# 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 14, 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)

 ${\bf (949)\ 900\text{-}6833} \\ {\bf (Registrant's\ telephone\ number,\ including\ area\ code)}$ 

sk the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under 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))
cate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 $0.405$ of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 ( $\S240.12b-2$ of this chapter). $\square$
emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. $\Box$

#### Item 2.02. Results of Operations and Financial Condition.

On August 14, 2018, MRI Interventions, Inc. (the "Company") issued a press release announcing its financial performance for the second fiscal quarter ended June 30, 2018. 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 14, 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: August 14, 2018 MRI INTERVENTIONS, INC.

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz Chief Financial Officer



#### **MRI Interventions Reports Second Quarter Results**

Biologics Trials, CE Mark Clearances and FDA Submissions Expand Market Opportunities

IRVINE, CA, August 14, 2018 - MRI Interventions, Inc. (OTCQB: MRIC) (the "Company") today announced financial results for its second fiscal quarter ended June 30, 2018.

#### **Second Quarter 2018 Highlights**

- Total revenue for the second quarter was \$1.65 million, which represented a decrease of 17% versus the prior year quarter;
- Case volume using the ClearPoint® platform was 147 cases, compared with 162 cases in the prior year quarter, and reflected a full quarter impact of the FDA actions affecting third-party providers of laser ablation systems;
- Biologics and drug delivery revenues, which include sales of products and services, grew to \$274,000, a 196% increase over the prior year quarter; with biologics and drug delivery service revenues having commenced during the second quarter pursuant to the agreement with Voyager Therapeutics signed in May 2018;
- Clinical services revenue commenced during the second quarter pursuant to the agreement with Voyager Therapeutics signed in May 2018;
- Gross margin increased to 63% for the quarter, compared with 60% in the prior year quarter;
- Net loss in the second quarter 2018 was \$1.9 million, as compared with \$2.0 million in the same period of 2017;
- Cash flow used in operations was \$1.1 million, better than guidance of \$1.2 million and an improvement of 43% from \$2.0 million in the first quarter of 2018;
- Received CE Mark approval for MRI's SmartFlow<sup>TM</sup> cannula for the indication of delivery of fluids to the brain, with the expectation of clinical use in Europe before the end of 2018; and
- Submitted for FDA 510(k) Clearance for both the ClearPoint 2.0 software platform upgrade and for the ClearPoint PURSUIT<sup>TM</sup> neuro-aspiration device developed in concert with the Mayo Clinic.

Joe Burnett, President and Chief Executive Officer of MRI Interventions, Inc. said, "Despite the obvious headwinds we experienced in revenue and case volume, primarily as a result of the FDA actions adversely affecting third-party providers in the laser ablation space, our team had a strong quarter executing on our strategic initiatives. This included, among other things, strong progress on product development submissions and partnerships in the biologics and drug delivery space. We also demonstrated careful expense management to meet our cash flow guidance and bring down operating expenses. We believe sales in the quarter were adversely impacted by approximately 25 cases lost or postponed, and two capital deals that continue to be on hold, while the third-party providers of laser ablation systems work to implement solutions to issues raised by the FDA. We currently expect that implementation to be complete sometime in the first quarter of 2019."

"We also made significant progress on our four-part growth strategy," continued Mr. Burnett. "First, in functional neurosurgery, we submitted for 510(k) clearance of our ClearPoint 2.0 software platform, which we believe will deliver significant functionality advantages and procedural time savings through more efficient workflows in deep brain stimulation, laser ablation and tumor biopsy. Second, in biologics and drug delivery, we received CE Mark for our SmartFlow cannula to be used for the delivery of fluids to the brain and signed an agreement with Voyager Therapeutics to provide product, development and clinical support as Voyager moves into Phase 2-3 of their Parkinson's program. Third, in therapy, we submitted our 510(k) to the FDA for the ClearPoint PURSUIT neuro-aspiration device and believe that we remain on

5 Musick, Irvine, California 92618 949.900.6833

track to perform our first human case with this product before the end of 2018. Finally, for global expansion and scale, we completed translations and documentation for our SmartFrame navigation disposables and expect to perform our first case in Europe before the end of the year. All of these successes were achieved while reducing operating expenses and expanding gross margin.

