
**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):
September 27, 2018

MRI INTERVENTIONS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-34822
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

On September 27, 2018, MRI Interventions, Inc. 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 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

[Exhibit 99.1](#) [Investor Presentation dated September 2018.](#)

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: September 27, 2018

MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz
Harold A. Hurwitz
Chief Financial Officer



Investor Presentation

Joe Burnett, President & CEO

September 2018



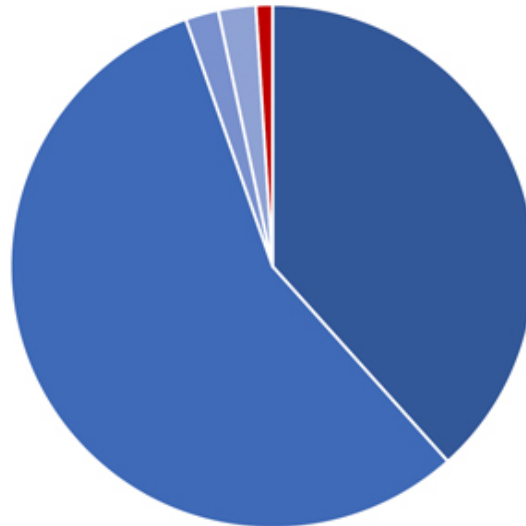
Forward Looking Statements

Statements herein concerning MRI Interventions, Inc. (the “Company”) 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. Uncertainties and risks may cause the Company's actual results to differ materially from those expressed in or implied by forward-looking statements. 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 Annual Report on Form 10-K for the year ended December 31, 2017, and the Company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, both of which have been filed with the Securities and Exchange Commission



Only a Fraction of Patients with Debilitating Neurological Disorders are being Treated Surgically Today...

Prevalence of Neurological Disorders



■ Parkinson's ■ Epilepsy ■ Tumor ■ ICH ■ Surgical Procedures

Note: Prevalence numbers are 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.



The Movement to Minimally Invasive Procedures has Happened Everywhere Else in the Body...



This transition has always had two things in common;

1. More patients being treated
2. Procedures are ***ENABLED BY LIVE IMAGE GUIDANCE***

Traditional Stereotactic Neurosurgery is Limited



Primary Challenge: The Skull is not 'See Through'

1. X-Ray and CT do not show structures of the brain
2. Large, Metallic Navigation Frames are not compatible inside an MRI Magnet

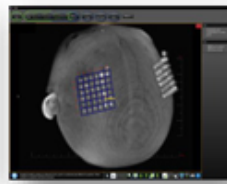
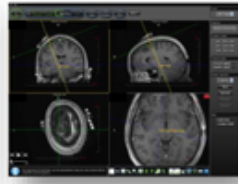
Our Solution: ClearPoint® Neuro Navigation System Platform

The only Neuro-Navigation System with 'Sub-millimeter' Accuracy

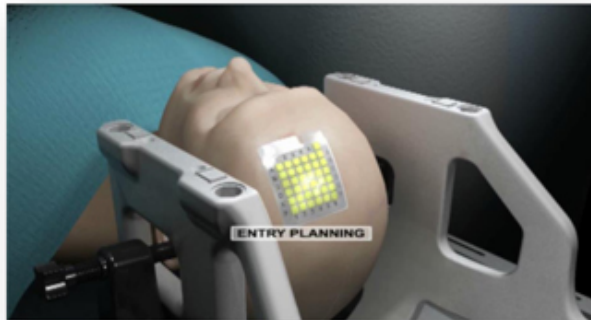
ClearPoint Procedure Overview:



ClearPoint Video
Entry and Trajectory



ClearPoint Video
Alignment and Insertion



Our Value: We DECIDE, GUIDE & CONFIRM the most challenging neurosurgery therapies

Decide

1

Advanced Planning Software and Fusion Algorithms enable 'Fly Through' entry point and trajectory planning the day of the procedure using live MRI Images

Guide

2

Uniquely enable changes to trajectory live, in the MRI, to accommodate anatomical shift or procedural challenges to deliver pinpoint or *CLEARPOINT accuracy*

Confirm

3

Take final images and measurements of the targeting cannula in place to confirm the patient had the best possible chance at success before ending the therapy procedure

