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 6, 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 ine. Ca. 9261

Irvine, Ca. 92618 (Address of principal executive offices, zip code)

(949) 900-6833

(Registrant's telephone number, including area code)

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		

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))

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 \Box

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 2.02. Results of Operations and Financial Condition.

August 6, 2019, MRI Interventions, Inc. (the "Company") issued a press release announcing its financial performance for the second fiscal quarter and six months ended June 30, 2019. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit 99.1 Press Release dated August 6, 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 6, 2019

MRI INTERVENTIONS, INC.

By: <u>/s/ Harold A. Hurwitz</u> Harold A. Hurwitz

Chief Financial Officer





MRI Interventions Reports 58% Increase in 2019 Second Quarter Revenue

Record \$2.6 Million Quarterly Revenue and Case Volume

IRVINE, CA, August 6, 2019 – MRI Interventions, Inc. (NYSE American: MRIC) (the "Company") today announced financial results for its second fiscal quarter ended June 30, 2019.

2019 Second Quarter Highlights

- · Increased revenue 58% year-over-year to a record \$2.6 million.
 - Functional neurosurgery revenue increased 46% to \$1.7 million.
 - \circ \qquad Biologics and drug delivery revenue increased 51% to \$413,000.
 - Capital equipment sales and related service revenue increased 128% to \$485,000, bringing the total to 65 systems in circulation, with 55 such systems at active clinical sites.
- Completed a record 197 supported cases, compared with 175 in the 2019 first quarter and 147 in the 2018 second quarter.
- · Completed first therapeutic products distribution sales under the company's agreement with Clinical Laserthermia Systems ("CLS").
- \cdot Continued cash management program, using cash in operations of \$810,000.
- · Completed a private equity placement with proceeds of \$7.5 million, led by a \$4.0 million investment from PTC Therapeutics, Inc.
- · Announced that the Company's common stock was approved for listing on the NYSE American exchange, effective July 3, 2019.

Joe Burnett, President and Chief Executive Officer of MRI Interventions, Inc., said, "The second quarter showed continued momentum year-to-date in 2019, with revenue increasing 58% to a record \$2.6 million and a record 197 supported cases. We also secured a strategic investment from PTC Therapeutics as part of a \$7.5 million capital infusion and completed a successful uplisting onto the NYSE American exchange. Further, we accomplished these milestones while continuing to demonstrate the operating leverage in our business, with only 7% year-over-year increase in quarterly operating expenses."

Mr. Burnett noted further, "We also made exciting progress on a number of other key initiatives, including our first therapeutic revenues recognized from the sale of CLS's FDA-cleared laser ablation products for non-neuro applications under our distribution agreement for sales in the U.S. and Canada. This milestone was achieved one quarter sooner than anticipated. We also fulfilled our first order of drug delivery products to our strategic partner, PTC Therapeutics, for its planned use in its AADC deficiency program. We have now shipped product or performed services for ten biologics and drug delivery partners in the first half of 2019. We continue to be committed to our four-pillar growth strategy, which saw our core functional neurosurgery business grow 46% in the second quarter, supplemented by the growth in sales of biologics and drug delivery products, and capital equipment and related services.

<u>Financial Results – Three Months Ended June 30, 2019</u>

Functional neurosurgery revenue, which consists of disposable product sales related to cases utilizing the ClearPoint system, increased 46% to a record \$1.7 million for the three months ended June 30, 2019, from \$1.2 million for the same period in 2018. The increase was primarily due to an expanded customer base, increased utilization of MRI scanner availability by existing customers, and resolution of the previously announced FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials and services, increased 51% to \$413,000 for the three months ended June 30, 2019, from \$274,000 for the second quarter of 2018 due primarily to an increase in biologic and drug delivery product revenues.