"Looking ahead to the second half of the year, we expect case volume to rebound from a low in the second quarter as new sites begin evaluations with the ClearPoint system, current sites continue to improve workflow and move toward two cases a day, and drug delivery cases increase as Voyager expects to commence enrollment in its Phase 2-3 trial for treatment of Parkinson's disease in the months ahead. After achieving our guidance for operational cash flow in the second quarter, we continue to maintain our prior guidance of \$1.0 million in cash burn in the third quarter and \$800,000 in cash burn during the fourth quarter as we continue to show progress toward breakeven."

#### Financial Results - Three Months Ended June 30, 2018

Functional neurology revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 14% to \$1.2 million for the three months ended June 30, 2018, from \$1.3 million for the same period in 2017. The decrease was primarily due to deferred cases related to the FDA actions taken in early 2018 that adversely affected third-party providers in laser ablation space and the introduction of a new deep brain stimulation system that does not yet have approval for use in the MRI suite.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials, increased 196% to \$274,000 for the three months ended June 30, 2018, from \$92,000 for the same period in 2017, and reflected the commencement, during the three months ended June 30, 2018, of clinical trial support and related services.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, decreased 69% to \$141,000 for the three months ended June 30, 2018, from \$457,000 for the same period in 2017. Revenues from this product line historically have varied from quarter to quarter and have been impacted by the above-mentioned FDA warning letters to two laser system providers.

Gross margin for the three months ended June 30, 2018 improved to 63% from 60% in the same period in 2017, due primarily to reductions in indirect manufacturing costs as a percentage of sales.

Research and development costs were \$665,000 for three months ended June 30, 2018, compared to \$1.1 million for the same period in 2017, a decrease of 39%. The decrease was due primarily to upfront payments required under certain license and product co-development agreements entered into in April 2017.

Sales and marketing expenses were \$926,000 for the three months ended June 30, 2018, compared to \$980,000 for the same period in 2017, a decrease of 5%.

General and administrative expenses were \$1.1 million for the three months ended June 30, 2018, compared to \$936,000 for the same period in 2017, an increase of \$153,000, or 16%. This increase was due primarily to an increase in stock-based compensation.

Net interest expense for the three months ended June 30, 2018 was \$248,000, compared with \$213,000 for the same period in 2017. The increase was due to increased amortization of the discount and deferred issuance costs associated with notes payable.

#### **Teleconference Information**

Investors and analysts are invited to listen to a live broadcast review of the Company's 2018 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 <a href="https://www.mriinterventions.com">www.mriinterventions.com</a> 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 28, 2018 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 <a href="https://www.mriinterventions.com">www.mriinterventions.com</a>, on the "Investor Relations" page.

#### About MRI Interventions, Inc.

Building on the imaging power of magnetic resonance imaging ("MRI"), MRI Interventions is creating innovative platforms for performing the next generation of minimally invasive surgical procedures in the brain. The ClearPoint Neuro Navigation 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. 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: 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 Neuro Navigation System products; and the company's ability to market, commercialize and achieve broader market acceptance for the company's ClearPoint Neuro Navigation 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.

#### **Contact:**

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

For The Three Months Ended June 30.

		June 30,		
	·	2018		2017
Revenues:			-	
Product revenues	\$	1,412,599	\$	1,892,638
Service and other revenues		233,736		83,367
Total revenues		1,646,335		1,976,005
Cost of revenues		602,236		798,498
Research and development costs		665,310		1,084,202
Sales and marketing expenses		926,231		979,900
General and administrative expenses		1,088,496		935,701
Operating loss		(1,635,938)	-	(1,822,296)
Other income (expense):				
Gain from change in fair value of derivative liabilities		7,580		31,307
Other expense, net		(87)		(715)
Interest expense, net		(248,091)		(212,709)
Net loss	\$	(1,876,536)	\$	(2,004,413)
Net loss per share attributable to common stockholders:				_
Basic and diluted	\$	(0.17)	\$	(0.32)
Weighted average shares outstanding:				
Basic and diluted		10,959,532		6,315,759