Our PLATFORM enables CHOICE of Precision-Guided Therapies for DBS, LITT, Biopsy and Drug Delivery



MRIC: The Premier Company for Precision MRI-Guided Therapy

- **MRI Interventions: Leader in Precision MRI-Guided Therapy**
 - Unique Platform that allows delivery of therapies to the brain with pinpoint accuracy under live MRI Guidance
 - Entire procedure can take place in the MRI suite, reducing the risk of hospital acquired infections and complications
 - Extensive Intellectual Property position: 70+ issued US patents, 45 international
- **Procedure Growth Fueled By Expanding Installed Base and Increased Utilization**
 - 53 Installed systems in the U.S. at leading Neurosurgery Hospitals and Teaching Programs
 - Each new system placement enables razor – razorblade disposable product sales
 - Procedure count continues to grow; 43% CAGR (est.) the past four years
 - Established direct sales channel totaling 16 people supporting cases in the U.S.
- **Expanding Platform into Adjacent Areas to Address Additional Unmet Medical Needs**
 - Five current Biologics and Drug Partners using MRIC for delivery in therapy trials
 - Internally developed Neuro-Aspiration device will add therapy to our sales team portfolio
 - Existing and New addressable markets > \$1B in potential



MRIC: A Proven Platform

MRI Interventions, Inc.:

Headquarters: Irvine, CA
 Employees: 38 (16 Sales, 19 Product Dev.)
 2017 Revenue: \$7.4 Million
 Market Cap: \$20 Million ^(A)
 Cash: \$6.7 million ^(B)
 Gross margin: 64% ^(B)

(A) As of September 25, 2018

(B) Financial data as of and for the six months ended June 30, 2018

Key Products:

ClearPoint
Platform



SmartFrame
& Accessories



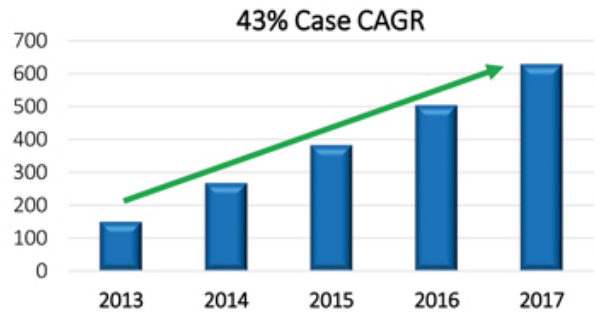
SmartFlow
Canulae



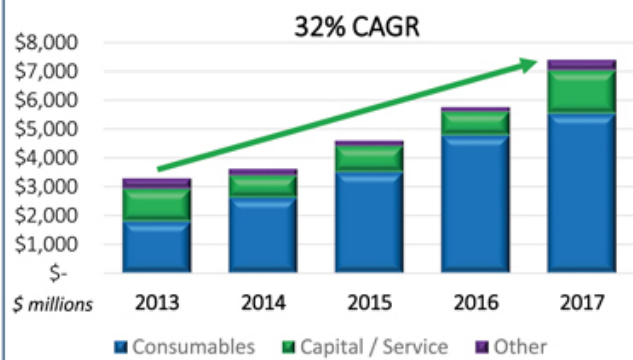
80% Disposables, 20% Capital Revenue Mix
 FDA / CE Marked Platforms
 79 U.S. Patents, 27 Pending Applications



Increasing Market Adoption:



Proven Revenue Growth:



Broad and Growing User Base of Leading Neurosurgeons

ClearPoint Is Installed in 53 Top US Hospitals and Growing

*UC San Francisco
San Francisco VA
Stanford Univ
UCSF Benioff Childrens
USC
UC San Diego
Univ of Colo
Univ of Utah
Univ of Arizona
Cook Children's
MD Anderson
Methodist Hosp
Texas Children's Hosp
Riverside
Nationwide Children's
Children's Mercy
Kansas Univ Med Center
Univ of Wisconsin
Spectrum Health
Ohio State Univ
Univ of Cincinnati
Univ of Michigan*



