### 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): November 3, 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)

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))

D 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 November 3, 2015, MRI Interventions, Inc. (the "Company") issued a press release announcing its 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 November 3, 2015, the Company posted an updated investor presentation to its website at <u>http://ir.stockpr.com/mriinterventions/presentations</u>. 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 November 3 2015.

Exhibit 99.2 MRI Interventions, Inc. investor presentation dated November 3, 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: November 3, 2015

#### MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer

#### INDEX TO EXHIBITS

Exhibit	
Number	Description
Exhibit 99.1	Press Release dated November 3, 2015.
Exhibit 99.2	MRI Interventions, Inc. investor presentation dated November 3, 2015



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

For Immediate Release

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

**IRVINE, CA,** November 3, 2015 – MRI Interventions, Inc. (OTCQB: MRIC) today announced financial results for the third quarter ended September 30, 2015.

#### Quarter Ended September 30, 2015

Revenues were \$1.2 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<sup>®</sup> 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.

Gross margin on product revenues was 54% for the three months ended September 30, 2015, compared to 46% for the same period in 2014. The improvement was attributable primarily to increased average unit selling prices, decreased unit costs and greater production efficiencies arising from increased volume in the 2015 period, relative to the 2014 period.

Research and development costs were \$480,000 for the three months ended September 30, 2015, compared to \$873,000 for the same period in 2014, a decrease of \$393,000, or 45%. Approximately \$229,000 of the decrease related to reduced spending on the Company's ClearTrace development program, and \$61,000 related to reductions in sponsored research.

Selling, general and administrative expenses were \$2.1 million for each of the three-month periods ended September 30, 2015 and 2014.

During the three months ended September 30, 2015, the Company recorded a gain of \$1.95 million, and during the three months ended September 30, 2014, it recorded a loss of \$781,000, from changes in the fair value of derivative liabilities associated with certain warrants the Company issued in private placement transactions.

5 Musick, Irvine, California 92618 949.900.6833

#### Nine Months Ended September 30, 2015

Revenues were \$3.1 million for the nine months ended September 30, 2015, and \$2.6 million for the same period in 2014, an increase of \$438,000, 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 \$2.5 million, compared with \$1.9 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 5%.

Gross margin on product revenues for the nine months ended September 30, 2015 was 55%, compared to gross margin of 49% for the corresponding period in 2014. The improvement was attributable primarily to increased average unit selling prices, decreased unit costs and greater production efficiencies arising from increased volume in the 2015 period, relative to the 2014 period.

Research and development costs were \$1.4 million for the nine months ended September 30, 2015, compared to \$2.6 million for the same period in 2014, a decrease of \$1.2 million, or 45%. Approximately \$592,000 of the decrease related to a reduction in spending on the Company's ClearTrace development program and \$200,000 related to reductions in sponsored research.

Selling, general and administrative expenses were \$6.6 million for the nine months ended September 30, 2015, compared with \$5.8 million for the same period last year, an increase of \$817,000, or 14%. The increase was primarily attributable to an increase during the nine months ended September 30, 2015 in cash compensation costs of approximately \$466,000, a portion of which was associated with overlapping executives' terms of employment so as to provide for a coordinated transition of duties during the period in which the Company, as previously announced, consolidated its business functions into its Irvine, California headquarters and closed its executive offices in Memphis, Tennessee. Also contributing to the increase was an increase in share-based compensation of \$417,000.

In March 2015, the Company announced the consolidation of all major business functions into its Irvine, California headquarters. In connection with this consolidation, the Company closed its Memphis, Tennessee office in May 2015. The Company did not retain any of its Memphis-based employees. A total of seven employees were impacted by the consolidation, including three executives, whose termination of employment triggered a modification in the terms of stock options previously granted to them. In connection with this consolidation, the Company recorded restructuring charges of \$1.3 million during the nine months ended September 30, 2015, primarily related to severance costs, and to the revaluation of the stock options with modified terms and the resulting accrual of additional sharebased compensation expense.

During the nine months ended September 30, 2014, the Company recorded a gain of \$4.3 million related to the sale of certain intellectual property to Boston Scientific. The purchase price was satisfied through the cancellation of related party convertible notes payable the Company previously issued to Boston Scientific in the aggregate principal amount of \$4.3 million. The Company recorded a gain equal to the purchase price, as the assets sold had not been previously recorded on its balance sheet.

During the nine months ended September 30, 2015 and 2014, the Company recorded gains of \$981,000 and \$578,000, respectively, resulting from changes in the fair value of derivative liabilities associated with certain warrants the Company issued in private placement transactions.

