
**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 12, 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 2.02. Results of Operations and Financial Condition.

On November 12, 2019, MRI Interventions, Inc. (the “Company”) issued a press release announcing its financial performance for the third fiscal quarter and nine months ended September 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 November 12, 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: November 12, 2019

MRI INTERVENTIONS, INC.

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



MRI Interventions Reports 62% Increase in 2019 Third Quarter Revenue

Performance marks fourth consecutive quarter of record revenue and case volume

IRVINE, CA, November 12, 2019 – MRI Interventions, Inc. (NYSE American: MRIC) (the “Company”) today announced financial results for its third fiscal quarter ended September 30, 2019.

2019 Third Quarter Highlights

- Increased revenue 62% year-over-year to a record \$2.9 million.
 - Functional neurosurgery revenue increased 28% to \$1.9 million.
 - Biologics and drug delivery revenue increased 188% to \$564,000.
 - Therapy revenue increased to \$64,000.
 - Capital equipment sales and related service revenue increased 144% to \$395,000; resulting in 57 active surgical centers.
- Supported a record 233 cases, compared with 197 in the preceding quarter and 175 in the 2018 third quarter, a year-over-year growth of 33%.
- Increased to 10 centers using the Company’s two cases per day protocol.
- Completed the 3,000th ClearPoint Neuro Navigation System case.
- Signed an additional product development agreement in the biologics and drug delivery space; shipped product or performed services for 15 programs during 2019.
- Continued cash management program, using cash in operations of \$964,000, a significant portion of which was used to support our continued growth.
- Appointed healthcare veteran B. Kristine Johnson to the board of directors.
- Increased full-year 2019 revenue forecast to a range of \$10.5 million to \$11.5 million.

Joe Burnett, President and Chief Executive Officer of MRI Interventions, Inc., said, “The third quarter continued our string of setting quarterly revenue and ClearPoint case records in 2019, with revenue increasing 62% to a record \$2.9 million and the supported case total reaching 233. We also crossed a major milestone, reporting our 3,000th ClearPoint case during the quarter, which further demonstrates the maturity of our ClearPoint system in the clinical environment. In addition to new site launches, the strong case growth this year has been driven in part by a growing number of centers adopting our two case per day protocol, which leverages best practices in patient case management and tools in our ClearPoint 2.0 software platform to maximize the economic value of MRI scanner time available at those centers. We now have 10 centers using this protocol, and we continue to work with additional centers’ transition to this approach. Currently 29 of our installed base of 57 active surgical centers have our ClearPoint 2.0 software installed, continuing the rapid adoption since its full market release earlier this year.”

Mr. Burnett further noted, “We also made exciting progress on a number of other key initiatives, including continued growth in 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. We signed an additional co-development agreement with a new partner in the biologics and drug delivery space and have now shipped product or performed services for 15 biologics and drug delivery partners in 2019. We continue to be committed to our four-pillar growth strategy, which saw our core functional neurosurgery business grow 28% in the third quarter, supplemented by the growth in sales of biologics and drug delivery products, and capital equipment and related services. In fact, all four of our product segments saw significant revenue growth in the third quarter, which demonstrates our diversification into a platform company, with all elements of our business contributing to this result.”

Financial Results – Three Months Ended September 30, 2019

Functional neurosurgery revenue, which consists of disposable product sales related to cases utilizing the ClearPoint system, increased 28% to a record \$1.9 million for the three months ended September 30, 2019, from \$1.4 million for the same period in 2018. The increase was primarily due to an expanded customer base and increased utilization by our existing customers of MRI scanner availability.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials and services, increased 188% to \$564,000 for the three months ended September 30, 2019, from \$196,000 for the third quarter of 2018.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, and related service revenue, increased 144% to \$395,000 for the three months ended September 30, 2019, from \$162,000 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 September 30, 2019 was 66%, a slight decline from gross margin of 69% for the same period in 2018, but an increase from 60% in the second quarter of 2019, primarily due to shifts in product mix that vary on a quarterly basis between high-margin single use disposable sales and capital equipment sales which carry a lower margin.

Research and development costs were \$762,000 for three months ended September 30, 2019, compared to \$617,000 for the same period in 2018, an increase of 23%. Sales and marketing expenses were \$1.1 million for the three months ended September 30, 2019, compared to \$765,000 for the same period in 2018, an increase of 39%, attributable primarily to increases in incentive compensation tied to increased sales, and in the expansion of our field clinical team. General and administrative expenses were \$1.0 million for the three months ended September 30, 2019, compared to \$1.1 million for the same period in 2018, a decrease of 4%.

Outlook

“Based on our strong third quarter and year-to-date results combined with confidence in our anticipated fourth quarter sales, we are increasing our full-year 2019 revenue forecast to a range of \$10.5 million to \$11.5 million, from our previous forecast calling for a range of \$10.0 million to \$11.0 million,” said Mr. Burnett.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company’s 2019 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 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 November 26, 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 www.mriinterventions.com, 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 57 active surgical centers in the U.S. To date, more than 3,000 procedures have been performed leveraging the sub-millimetric accuracy of the ClearPoint platform. For more information, please visit www.mriinterventions.com.