*Univ of Minnesota Med Ctr
Brigham & Women's
Boston Children's
Yale Univ
Univ of Pitt Med Center
Memorial Sloan Kettering
Hackensack Univ Med Center
Cornell
Central Du Page
Nat. Institutes of Health
Nat Children's Hospital
Children's Hosp of Philadelphia
Univ of Virginia
Emory University
Carillion
Duke University
Children's of Alabama
CHOA Scottish Rite
Willis Knighton
Mayo Clinic Jacksonville
Miami Children's*

Strong Commercial Sales and Clinical Support Teams in Place



Our MRI-Guided Therapy Platform is Currently Being Used to:

Implant Neuro Stimulation Leads from:

- Medtronic
- St. Jude Medical
- Boston Scientific
- NeuroPace



Place Laser Ablation Probes from:

- Medtronic-Visualase
- Monteris Medical



Deliver Biologics and Drugs from:

- Voyager
- Medicenna
- Oxford Biomedica
- International Stem Cell Corporation

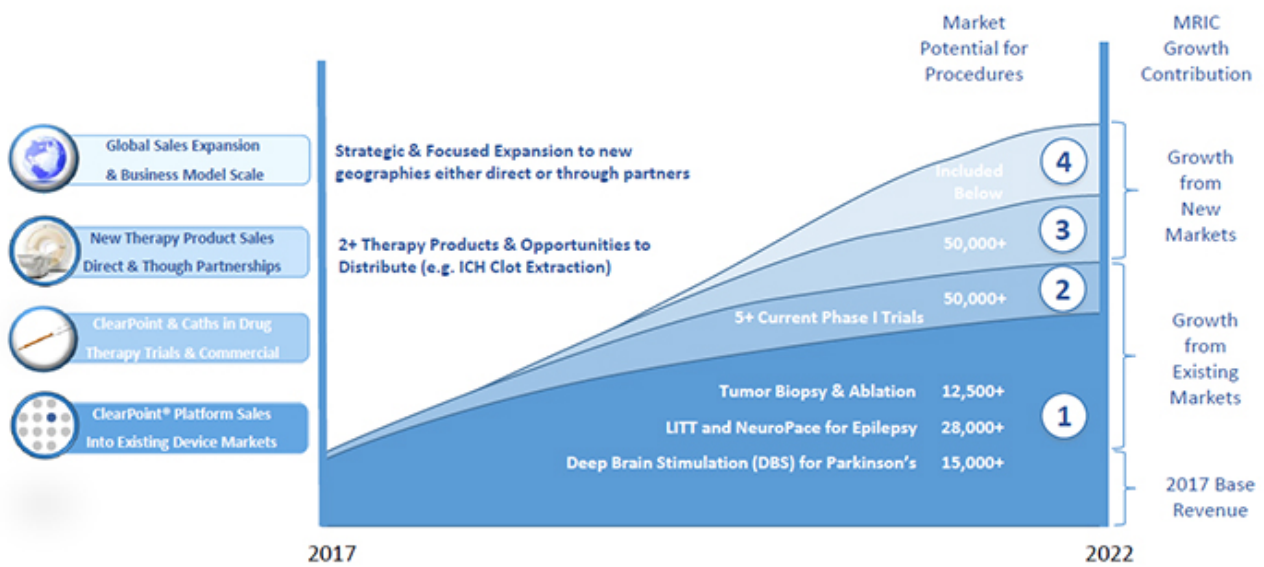


MRIC Platform Runs on All Major Scanners:

- Siemens
- GE
- Philips
- IMRIS



MRIC: ④-Part Growth Strategy



Target Indications of > 150,000 procedures per year represents
Potential Addressable Market for MRIC of \$1B+

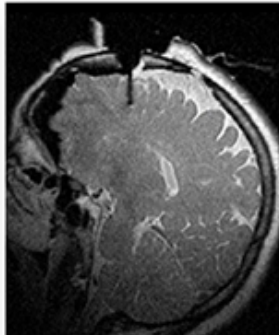
Note: Market sizes for brain tumor, ICH and Pancreatic cancer are incidence numbers because of the nature of those diseases. Prevalence numbers are based on either market research conducted by a third party on behalf of MRI Interventions or research conducted by MRI Interventions of publicly available sources.