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

"We are pleased with the business's progress as reflected in our third quarter results. Revenues showed strong growth overall, and in particular, ClearPoint disposables in the 2015 third quarter grew 68% from the same period in 2014, while total revenue grew 97%. This reflects the growing procedural adoption of ClearPoint, and the impact of laser ablation on our business. Laser cases in Q3 were once again nearly a quarter of our mix, with application in both tumor and hippocampal ablation cases. Surgeons are recognizing our strong value proposition in laser ablation, and we expect these cases will be an increasingly larger portion of our procedures.

"We exhibited at the Congress of Neurological Surgeons meeting in New Orleans in September, and interest in the use of our products for laser ablation was particularly high. At a "lunch and learn" we co-sponsored with Medtronic, more than 140 attendees were present to hear leading neurosurgeons speak to their experience with ClearPoint in a variety of procedures, including electrode placement, laser ablation and drug delivery. We have had several recent inquiries regarding participation in additional drug delivery trials, and expect to move forward on these in the next couple of quarters.

"This was our first full quarter as a newly focused company headquartered in Irvine, CA. The efforts we have made in focusing and streamlining the Company are reflected in noticeably lower cash utilization for operating activities, which was \$1.6 million in Q3. This is a reduction of more than 40% from each of the last two quarters, and we expect to see continued efficiencies going forward.

"As we enter the fourth quarter of the year, we see growing adoption of our technology, greater efficiency in our company, and numerous opportunities for additional drug delivery partnerships. Our revenue was up 97%, and our expenses were down significantly. We are focused and well positioned to create the future of MRI guided neuro-navigation for a variety of neurosurgical procedures."

#### **Teleconference Information:**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2015 third quarter financial results today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) that may be accessed by visiting the Company's website at <u>www.mriinterventions.com</u> and selecting "Investors" / "News" / "IR Calendar." The conference call may also be accessed at <u>http://mriinterventions.equisolvewebcast.com/q3-2015</u>. Investors and analysts who would like to participate in the conference call may do so via telephone at (877) 407-9034, or at (201) 493-6737 if calling from outside the U.S. or Canada.

For those who cannot access the live broadcast, a replay will be available shortly after the completion of the call until November 9, 2015 by calling (877) 660-6853, or (201) 612-7415 if calling from outside the U.S. or Canada, and then entering conference I.D. number 413671. An online archive of the broadcast will be available on the Company's website at <u>www.mriinterventions.com</u>, on the "Investor Relations" page.

#### 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 <u>www.mriinterventions.com</u>.

#### **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: the Company's ability to obtain additional financing; estimates regarding the sufficiency of the Company's cash resources; future revenues from sales of the Company's ClearPoint system products; and the Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint system products. More detailed information on these and additional factors that could affect the Company's actual results are described in the "Risk Factors" section of the Company's Form 10-K for the year ended December 31, 2014 and Form 10-Q for the quarter ended June 30, 2015, both of which have been filed with the Securities and Exchange Commission, as well as the Company's Form 10-Q for the quarter ended September 30, 2015, which will be filed with the Securities and Exchange Commission on or about November 16, 2015.

(tables follow)

#### MRI INTERVENTIONS, INC. Condensed Consolidated Balance Sheets (Unaudited)

	Se	ptember 30, 2015	De	ecember 31, 2014
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	1,851,862	\$	9,244,006
Accounts receivable		837,441		468,949
Inventory, net		1,802,818		1,965,039
Prepaid expenses and other current assets		133,341		29,220
Total current assets		4,625,462		11,707,214
Property and equipment, net		495,084		482,970
Software license inventory		919,600		910,000
Other assets		232,982		285,498
Total assets	\$	6,273,128	\$	13,385,682
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$	640,637	\$	997,090
Accrued compensation		459,142		323,644
Other accrued liabilities		1,092,112		1,297,712
Derivative liabilities		1,216,939		2,198,162
Deferred product and service revenues		165,562		102,710
Senior secured note payable, net of unamortized discount of \$118,342		4,171,103		-
Total current liabilities		7,745,495		4,919,318
Accrued interest		524,625		876,025
Senior secured note payable, net of unamortized discount of \$271,305		-		4,018,138
2014 junior secured 12% notes payable, net of unamortized discount of \$317,364 and \$369,299 at				
September 30, 2015 and December 31, 2014, respectively		3,407,636		3,355,701
2010 junior secured notes payable, net of unamortized discount of \$2,582,256 and \$2,683,171 at				
September 30, 2015 and December 31, 2014, respectively		417,744		316,829
Total liabilities	_	12,095,500		13,486,012
Commitments and contingencies				
Stockholders' deficit:				
Common stock, \$0.01 par value; 200,000,000 shares authorized; 74,971,026 shares issued and				
outstanding at September 30, 2015; and 74,842,428 issued and outstanding at December 31, 2014		749,709		748,424
Additional paid-in capital		77,956,063		76,428,580
Accumulated deficit		(84,528,144)		(77,277,334)
Total stockholders' deficit		(5,822,372)		(100,330)
Total liabilities and stockholders' deficit	\$	6,273,128	\$	13,385,682

