

**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 28, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	MRIC	NYSE American

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.

August 28, 2019, 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 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 August 2019.](#)

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 28, 2019

MRI INTERVENTIONS, INC.

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





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: future revenues from sales of the Company's ClearPoint® Neuro Navigation Platform products; the

Company's ability to market, commercialize and achieve broader market acceptance for the Company's ClearPoint Neuro Navigation Platform products; and estimates regarding the sufficiency of the Company's cash resources. 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, 2018, and the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, both of which have been filed with the Securities and Exchange Commission.

Executive Summary



Unique platform technology enabling precision MRI-guided therapies to restore quality of life for some of the most debilitating disorders



80% of forecast revenue from single-use, high-margin disposables



Large, growing installed base in 55 of 250+ leading neurology centers in U.S.



Pipeline of new revenue streams from product improvements, biologic and drug delivery partnerships, and standalone therapy products



Procedure volume has grown at a 33%+ CAGR from 2013-2018



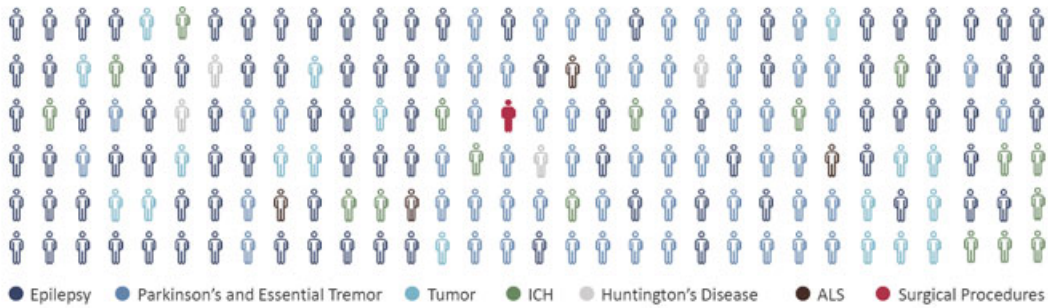
Total potential addressable market > \$1B for our products and pipeline



A passionate team of embedded scientists and specialists

Only a fraction of patients with debilitating neurological disorders are being treated surgically **today**

Prevalence of Neurological Disorders



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

This transition has always had two things in common:

- More patients being treated
- Procedures **enabled by live image guidance**



PRIMARY CHALLENGE

Traditional Stereotactic Neurosurgery is Limited

The Skull is Not 'See Through'

- X-Ray and CT do not show structures of the brain
- Large, Metallic Navigation Frames are not compatible inside an MRI Magnet
- Surgical Image Guidance in the Operating Room is not live but rather 'Co-Registered' to the MRI
- Each Co-Registration calculation introduces error and reduces accuracy



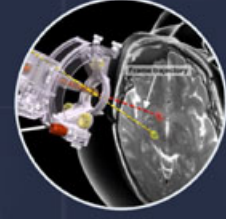
OUR SOLUTION

ClearPoint® Neuro Navigation Platform

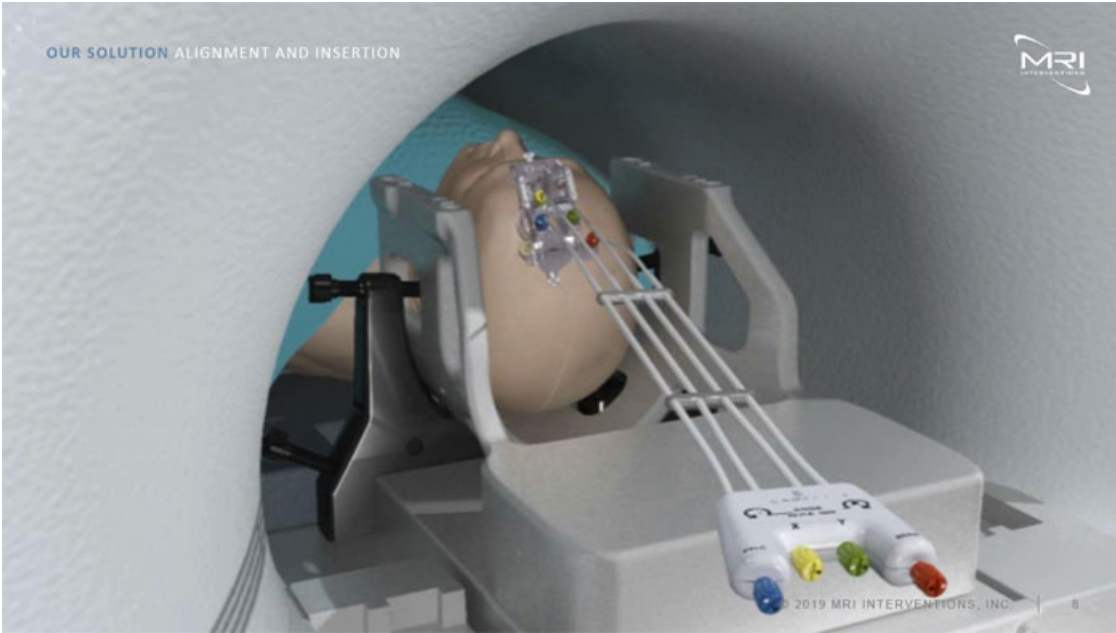
An MRI Compatible Navigation System Delivering Live MRI Guidance during the Procedure



