### 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): August 18, 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

D 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 August 18, 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 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 August 18, 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: August 18, 2016

#### MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer

#### INDEX TO EXHIBITS

ExhibitDescriptionNumberDescriptionExhibit 99.1MRI Interventions, Inc. Investor Presentation dated August 18, 2016



Ticker: MRIC

Investor Presentation August 18, 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, we undertake no obligation to publicly update or revise any forward-looking statements made in this presentation to reflect any change in our expectations or any change in events, conditions or circumstances on which any such statements are based.

# MRI Interventions Investment Opportunity



Commercial	<ul> <li>Focused commercial effort in neurosurgery; FDA/CE cleared products</li> </ul>
Business	<ul> <li>Enabling real-time MRI guided surgery; FDA-cleared, CE- marked and 45+ ClearPoint sites; growing procedure business</li> </ul>
Drug Delivery	Growing Presence in Drug Delivery
Upside	ClearPoint System now in 7 clinical trials; biotech like upside
	Restructuring complete; operating cash burn dramatically lower.
Investment Timing	Several near-term milestones:
	<ul> <li>1 for 40 reverse split completed in July 2016</li> <li>St. Jude's entry into the DBS market in the US</li></ul>
	<ul> <li>St. Jude's entry into the DBS market in the US – Q3/Q4 2016*</li> <li>Voyager reports results of first 10 patients – Q4, 2016*</li> </ul>
	<ul> <li>UniQure initiates second cohort of Phase 1 trial – Q1, 2017*</li> </ul>
	<ul> <li>Additional drug delivery partnerships under evaluation</li> </ul>
* Estimated date	© 2016 MRI INTERVENTIONS, INC.   3

# Experienced, Medical Device Leadership Team



Executive Frank Grillo Peter Piferi Wendelin Maners Robert Korn Hal Hurwitz		Title		Prior Experience			
		President, CEC					
		c00					
		VP Marketing		Scientific Cosa Medica			
		VP Sales					
		CFO		рис			
Board of Di	rectors						
Kimble Jenkins, Chairman	Maria Sainz CARDIOKINETICS (concentric Stryker GUIDANT	Dr. Phillip Pizzo	Pascal Girin WRIGHT.	Timothy Richards VILLS COVIDIEN BRAUN SHAMO EXPERTSE	Frank Grillo, CEO Scientific KYPHON-		
	Jack Sp	encer Charles	Koob Andre	ew Rooke			

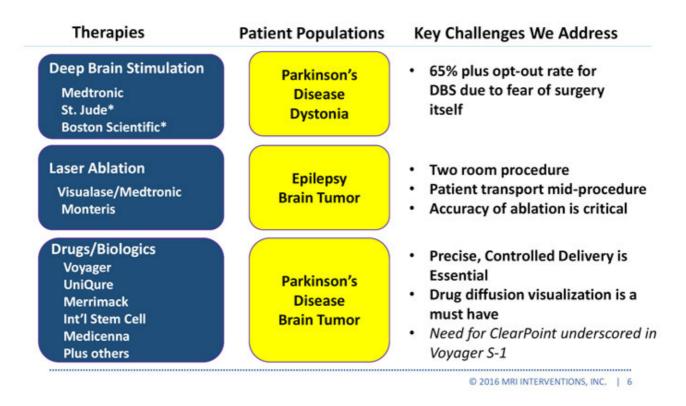
### ClearPoint<sup>®</sup> Neuro Navigation System Utilizes an existing diagnostic or intraoperative MRI to enable real time, intra-operative MRI Imaging during Neurosurgery



CLEARPOINT	• P d	<ul> <li>ClearPoint Software         <ul> <li>Proprietary software for targeting and trajectory calculation / determination</li> <li>Dicom image based</li> </ul> </li> </ul>					
	MRI Safe Hardware     MRI safe head fixation frame, monitor, other components for the procedure						
<ul> <li>SmartFrame®; SmartGrid®</li> <li>Single use devices, with MRI fiducials "seen" in MRI images enable targeting and trajectory calculations</li> <li>Proprietary drape for creating sterile environment</li> <li>Per procedure revenue</li> </ul>							
Compatible with All Major MRI Platforms							
SIEMENS	HILIPS	GE Healthcare	IMRIS O	BrainSUITE			
			© 201	16 MRUNTERVENTIONS, INC. 1.5			