#### MRI INTERVENTIONS, INC. Condensed Consolidated Statements of Operations (Unaudited)

	Fo	For The Three Months Ended September 30,		
		2015		2014
Revenues:				
Product revenues	\$	1,209,321	\$	588,343
Other service revenues		33,709		44,861
Development service revenues		3,404		-
Total revenues		1,246,434		633,204
Cost of product revenues		560,394		315,852
Research and development costs		480,280		873,366
Selling, general, and administrative expenses		2,132,777		2,062,309
Operating loss		(1,927,017)		(2,618,323)
Other income (expense):				
Gain (loss) on change in fair value of derivative liabilities		1,950,329		(781,157)
Other income, net		45,302		38,237
Interest income		2,692		2,804
Interest expense		(316,705)		(288,783)
Net loss	\$	(245,399)	\$	(3,647,222)
Net loss per share attributable to common stockholders:				
Basic and diluted	\$	(0.00)	\$	(0.06)
Weighted average shares outstanding:				
Basic and diluted		74,912,906		58,957,191

#### MRI INTERVENTIONS, INC. Condensed Consolidated Statements of Operations (Unaudited)

	For The Nine Mon September	in Diracta
	2015	2014
Revenues:		
Product revenues	\$ 2,963,073 \$	2,456,171
Other service revenues	93,663	84,623
Development service revenues	25,842	103,846
Total revenues	3,082,578	2,644,640
Cost of product revenues	1,340,824	1,243,472
Research and development costs	1,434,723	2,589,410
Selling, general, and administrative expenses	6,608,829	5,792,241
Restructuring charges	1,252,584	-
Gain on sale of intellectual property	-	(4,338,601)
Operating loss	(7,554,382)	(2,641,882)
Other income (expense):		
Gain on change in fair value of derivative liabilities	981,222	578,179
Other income, net	243,505	167,614
Interest income	14,887	10,055
Interest expense	(936,043)	(723,886)
Net loss	\$ (7,250,811) \$	(2,609,920)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.10) \$	(0.04)
Weighted average shares outstanding:		
Basic and diluted	74,878,962	58,864,305

#### MRI INTERVENTIONS, INC. Condensed Consolidated Statements of Cash Flows (Unaudited)

	For The Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (7,250,811)	\$ (2,609,920)
Adjustments to reconcile net income (loss) to net cash flows from operating activities:		
Depreciation and license amortization	153,545	294,639
Share-based compensation	1,421,198	555,909
Expenses paid through the issuance of common stock	107,570	374,546
Gain on change in fair value of derivative liabilities	(981,222)	(578,179)
Gain on negotiated reductions in accounts payable	-	(70,000)
Gain on sale of intellectual property	-	(4,338,601)
Amortization of debt issuance costs and original issue discounts	342,645	233,865
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(368,492)	221,586
Inventory	83,987	(657,948)
Prepaid expenses and other current assets	(104,121)	126,778
Other assets	(9,317)	-
Accounts payable and accrued expenses	(777,956)	1,203,834
Deferred revenue	62,852	(12,796)
Net cash flows from operating activities	(7,320,122)	(5,256,287)
Cash flows from investing activities:		
	(72,021)	(11,590)
Purchases of property and equipment		
Net cash flows from investing activities	(72,021)	(11,590)
Cash flows from financing activities:		
Net proceeds from debt private placement	-	3,503,314
Proceeds from stock option exercises	-	143,000
Net cash flows from financing activities	-	3,646,314
Net change in cash and cash equivalents	(7,392,144)	(1,621,563)
Cash and cash equivalents, beginning of period	9,244,006	3,516,244
Cash and cash equivalents, end of period	\$ 1,851,862	\$ 1,894,681
	+ -,	<u>+ -,</u>
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	\$-	\$-
Interest	\$ 223,500	\$ 223,823
	¢ 225,500	÷ 223,023



#### **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	
Large Market	<ul> <li>Market is large and growing</li> <li>55,000 potential ClearPoint procedures across multiple therapies</li> </ul>	
Navigation System for Multiple 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 Attracting 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 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>	
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RI Int	terventions: Real Time MRI Guided Surgery
	to-market technology platform enabling real-time MRI guided surgery; FDA-cleared, arked and 40+ ClearPoint sites
Focus	sed commercialization of neuro platform underway; recent restructuring complete
Attra	ctive razor/razorblade business model with strong potential margins
	patible with all major MRI manufacturers; Interoperability w/ Medtronic, Monteris, o products
Estab	lished intellectual property portfolio
	essional management team with relevant medical device commercialization rience: Intuitive, Medtronic, Kyphon, Boston Scientific, ev3, Edwards Lifescience, is
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# Leadership – A History of Med Device Experience