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

For The Six Months Ended

		June 30,		
		2018		2017
Revenues:				
Product revenues	\$	2,951,198	\$	3,814,853
Service and other revenues		318,504		168,224
Total revenues		3,269,702		3,983,077
Cost of revenues		1,191,203		1,550,962
Research and development costs		1,211,638		1,641,901
Sales and marketing expenses		1,888,445		2,046,159
General and administrative expenses		2,041,446		1,919,971
Operating loss		(3,063,030)		(3,175,916)
Other income (expense):				
Gain (loss) from change in fair value of derivative liabilities		42,023		(61,739)
Other income (expense), net		(883)		3,412
Interest expense, net		(495,563)		(425,908)
Net loss	\$	(3,517,453)	\$	(3,660,151)
Net loss per share attributable to common stockholders:	_			
Basic and diluted	\$	(0.32)	\$	(0.74)
Weighted average shares outstanding:				
Basic and diluted		10,851,177		4,976,337

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

	June 30, 2018		December 31, 2017	
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 6,697,370	\$	9,289,831	
Accounts receivable, net	770,786		949,415	
Inventory, net	2,661,712		2,314,184	
Prepaid expenses and other current assets	321,550		192,727	
Total current assets	10,451,418		12,746,157	
Property and equipment, net	289,025		267,667	
Software license inventory	836,900		871,900	
Other assets	10,640		11,641	
Total assets	\$ 11,587,983	\$	13,897,365	
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$ 954,996	\$	759,445	
Accrued compensation	461,754		806,445	
Other accrued liabilities	378,912		480,159	
Derivative liabilities	22,295		95,786	
Deferred revenue	214,701		256,178	
Senior secured note payable	2,000,000		2,000,000	
2014 junior secured notes payable, net	1,914,742		_	
Total current liabilities	5,947,400		4,398,013	
Accrued interest	805,000		752,500	
2014 junior secured notes payable, net	_		1,874,570	
2010 junior secured notes payable, net	1,276,228		1,043,542	
Total liabilities	8,028,628		8,068,625	
Commitments and contingencies	, ,			
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at June 30, 2018 and December 31, 2017	_		_	
Common stock, \$0.01 par value; 200,000,000 shares authorized; 11,006,439 shares issued and outstanding at June 30, 2018; and 10,693,851 issued and outstanding at December 31,				
2017	110,064		106,937	
Additional paid-in capital	108,002,861		106,757,920	
Accumulated deficit	(104,553,570)		(101,036,117)	
Total stockholders' equity	3,559,355		5,828,740	
Total liabilities and stockholders' equity	\$ 11,587,983	\$	13,897,365	

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

For The Six Months Ended

		June 30,		
		2018		2017
Cash flows from operating activities:				_
Net loss	\$	(3,517,453)	\$	(3,660,151)
Adjustments to reconcile net loss to net cash flows from operating activities:				
Depreciation and amortization		55,418		65,824
Share-based compensation		607,124		429,026
Expenses paid through the issuance of common stock		77,500		502,032
(Gain) loss from change in fair value of derivative liabilities		(42,023)		61,739
Amortization of debt issuance costs and original issue discounts		272,858		201,243
Increase (decrease) in cash resulting from changes in:				
Accounts receivable		178,629		115,182
Inventory, net		(337,807)		(68,312)
Prepaid expenses and other current assets		(128,823)		(135,485)
Other assets		1,001		_
Accounts payable and accrued expenses		(197,888)		(279,435)
Deferred revenue		(41,477)		202,784
Net cash flows from operating activities		(3,072,941)		(2,565,553)
Cash flows from investing activities:				
Purchases of property and equipment		(51,497)		(3,134)
Net cash flows from investing activities		(51,497)		(3,134)
Cash flows from financing activities:				
Proceeds from private offering, net of offering costs		_		11,993,496
Proceeds from warrant exercises		531,977		
Net cash flows from financing activities		222,277		
3 · · · · · · · · · · · · · · · · · · ·		531,977		11,993,496
Net change in cash and cash equivalents		(2,592,461)		9,424,809
Cash and cash equivalents, beginning of period		9,289,831		3,315,774
Cash and cash equivalents, end of period	\$	6,697,370	\$	12,740,583
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SUPPLEMENTAL CASH FLOW INFORMATION				
Cash paid for:				
Income taxes	\$	_	\$	_
Interest	\$	146,000	\$	\$146,611
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