Anon2014-09-26_07-0
26-Sep-14 11:00:10 AM
WL: 9.001-4.003



Decide, Guide, Treat & Confirm with Sub-millimetric Accuracy



MRIC & ClearPoint: A Proven Platform

Key Products: FDA CE Marked Platforms; More than 3,000 Procedures Performed to Date

HEADQUARTERS
Irvine, CA

EMPLOYEES
40+
19 sales | 19 production & development

2018 REVENUE
\$7.4m

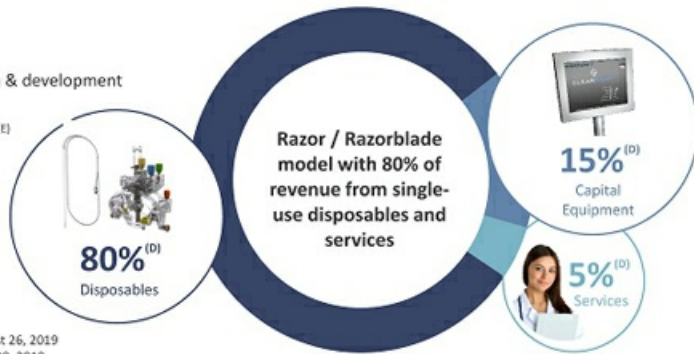
2019 REVENUE FORECAST ^(E)
\$10.0m – 11.0m

MARKET CAP
\$50m ^(A)

CASH ^(B)
\$7.5m

U.S. PATENTS ISSUED
79
+ 29 pending

GROSS MARGIN ^(C)
62%



(A) As of August 26, 2019
(B) As of June 30, 2019
(C) For the six months ended June 30, 2019
(D) 2019 Forecast
(E) April 30, 2019 earnings release

BROAD AND GROWING USER BASE OF LEADING NEUROSURGEONS



ClearPoint® is Installed in 55 Active Clinical Sites at Top US Hospitals and Growing

Strong Commercial
Sales and Clinical
Support Teams
in Place

UC San Francisco
San Francisco VA
Stanford Univ
Lucile Packard (Stanford Children's)
UCSF Benioff Children's
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
Henry Ford Health System
Nationwide Children's
Children's Mercy
Kansas Univ Med Center
Univ of Wisconsin
Spectrum Health
Ohio State Univ
Cincinnati Children's
Dallas Presby
Univ of Cincinnati
University of Wisconsin

Cincinnati Jewish
Univ of Michigan
Univ of Minnesota Med Ctr
Brigham & Women's
Boston Children's
Mass General
Mt Sinai West
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
Mayo Phoenix
Dartmouth Hitchcock

University of Pennsylvania HUP
INOVA Fairfax
LeBonheur
Johns Hopkins
Tampa General



Our MRI-Guided therapy platform is currently being used to...

IMPLANT NEURO STIMULATION LEADS

PLACE LASER ABLATION PROBES

DELIVER BIOLOGICS AND DRUGS

MRIC PLATFORM RUNS ON ALL MAJOR SCANNERS

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

- Medtronic Visualase
- Monteris Medical

- Voyager Therapeutics
- PTC Therapeutics
- Axovant Gene Therapies
- StemCell Therapeutics
- Lysogene
- BlueRock Therapeutics

- Siemens
- GE
- Philips
- Imris

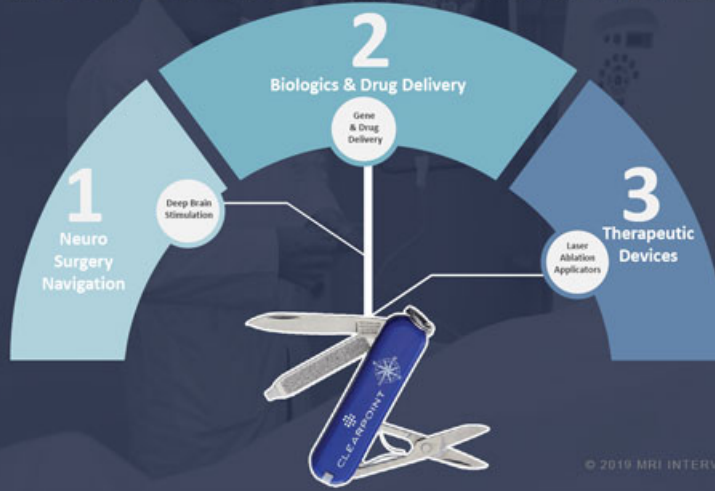
Our platform enables choice of precision-guided therapies and services