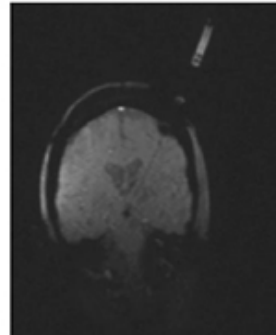
Part ①: Grow Our Core Functional Neurosurgery Business

Focus on Complex Procedures Where Precision is Paramount

Electrode Placement for
Deep Brain Stimulation



Laser Catheter Placement
for Ablation Procedures

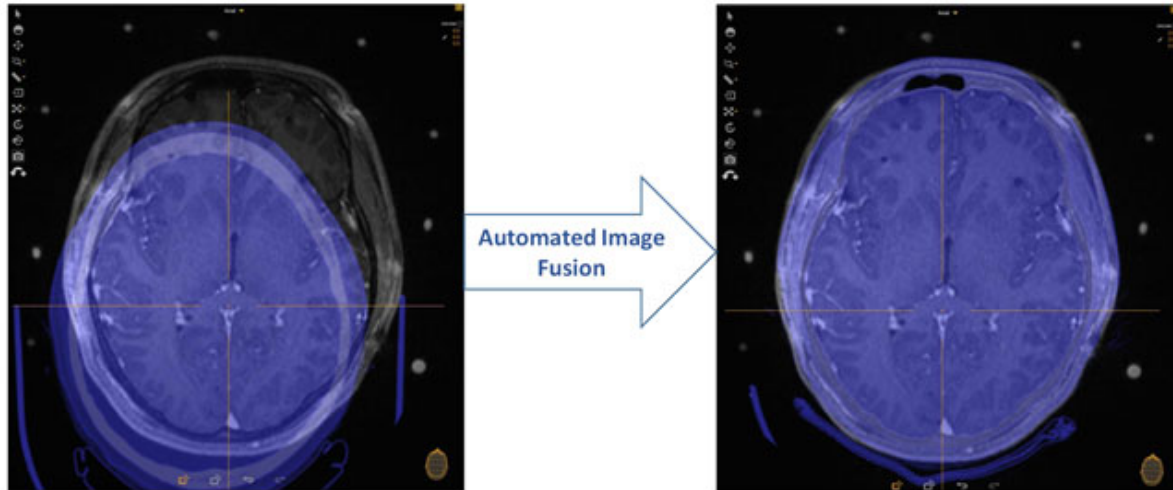


Key Strategies & Tactics for 2018:

- Add 8-10 new centers from existing funnel via capital sales and evaluation agreements
- Publish 'Best Practices' workflows to get procedures predictably under four hours enabling two procedures a day in MRI scanners instead of one, present to entire installed base
- Pursue clinical pathway for an 'Asleep DBS' Indication to allow more substantial marketing, training and education of the benefits of asleep procedures which patients desire

Part ①: Grow Our Core Functional Neurosurgery Business
Focus on Complex Procedures Where Precision is Paramount

ClearPoint 2.0 Image Fusion Feature
(Pending FDA Clearance)



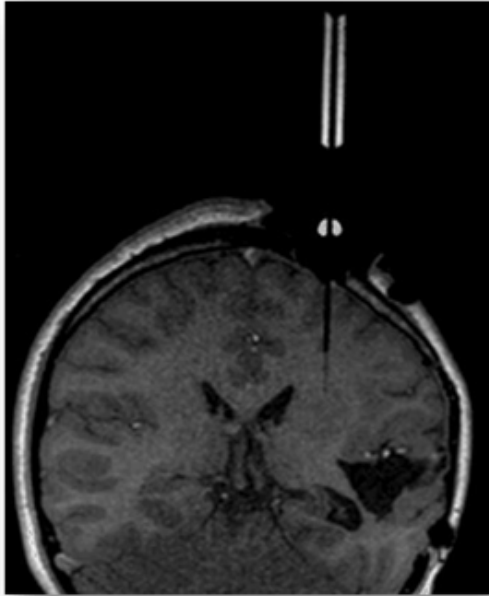
**Designed to reduce procedure time by fusing pre-procedure
planning to real-time MRI imaging**



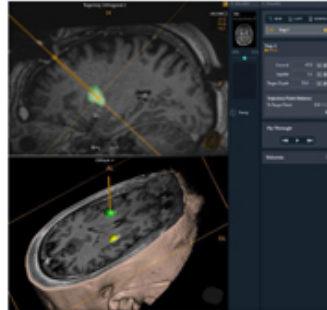
Part ②: Become the Premier Partner for Biologics and Drug Delivery