5 Musick, Irvine, California 92618 949.900.6833

Capital equipment and related services revenue, consisting of sales of ClearPoint reusable hardware and software and services (other than those related to biologics and drug delivery), increased 128% to \$485,000 for the three months ended June 30, 2019, from \$213,000 for the same period in 2018, due primarily to an increase in sales of new ClearPoint system installations, ClearPoint 2.0 software upgrades and service contract sales.

Gross margin for the three months ended June 30, 2019 was 60%, a slight decline from gross margin of 63% for the same period in 2018, primarily a reflection of shifts in product mix that vary on a quarterly basis.

Research and development costs were \$698,000 for three months ended June 30, 2019, compared to \$665,000 for the same period in 2018, an increase of 5%. Sales and marketing expenses were \$1.1 million for the three months ended June 30, 2019, compared to \$926,000 for the same period in 2018, an increase of 23%. General and administrative expenses were \$1.0 million for the three months ended June 30, 2019, compared to \$1.1 million for the same period in 2018, a decrease of 6%. Total operating expenses for the three months ended June 30, 2019, compared to \$1.1 million for the same period in 2018, a decrease of 6%. Total operating expenses for the three months ended June 30, 2019 was \$2.9 million, as compared with \$2.7 million for the same period in 2018, an increase of 7%.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2019 second 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 www.mriinterventions.com and selecting "Investors" / "News" / "IR Calendar." 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 August 20, 2019 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.

MRI Interventions is a leading platform company for MRI-guided neurosurgery procedures, including deep-brain stimulation, ablation, aspiration, biopsy, and gene therapy delivery. The ClearPoint Neuro Navigation System is FDA cleared and CE marked, and is installed in more than 55 surgical centers in the U.S. To date, nearly 3,000 procedures have been performed leveraging the sub-millimetric accuracy of the ClearPoint platform. For more information, please visit <u>www.mriinterventions.com</u>.

Forward-Looking Statements

Statements herein concerning MRI Interventions, Inc.'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. 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 System products; the company's ability to market, commercialize and achieve broader market acceptance for the company's ClearPoint Neuro Navigation System 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-Q for the period ended March 31, 2019, both of which have been filed with the Securities and Exchange Commission, and the company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, which the company intends to file with the Securities and Exchange Commission on or before August 14, 2019.

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

Matt Kreps Darrow Associates Investor Relations (214) 597-8200 mkreps@darrowir.com

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

	For The Three Months Ended June 30,		
	 2019		2018
Revenues:	 		
Product revenues	\$ 2,194,194	\$	1,412,599
Service and other revenues	412,204		233,736
Total revenues	2,606,398		1,646,335
Cost of revenues	1,030,316		602,236
Research and development costs	697,803		665,310
Sales and marketing expenses	1,143,056		926,231
General and administrative expenses	1,028,291		1,088,496
Operating loss	 (1,293,068)		(1,635,938)
Other income (expense):			
Gain from change in fair value of derivative liabilities			7,580
Other income (expense), net	1,693		(87)
Interest expense, net	(259,020)		(248,091)
Net loss	\$ (1,550,395)	\$	(1,876,536)
Net loss per share attributable to common stockholders:			
Basic and diluted	\$ (0.13)	\$	(0.17)
Weighted average shares outstanding:			
Basic and diluted	 12,302,667		10,959,532

	For The Six Months Ended June 30,		
	 2019		2018
Revenues:			
Product revenues	\$ 4,358,148	\$	2,951,198
Service and other revenues	720,767		318,504
Total revenues	 5,078,915		3,269,702
Cost of revenues	1,916,798		1,191,203
Research and development costs	1,282,343		1,211,638
Sales and marketing expenses	2,183,769		1,888,445
General and administrative expenses	1,961,323		2,041,446
Operating loss	 (2,265,317)		(3,063,030)
Other income (expense):			
Gain from change in fair value of derivative liabilities			42,023
Other income (expense), net	7,322		(883)
Interest expense, net	(513,125)		(495,563)
Net loss	\$ (2,771,120)	\$	(3,517,453)
Net loss per share attributable to common stockholders:			
Basic and diluted	\$ (0.24)	\$	(0.32)
Weighted average shares outstanding:	 		
Basic and diluted	 11,676,872		10,851,177

