

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





## Growing the ClearPoint Footprint

Installed Base of 40 sites in the US





Europe: Warsaw, Poland

## **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.

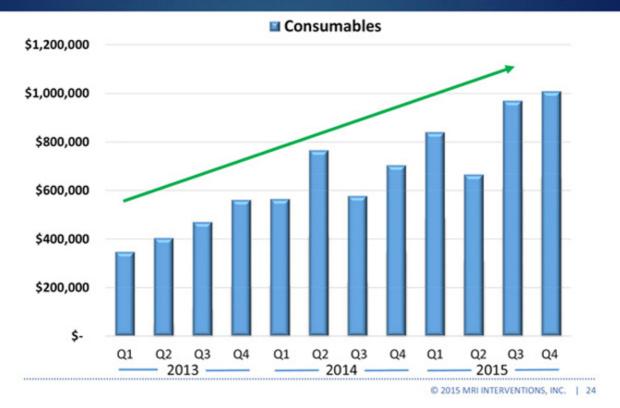
# ClearPoint Future Opportunities Multiple Therapies for Future Growth



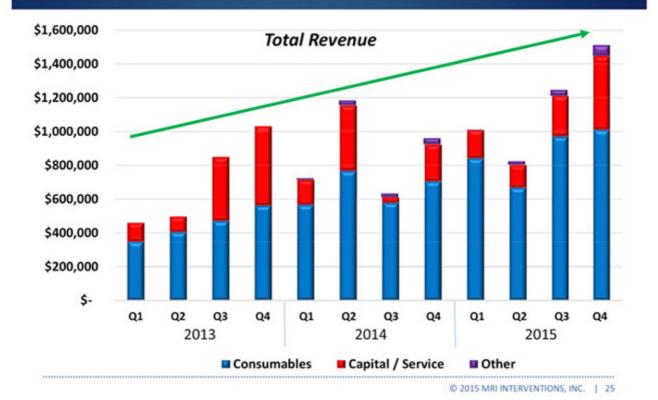
<u>Neuro Disorder</u>	<u>Patient</u> <u>Population</u>	Treatment Resistant Patient Population	<u>ClearPoint Enabled</u> <u>Therapy</u>	<u>Current Status</u>
Dystonia	250,000	25,000	DBS	Active Use, HDE
OCD	3,300,300	100,000	DBS	Active Use, HDE
Severe Depression	6,000,000	1,200,000	DBS	IDE Trials (DBS)
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**



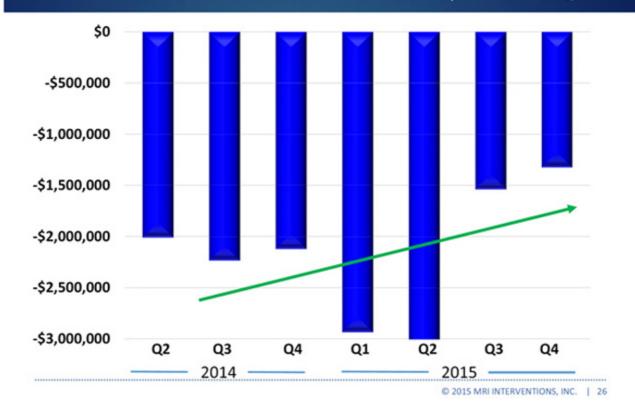


## Total Revenue, 2013 - 2015



## **Cash Flow From Operations**





#### **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

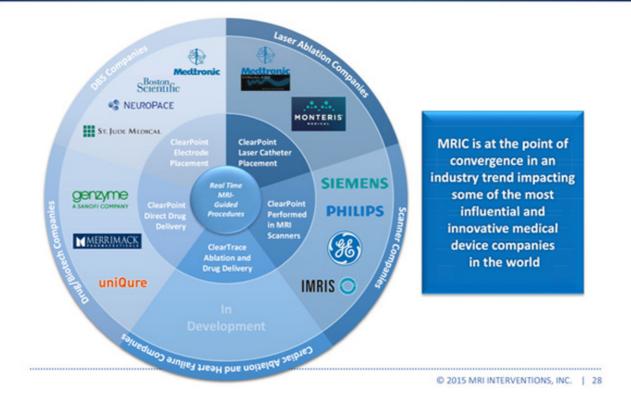
- Identify highest volume potential accounts across multiple procedures
- Support local hospital marketing efforts
- Capitalize on interest in drug delivery to expand in oncology accounts
- Add sales reps

#### **Achieve Cash Breakeven**

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

## 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