Focused Resources for Branding, Device Development and Distribution

Precise, Quantifiable
Drug Delivery



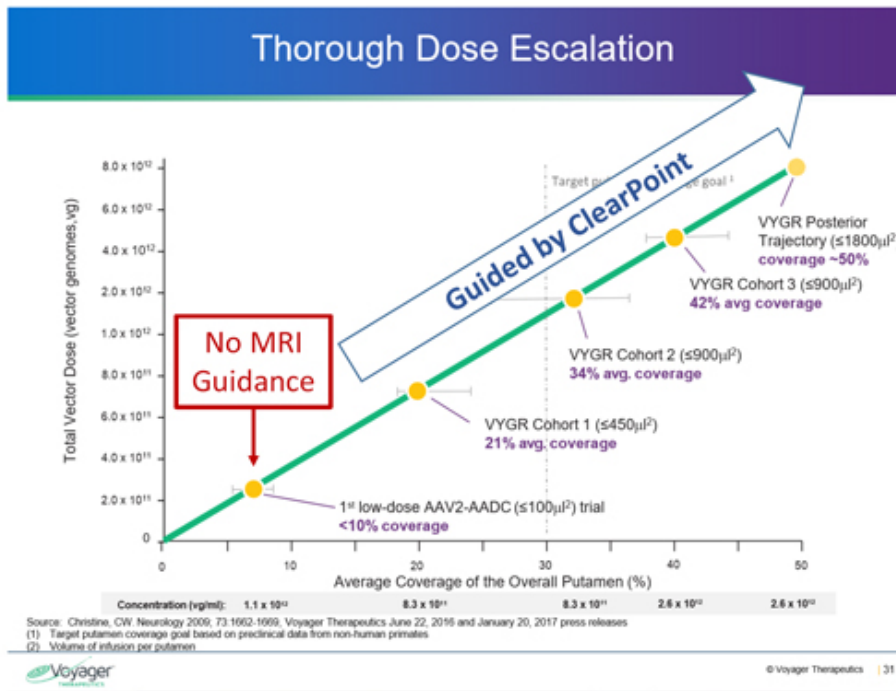
ClearPoint 2.0 Software
(Pending FDA Clearance)



Key Strategies & Tactics for 2018:

- Assign a 'Sales Portfolio Manager' to proactively build our brand as the premier partner in biologics and drug delivery to the brain
- Launch ClearPoint 2.0 software with live volumetric measurement capability
- Support VOYAGER phase II trial enrollment
- Add 1-2 partnerships for Phase 1 Trials

Part ②: Become the Premier Partner for Biologics and Drug Delivery Focused Resources for Branding, Device Development and Distribution



Part ②: Become the Premier Partner for Biologics and Drug Delivery *Focused Resources for Branding, Device Development and Distribution*



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Company News

MRI Interventions Announces Strategic Agreement with Voyager Therapeutics for Neurosurgical Device Service, Supply and Development

Agreement to include service and support of ClearPoint® and SmartFlow® Devices, and joint-development of new neurosurgical devices

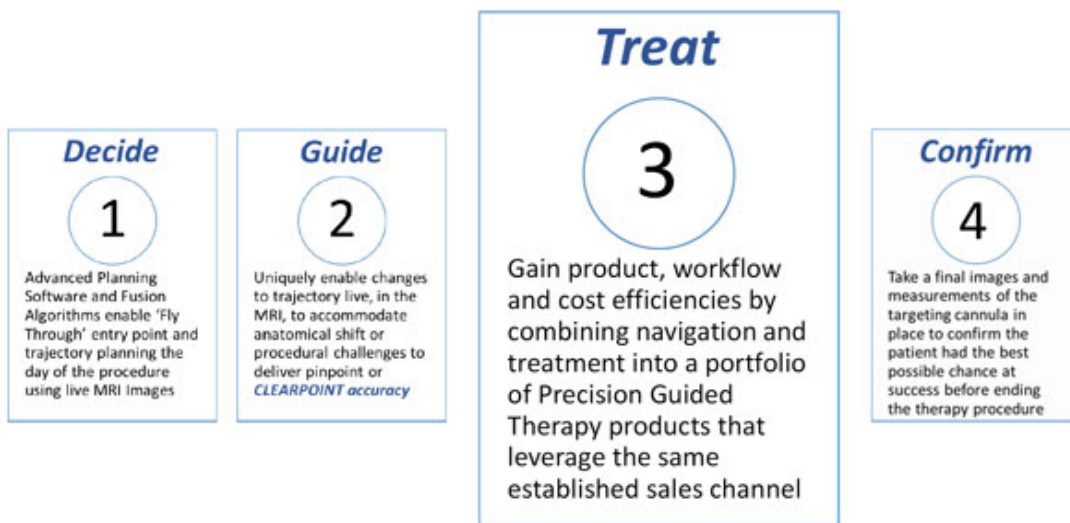
[Download PDF](#)