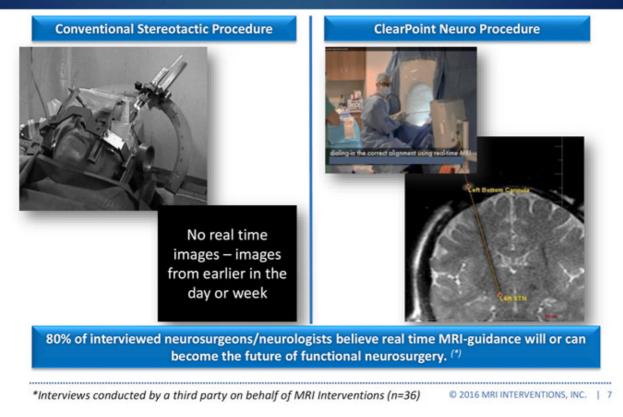
# Key Procedures for Our Technology ... and the challenges we address





### 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



# **Clinical Support, Validation**



#### 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



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



Dr. Russ Lonse OSU - NIH

#### Published Peer-Reviewed Journal Support



### Patented Intellectual Property Over 100 issued patents around the world



70+ U.S. Pater	nts 45+ 0	OUS Patents	20+ U.S. Patent Applicat	Construction and the second second	30+ OUS Patent Applications	

- 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

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

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

- Blood brain barrier blocks systemic delivery (pills, shots, IV) 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

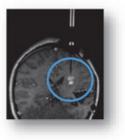
#### Major Benefits of Drug Delivery with ClearPoint

- 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 volume)

#### **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

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



# ClearPoint Drug Delivery w/ SmartFlow Cannula



· MR visualization of neuro target Growing Set of Peer-reviewed Publications... MR-guided placement of catheter • Therapeutic agent delivered under MR-guidance\* ٠ Stareptactic -- Function Neurosurgery 18 mm iginal article Novel Platform f Enhanced Delive Validation in No Interventional MRI-guided Putaminal Delivery of AAV2-GDNF for a Planned Clinical Trial in Parkinson's Disease - 1.68 mm 3 mm Peter G. tof 5. Bankle Adrian P.Kells', Katheyn H.Rosenble, Paul S.Larsov', Philip A.Stan', Ala John B.Forseyeth' and Koydol S.Ro 0<sup>7</sup>, Emerio Agailar Salego<sup>2</sup>, Gar J Martin<sup>2</sup>, Russell R Lonser<sup>3</sup>, Specialized, FDA-cleared drug delivery cannula's / Conclusion: The ClearPoint system catheters allows Real-time Convectionenhanced Delivery to be performed with a high level of precision, predictability, and safety. Influsion volume
 Post in the shale
 most Micheline # 22 Drug infusion is teril anterroy entra regre part set many parameters i remon in the put remon of PO p pathths and safe elucidate the nec-spread GDNF exp and attenut safe visible under realtime MRI one 2018, accepted 17 private 2011 KARGER CTODE of day form standards for tracing suit officies of day form standards for tracing suit one of Padismuch disease (PD), the theory days of the same programments for system gas theory offers on the Long Lange and Longe A ind of A.RVD sensitians. one work has shown that A.RVD (2002) and Companying & Mari Roberton, Department of

\* CAUTION: SmartFlow<sup>TM</sup> Cannula is approved for injection of Cytarabine or removal of CSF from the ventricles during intracranial procedures. © 2016 MRI INTERVENTIONS, INC. | 13 Uses other than the approved indication are limited by Federal law to investigational use.

### ClearPoint's Use in Drug Delivery Seven Programs Underway Now...



<b>Current Drug Delivery Trials Utilizing the ClearPoint System:</b>					
	<ul> <li>AAV2-hAADC for Parkinson's disease</li> <li>Phase 1 Study at UCSF Initial sponsorship by Michael J. Fox Foundation</li> </ul>		OLAL INSTITUTES	<ul> <li>IL13 for Brain Tumor</li> <li>Phase 1 study at the NIH</li> </ul>	
uniQure	AAV2-GDNF for Parkinson's disease • Phase 1 Study at the NIH		of the course charter	Radio Immunotherapy for Brain Tumor • Phase 1 Study at MSK	
	MDNA55 for Recurrence or Progression of Glioblastoma • Preparing Phase 2		MERRIMACK	Nanoliposomal Irinotecan for Brain Tumor • Phase 1 Study at UCSF	
	Human Parthenogenetic Stem Cell-Derived Neural Stem Cells for Parkinson's disease • Pre-clinical leading to Ph. 1				