MRI INTERVENTIONS, INC. Consolidated Balance Sheets

		June 30, 2019 (Unaudited)		December 31, 2018	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	7,461,648	\$	3,101,133	
Accounts receivable, net		1,371,827		1,233,896	
Inventory, net		2,529,159		2,105,976	
Prepaid expenses and other current assets		430,638		213,684	
Total current assets		11,793,272		6,654,689	
Property and equipment, net		471,427		377,706	
Software license inventory		416,900		801,900	
Operating lease rights of use		427,927		—	
Other assets		160,010		22,538	
Total assets	\$	13,269,536	\$	7,856,833	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	1,302,456	\$	500,929	
Accrued compensation	Ŧ	711.623	+	764,960	
Operating lease liabilities, current portion		113,914			
Other accrued liabilities		382,872		390,838	
Deferred revenue		740,163		350,963	
Total current liabilities		3,251,028		2,007,690	
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Accrued interest		910,000		857,500	
2014 junior secured notes payable, net		—		1,939,850	
Operating lease liabilities		332,261			
2010 junior secured notes payable, net		1,869,105		1,540,791	
Total liabilities		6,362,394		6,345,831	
Commitments and contingencies					
Stockholders' equity:					
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2019 and December 31, 2018					
		—		—	
Common stock, \$0.01 par value; 200,000,000 shares authorized; 13,686,320 shares issued and outstanding at June 30, 2019; and 11,018,364 issued and outstanding at December 31, 2018		136.863		110.183	
Additional paid-in capital		116,741,229		108,600,405	
Accumulated deficit		(109,970,950)		(107,199,586)	
Total stockholders' equity		6,907,142		1,511,002	
Total liabilities and stockholders' equity	\$	13,269,536	\$	7,856,833	
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MRI INTERVENTIONS, INC. Consolidated Statements of Cash Flows (Unaudited)

		For The Six Months Ended June 30,		
		2019	<i>.</i>	2018
Cash flows from operating activities:				
Net loss	\$	(2,771,120)	\$	(3,517,453)
Adjustments to reconcile net loss to net cash flows from operating activities:				
Depreciation		69,600		55,418
Share-based compensation		356,580		607,124
Expenses paid through the issuance of common stock				77,500
Gain from change in fair value of derivative liabilities				(42,023)
Amortization of debt issuance costs and original issue discounts		363,465		272,858
Amortization of lease rights of use, net of accretion in lease liabilities		51,255		—
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		(137,931)		178,629
Inventory, net		(201,503)		(337,807)
Prepaid expenses and other current assets		(216,953)		(128,823)
Other assets		11,899		1,001
Accounts payable and accrued expenses		716,222		(197,888)
Lease liabilities		(50,285)		
Deferred revenue		389,201		(41,477)
Net cash flows from operating activities		(1,419,570)		(3,072,941)
Cash flows from investing activities:				
Purchases of property and equipment		_		(51,497)
Acquisition of licensing rights		(150,000)		(,,)
Net cash flows from investing activities		(150,000)		(51,497)
		(150,000)		(51,477)
Cash flows from financing activities:				
Proceeds from private offering		7.522.010		
Proceeds from warrant exercises		383,075		531,977
Repayment of 2014 junior secured notes payable		(1,975,000)		
Net cash flows from financing activities		5,930,085		531,977
Net change in cash and cash equivalents		4,360,515		(2,592,461)
Cash and cash equivalents, beginning of period		4,500,515		(2,392,401)
Cash and cash equivalents, beginning of period		3,101,133		9,289,831
Cash and cash equivalents, end of period	¢		¢	((
cash and cash equivalents, end of period	\$	7,461,648	\$	6,697,370
SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:				
Income taxes	\$	_	\$	_
Interest	\$	164,157	\$	146,611