IRVINE, Calif., May 15, 2018 (GLOBE NEWSWIRE) -- MRI Interventions, Inc. (OTCQB:MRIC) today announced a strategic agreement with Voyager Therapeutics, Inc. (NASDAQ:VYGR), a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases. The agreement includes service and clinical case support of MRI Interventions' ClearPoint® and SmartFlow® products employed in Voyager's planned Phase 2-3 pivotal program of its gene therapy, VY-AADC, for



Part 3: Expand into Direct Therapy Markets

Achieve first-in-human case for our Neuro-Aspiration System



Integrated Therapy Products benefit the patient and hospital by simplifying workflow and making procedures more efficient and cost effective

Adding therapy helps MRIC generate additional revenue per procedure



Part ③: Expand into Direct Therapy Markets

Achieve first-in-human case for our Neuro-Aspiration System

Initial Stroke Product (ClearPoint PURSUIT™) Targets Intracerebral Hemorrhage (ICH)

- Collaboration with Mayo Clinic
- Major stroke subtype w/o clearly effective therapy – major unmet medical need
- Affects 80,000 to 100,000 people in the US each year

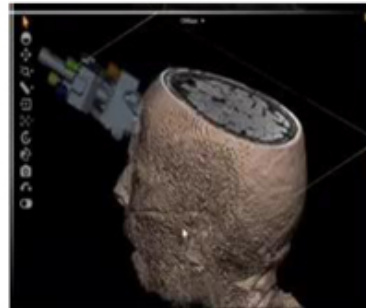
Current Approaches for Hemorrhage Removal and Decompression are Inadequate:

- Open craniotomy provides visibility but is highly invasive, destroys brain tissue
- Minimally invasive approach has very limited ability to quantify volume reduction of the hemorrhage or monitor subsequent bleeds

Our Unique ClearPoint PURSUIT™ Approach to ICH

- Detailed, continuous, high resolution, 4-D visibility
- Minimally invasive approach

4-D Guidance of Neuro Clot Aspiration



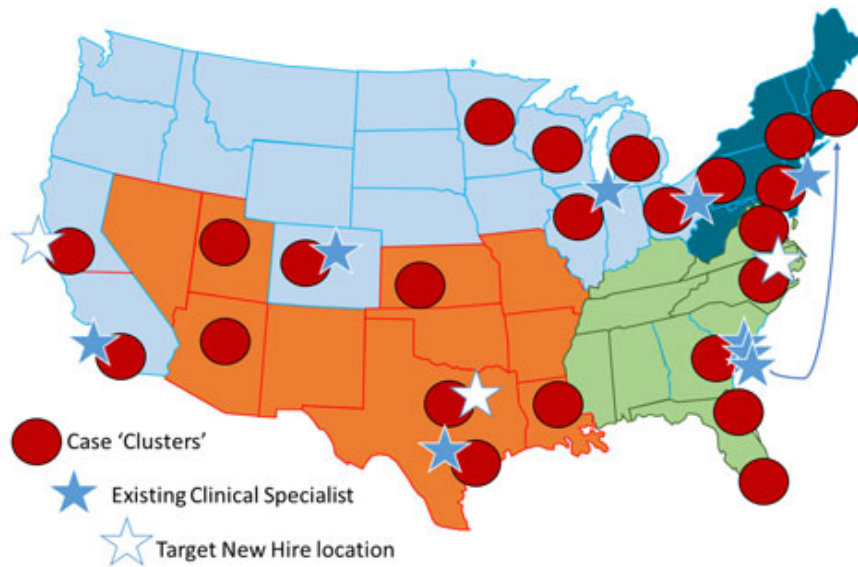
Key Strategies & Tactics for 2018:

- Complete product development for FDA submission in Q3
- Perform first-in-human case by December 2018



Part ④: Achieve Business Model Scale, Go Global

Execute initiatives along a path-to-profitability



- Relocating Clinical Specialists closer to case 'clusters' to reduce travel
- Hiring new specialists to locations where new placements are planned
- Prioritize shorter procedure times so two cases are performed in the same day

Part ④: Achieve Business Model Scale, Go Global

Execute initiatives along a path-to-profitability

Manufacturing Facility in Irvine, CA



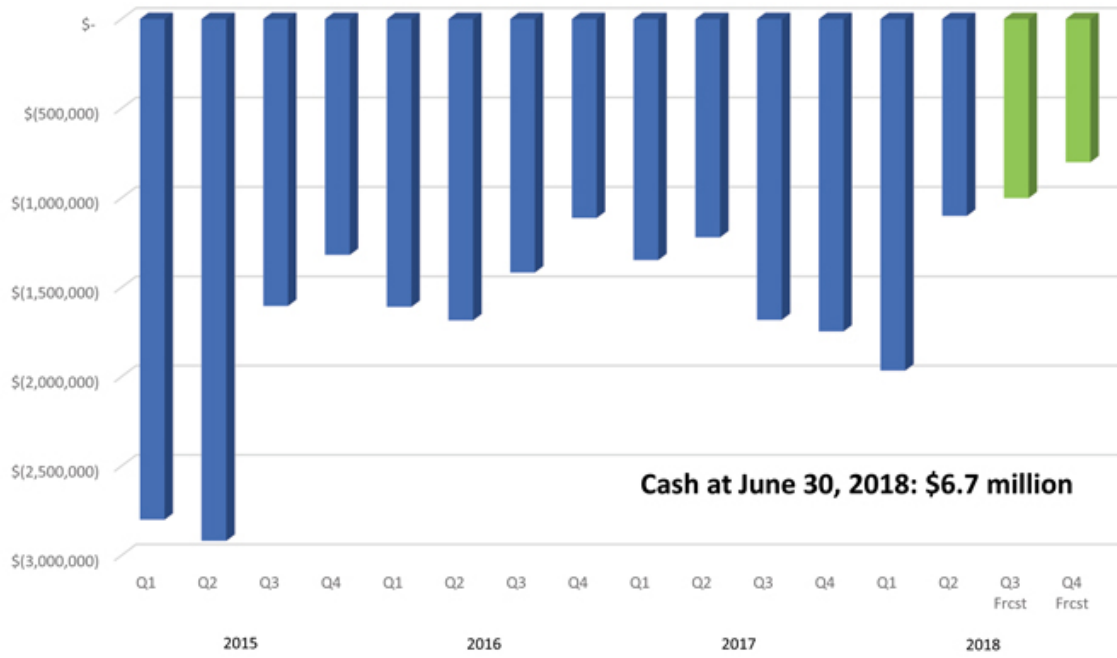
- Current facility capable of producing 5x more product without expansion
- Target gross margin expansion above 70% in next five years

SmartFlow® Drug Delivery Cannula



- Global Strategy being prioritized based on adoption of partner therapies
- ***SmartFlow® Cannula is now CE Mark Approved and will be in more OUS drug trials***

Cash Flow From Operations: 2015 - 2018



MRIC: Executive Summary

- Unique, Platform technology enabling Precision MRI-Guided Therapies to restore quality of life for some of the most debilitating disorders
- Large, Growing installed base in 53 of 250+ leading Neurology centers in U.S.
- Procedure volume has grown 43%+ CAGR from 2013-2017
- 80%+ of current revenue from single-use, high-margin disposables
- Pipeline of new revenue streams from product improvements, new drug therapy trials, and standalone therapy products
- Total potential addressable market > \$1B for our products and pipeline
- A passionate team of embedded scientists and specialists