The ClearPoint System is being used in the ongoing Phase 1b clinical trial of VY-AADC01 as a treatment for advanced Parkinson's disease, and we expect to continue to use the ClearPoint System in future clinical trials of VY-AADC01 and any other of our product candidates that are injected directly into the brain. <u>IPO S-1</u>, Voyager Therapeutics

# **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 44 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

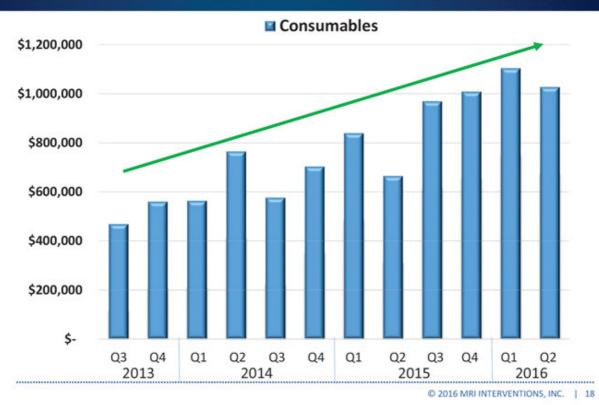
Note: Prevalence and incidence based on either market research conducted by a third party on behalf of MRI Interventions or research conducted by MRI Interventions of publicly

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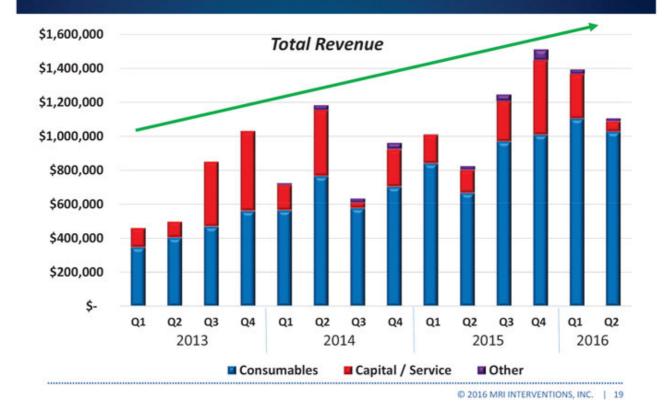
Note: Prevalence and incidence our cost of the second state of the

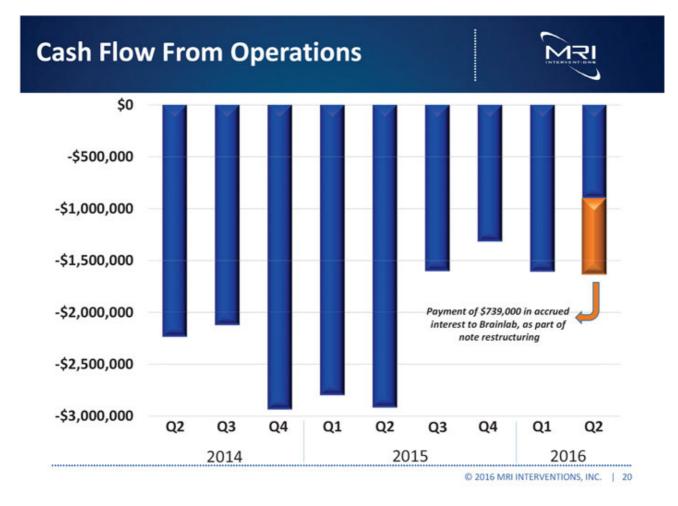
**ClearPoint Consumable Revenues** 





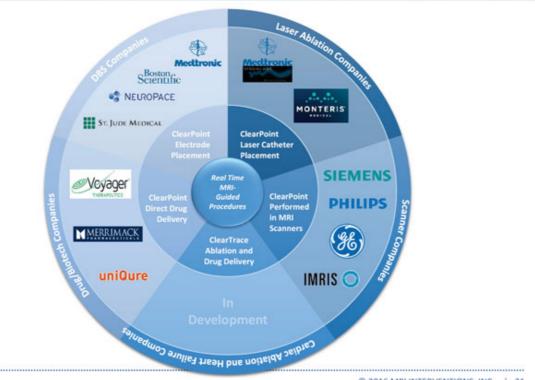
# Total Revenue, 2013 - 2016





# Leading a New, Emerging Industry Trend







#### Ticker: MRIC

MRI Interventions, Inc. Irvine, CA

949.900.6833

www.mriinterventions.com



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