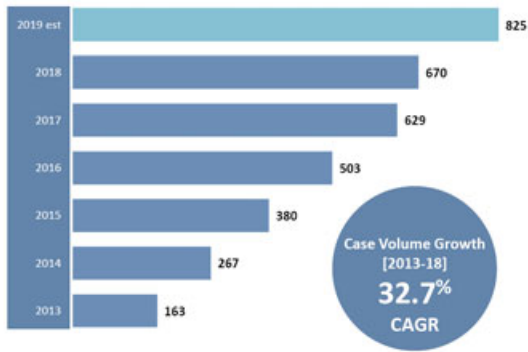
CLEARPOINT

Hardware & Software | Artificial Intelligence | Robotics

Example: *The Parkinson's Disease Patient* Enabling Surgeons to choose the right tool for the right patient



Growth in Case Volume, Revenue



2019 Revenue Forecast Range of \$10.0 - \$11.0 M as of May, 2019

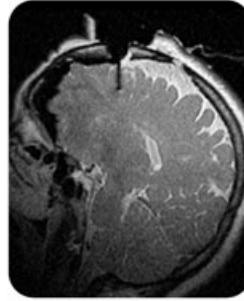


Grow Our Core Functional Neurosurgery Business: Focus on Complex Procedures Where Precision is Paramount

2019

Key Achievements

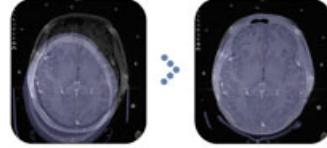
- Record Q2 quarterly case volume (197), and Disposable Revenue
- Increase to 10 sites using two-a-day procedure workflow, expanding adoption driving volumes, efficiency
- Full Market Release of ClearPoint 2.0 Hardware & Software Platform and installation into 22 centers
- 5 additional site installations in first half of 2019



Electrode Placement for Deep Brain Stimulation

FEATURE

ClearPoint 2.0 Image Fusion



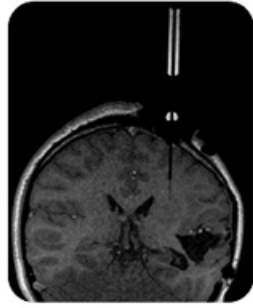
Designed to reduce procedure time by fusing pre-procedure planning to real-time MRI imaging

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

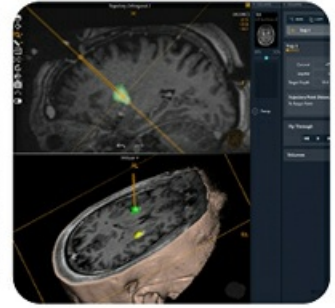
2019

Key Achievements

- Raised \$7.5 M via strategic investment led by PTC Therapeutics and first sales
- Trained clinical specialists for Voyager VY-AADC trial support; first treatment in December 2018
- Shipment of products, development services to 10 individual corporate customers in first half of 2019, 20+ in last two years



Precise, quantifiable drug delivery



ClearPoint 2.0 software illustrating drug infusion

Expand into Direct Therapy Markets: Achieve Greater Share of Total Procedure Revenue

2019

Key Achievements

- Acquired License from CLS for Laser System and Applicators for Neurosurgery and Spine Indications
- Opportunity to fine tune our Navigations system to work seamlessly with laser applicator design enhancements
- Adding laser therapeutics has potential to turn lowest revenue and margin procedure into highest
- Expect first human cases 2H 2020

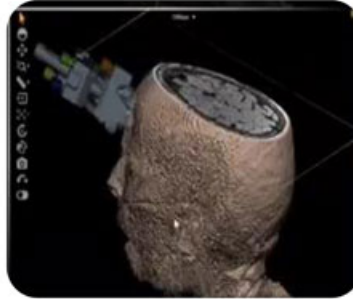


Expand into Direct Therapy Markets: Achieve first-in-human case for our Neuro-Aspiration System

2019

Key Achievements

- Achieved FDA Clearance for the PURSUIT™ Neuro Aspiration System in December 2018
- Collaboration with Mayo Clinic
- Affects 80,000 to 100,000 people in the US each year
- Three sites in the U.S. have been trained as part of limited market release



4-D Guidance of Neuro Aspiration

Our unique ClearPoint® PURSUIT™ approach:

Detailed and continuous

High resolution of target

4-D visibility

Minimally invasive

Confirmation of Result

Achieve Global Scale and progress toward profitability

Capabilities

Established Sales Channel capable of distributing other surgical products

- Current Revenue for non-neuro CLS Laser Applicators

Manufacturing Facility in Irvine capable of producing 5x current demand with existing footprint

CE Mark labeling for targeted global expansion when time is right





Cash Flow From Operations (6 months)



Executive Summary



Unique Platform technology enabling Precision MRI-Guided Therapies to restore quality of life for some of the most debilitating disorders



80% of forecast revenue from single-use, high-margin disposables



Large, Growing installed base in 55 of 250+ leading Neurology centers in U.S.



Pipeline of new revenue streams from product improvements, biologic and drug delivery partnerships, and standalone therapy products



Procedure volume has grown 33%+ CAGR from 2013-2018



Total potential addressable market > \$1B for our products and pipeline



A passionate team of embedded scientists and specialists