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-K for the year ended December 31, 2018, the company's Quarterly Report on Form 10-Q for the period ended June 30, 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 September 30, 2019, which the company intends to file with the Securities and Exchange Commission on or before November 14, 2019.

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

	For The Three Months Ended September 30,	
	2019	2018
Revenues:		
Product revenues	\$ 2,594,428	\$ 1,739,804
Service and other revenues	333,038	67,238
Total revenues	<u>2,927,466</u>	<u>1,807,042</u>
Cost of revenues	983,042	553,221
Research and development costs	761,881	617,241
Sales and marketing expenses	1,063,143	764,599
General and administrative expenses	1,029,929	1,078,171
Operating loss	<u>(910,529)</u>	<u>(1,206,190)</u>
Other income (expense):		
Gain from change in fair value of derivative liabilities	–	22,295
Other income, net	728	2,643
Interest expense, net	<u>(213,167)</u>	<u>(246,824)</u>
Net loss	\$ <u>(1,122,968)</u>	\$ <u>(1,428,076)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.13)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>14,053,508</u>	<u>11,006,959</u>
	For The Nine Months Ended September 30,	
	2019	2018
Revenues:		
Product revenues	\$ 6,952,575	\$ 4,691,002
Service and other revenues	1,053,807	385,742
Total revenues	<u>8,006,382</u>	<u>5,076,744</u>
Cost of revenues	2,899,837	1,743,981
Research and development costs	2,044,224	1,828,846
Sales and marketing expenses	3,246,912	2,653,044
General and administrative expenses	2,991,305	3,119,617
Operating loss	<u>(3,175,896)</u>	<u>(4,268,744)</u>
Other income (expense):		
Gain from change in fair value of derivative liabilities	–	64,318
Other income, net	8,100	1,284
Interest expense, net	<u>(726,292)</u>	<u>(742,387)</u>
Net loss	\$ <u>(3,894,088)</u>	\$ <u>(4,945,529)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.45)</u>
Weighted average shares outstanding:		
Basic and diluted	<u>12,477,790</u>	<u>10,903,675</u>

MRI INTERVENTIONS, INC.
Consolidated Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,235,168	\$ 3,101,133
Accounts receivable, net	2,129,085	1,233,896
Inventory, net	3,180,250	2,105,976
Prepaid expenses and other current assets	364,273	213,684
Total current assets	11,908,776	6,654,689
Property and equipment, net	474,226	377,706
Software license inventory	451,900	801,900
Operating lease rights of use	400,755	-
Other assets	153,141	22,538
Total assets	\$ 13,388,798	\$ 7,856,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,671,722	\$ 500,929
Accrued compensation	993,150	764,960
Operating lease liabilities, current portion	113,263	-
Other accrued liabilities	403,054	390,838
Deferred revenue	1,097,644	350,963
Total current liabilities	4,278,833	2,007,690
Accrued interest	934,829	857,500
2014 junior secured notes payable, net	-	1,939,850
2010 junior secured notes payable, net	1,867,265	1,540,791
Operating lease liabilities	299,915	-
Total liabilities	7,380,842	6,345,831
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2019 and December 31, 2018	-	-
Common stock, \$0.01 par value; 200,000,000 shares authorized; 14,991,892 shares issued and outstanding at September 30, 2019; and 11,018,364 issued and outstanding at December 31, 2018	149,918	110,183
Additional paid-in capital	116,951,956	108,600,405
Accumulated deficit	(111,093,918)	(107,199,586)
Total stockholders' equity	6,007,956	1,511,002
Total liabilities and stockholders' equity	\$ 13,388,798	\$ 7,856,833

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

	For The Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (3,894,088)	\$ (4,945,529)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation	105,310	81,206
Share-based compensation	576,012	968,488
Expenses paid through the issuance of common stock	–	77,500
Gain from change in fair value of derivative liabilities	–	(64,318)
Amortization of debt issuance costs and original issue discounts	523,969	409,287
Amortization of lease rights of use, net of accretion in lease liabilities	76,871	–
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(895,189)	(105,911)
Inventory, net	(908,413)	(204,171)
Prepaid expenses and other current assets	(150,589)	(69,130)
Other assets	11,899	1,000
Accounts payable and accrued expenses	1,506,279	(361,886)
Lease liabilities	(82,448)	–
Deferred revenue	746,682	165,254
Net cash flows from operating activities	(2,383,705)	(4,048,210)
Cash flows from investing activities:		
Purchases of property and equipment	(10,190)	(62,651)
Acquisition of licensing rights	(150,000)	–
Net cash flows from investing activities	(160,190)	(62,651)
Cash flows from financing activities:		
Proceeds from private offering, net of offering costs	7,427,848	–
Proceeds from warrant and option exercises	387,426	531,977
Repayment of senior secured note payable	–	(2,000,000)
Repayment of 2014 junior secured notes payable	(1,975,000)	–
Repayment of 2010 junior secured notes payable	(162,344)	–
Net cash flows from financing activities	5,677,930	(1,468,023)
Net change in cash and cash equivalents	3,134,035	(5,578,884)
Cash and cash equivalents, beginning of period	3,101,133	9,289,831
Cash and cash equivalents, end of period	\$ 6,235,168	\$ 3,710,947

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:		
Income taxes	\$ –	\$ –
Interest	\$ 82,621	\$ 92,222