Executive		Title		Prior Experier	nce
Frank Grillo Peter Piferi		President, CEO			HON- Scientific
		COO		HeartWare Cordis.	
Wendelin Ma	aners	VP Marketing	Sc	Boston C	CSA MEDICAL
Robert Korn		VP Sales	đ	Medtronic	Codman
Hal Hurwitz		CFO		рис	ev3
oard of Dir	ectors				
		Dr. Phillip Pizzo	Pascal Girin	Timothy	Frank Grillo,
Exec Chair	Maria Sainz CARDIOKINETICS Concentric Stryker	STANFORD SCHOL OF VEDICINI Media Disease Refut Class	WRIGHT.	Richards VNUS COVIDIEN BRAUN SAARDE FEFFATIVE	
lorgan Keegan	CARDIOKINETICS	SCHOL OF HEREINE Badd Stand, Read San	WRIGHT.	VNUS" COVIDIEN BRAUN SUARAIS FRIFATIS	Scientific KYPHON-

### 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**







#### 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>

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 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<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
- (1) Medtronic Investor Presentation, June, 2014

- \$5,275/hour \$4,000 \$3,000 \$2,000 \$1,200/hour \$0
- (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.

viary by nospiral, 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% 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 at 15. 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





Published Peer-Reviewed Journal Support



Larson Dr. R

Dr. Robert Gross Emory University



Mayo Clinic -

Jacksonville



Dr. Krys Bankiewicz Bankiewicz Lab, UCSF



Dr. Russ Lonser OSU - NIH

<complex-block><complex-block><complex-block><complex-block><image><image>

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



50+ U.S. Pater	45+ (	OUS Patents	Patents 40+ U.S. Patent Applications Pate			50+ OUS t Applications
						A Construction of the second s
softwa	re and devices;	r areas such a the SmartFrame ts; active intrace	• trajectory gui	de; oth	er Clear	Point®

safety technology
Key ClearPoint-related patents do not begin to expire until 2027

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### Martin's Story ClearPoint-Enabled Electrode Placement



# Patient Benefit – Minimally Invasive Procedure



7 days after ClearPoint procedure – Arrow Indicates Surgery Site



### **ClearPoint Drug Delivery**



Received September 18, 2010 Accepted after residen December 18, 2010

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



Stereptactic --Functional Neurosurgery Stareotact Funct Neuromarg 2011,89.141-15

\* CAUTION: SmartFlow<sup>™</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 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

	IL13 for Brain Tumor – Phase 1 study at NIH - Sponsored by NIH	SANOFI	AAV2-hAADC for Parkinson's disease - Phase 1 study at UCSF - Sanofi – Genzyme; Michael J. Fox Foundation
	Radio Immunotherapy for Brain Tumor – Phase 1 Study at MSK - Sponsored by the Memorial Sloan-Kettering Cancer Center	uniQure	AAV2-GDNF for Parkinson's disease - Phase 1 study at the NIH - uniQure, B.V.
REFERENCIACIN	Nanoliposomal Irinotecan for Brain Tumor – Phase 1 Study at UCSF - Merrimack Pharmaceutical		

### 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 <sup>(1)</sup>	Patient may be under general anesthesia <sup>(1)</sup>
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 510(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 warming 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.



### 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 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 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> Population	<u>Treatment Resistant</u> <u>Patient Population</u>	<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 Priorit	ties
Increase Utilization	<ul> <li>Focus on adding surgeons at existing accounts</li> <li>Target high volume sites, including epilepsy and tumor neurosurgeons within each account; gain greater share of their procedures</li> <li>Add Clinical Specialists and sales reps to commercial team; compensate for utilization growth</li> </ul>
Enhance Communication	<ul> <li>Increase peer-to-peer events, presence at trade shows</li> <li>Highlight existing data on ClearPoint applications to neurologists and neurosurgeons</li> <li>Communicate value proposition across procedures:         <ul> <li>Accuracy</li> <li>Real time visualization</li> <li>Improved workflow</li> <li>Increase patient volume</li> </ul> </li> </ul>
Expand Account Base	<ul> <li>Identify highest volume potential accounts across multiple procedures</li> <li>Support local hospital marketing efforts</li> <li>Capitalize on interest in drug delivery to expand in oncology accounts</li> <li>Add sales reps</li> </ul>
Achieve Cash Breakeven	<ul> <li>Tightly control working capital, consumption of cash</li> <li>Hire additional personnel only in key functions – commercial team; engineering</li> </ul>
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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	in The
Drug Delivery	Establish additional drug delivery partnerships, and participate in additional clinical trials Become the neuro <u>drug delivery device</u> partner of choice	18 mm 18 mm 1.68 mm
Procedure Enhancements	Continue to enhance product line with a focus on procedure simplification and consistency	Bolt Driver for Laser Ablation
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## 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