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 13, 2018 (November 12, 2018)

MRI INTERVENTIONS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-34822**	**58-2394628**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 2.02. Results of Operations and Financial Condition.

On November 12, 2018, MRI Interventions, Inc. (the "Company") issued a press release announcing its financial performance for the third fiscal quarter ended September 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 November 12, 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: November 13, 2018

MRI INTERVENTIONS, INC.

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

Exhibit 99.1

MRI Interventions Reports Record ClearPoint® Cases and Disposable Functional Neurosurgery Revenue in Third Quarter

IRVINE, CA, November 12, 2018 – MRI Interventions, Inc. (OTCQB: MRIC) (the "Company") today announced financial results for its third fiscal quarter ended September 30, 2018.

Third Quarter 2018 and Recent Highlights

- Total revenue for the third quarter was $1.8 million, an increase of 5% versus the prior year quarter.
- Received total purchase orders of $2.0 million in the quarter.
- Performed a record 175 ClearPoint cases, an increase of 19% compared with the preceding quarter and up 9% versus the prior year quarter.
- Reported a record $1.4 million in functional neurosurgery revenue, which is made up of disposable SmartFrame kits, an increase of 13% over the prior year quarter.
- Gross margin increased to 69% for the quarter, compared with 60% in the prior year quarter.
- Cash used in operations was $975,000, a favorable comparison to the previously communicated forecast of $1.0 million and an improvement of 12% from $1.1 million in cash used in the second quarter of 2018.
- Retired $2.0 million in debt and extended another $2.0 million of debt by 18 months, to September 2020.
- Acquired an exclusive, worldwide license to CLS's laser ablation platform for neurosurgery and spine procedures, including a commitment to co-develop products designed to improve accuracy and efficiency, enabling physicians to perform multiple cases in a single day of MRI scanner time.
- Announced an additional agreement with CLS to distribute its laser ablation system in the U.S. and Canada for use beyond the previously announced neuro and spine procedures.
- Announced first clinical use of the SmartFlow® cannulae in a dosing clinical trial under Axovant Scientific's Parkinson's Disease gene therapy program.
- Announced a collaboration with Monteris Medical to build next generation head-fixation frame technology leveraging knowledge and intellectual property from both companies.

Joe Burnett, President and Chief Executive Officer of MRI Interventions, Inc., said, "The third quarter marked a terrific period with record ClearPoint cases and exciting execution against our four-pillar growth strategy. We made significant progress in each of these four pillars as we transform MRIC into a company that provides comprehensive solutions to help surgeons decide, guide, treat and confirm in clinical procedures where accuracy is paramount to outcomes and patient quality of life.

"In pillar one, functional neurosurgery, we reported record case volumes and record revenue in the quarter. Our marketing efforts increased the number of sites using our multiple procedures per day protocol from three to six and added an additional system placement. Furthermore, FDA clearance in October of Monteris' new laser ablation probe should have an immediate positive impact on fourth quarter case volume, and we believe our headframe collaboration will further benefit patient mobility and procedure times when that joint product becomes commercially available in the coming years. Additionally, in November we received FDA clearance of our ClearPoint 2.0 next-generation software platform. We plan to immediately commence shipment and installation of ClearPoint 2.0 under a limited market release and expect it will be made available for purchase by all new and existing ClearPoint customers in the first half of 2019.

"In pillar two, biologics and drug delivery, we shipped $103,000 of SmartFlow cannulae to Europe under our new CE Mark, which we received in the second quarter, with an additional $49,000 in purchase orders to be shipped. Axovant's Parkinson's program progressed to a clinical dosing stage and the first treatment in that trial used our cannulae for gene delivery. Our partnership with Voyager Therapeutics continues to progress as five of our clinical specialists have been trained on the infusion and clinical procedure and will soon be able to cover clinical cases on behalf of Voyager once their Phase 2-3 study for Parkinson's enrolls its first patient.

“In pillar three, therapy, we announced an agreement with Clinical Laserthermia Systems, AB (“CLS”) to acquire a worldwide license to their FDA-cleared Tranberg laser ablation system for use in neurosurgery and spine. This will allow us to co-develop hardware, disposables and software to make the ClearPoint platform work together with the Tranberg system in a single, coordinated and efficient workflow with the goals of increasing accuracy and reducing procedure time. We are now redeploying existing resources to these products. Adding laser therapy to our portfolio has the potential to turn our lowest revenue and margin procedure into our highest.

“And in pillar four, gaining global scale, our non-neuro distribution agreement with CLS for the U.S. and Canada enables additional operating cost leverage within our commercial infrastructure. Our clinical specialists will be able to cover local cases on non-neuro days, increasing their average cases per week and further reducing travel.

“Importantly, we accomplished all of these strategic growth initiatives while still reducing cash used in operations, which came in at just under $1.0 million, despite putting these programs in place. We are maintaining our previously communicated expectation of cash used in operations in the fourth quarter of this year, which we believe will be approximately $800,000.

“We believe these initiatives will transform our company, as we move away from being a single-play, U.S. neuro-navigation company, and emerge as a full-line neuro and spine therapy company, with products and partnerships for navigation, laser ablation, deep-brain stimulation, aspiration, gene therapy and more, treating some of the most complex and debilitating neuro disorders. This is an exciting time for employees at the company because of the opportunities ahead, and the positive impact we believe we are having on patients every day.”

Financial Results – Three Months Ended September 30, 2018

Functional neurology revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 13% to $1.4 million for the three months ended September 30, 2018, from $1.3 million for the same period in 2017. The increase was primarily due to a 9% increase in ClearPoint case volume and a favorable number of DBS cases, which use two disposable kits per case.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials and services, increased 40% to $191,000 for the three months ended September 30, 2018, from $137,000 for the same period in 2017, due primarily to increased product sales.

Capital equipment and related service revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased 45% to $162,000 for the three months ended September 30, 2018, from $296,000 for the same period in 2017. Revenues from this product line historically have varied from quarter to quarter and, we believe, have been adversely impacted by FDA warning letters to two laser system providers, causing the deferral of multiple capital equipment sales until resolution of the matters raised in the FDA letters.

Gross margin for the three months ended September 30, 2018 improved to 69% from 60% in the same period in 2017, due primarily to reductions in indirect manufacturing costs as a percentage of sales and more favorable revenue mix.

Research and development costs were $617,000 for three months ended September 30, 2018, compared to $590,000 for the same period in 2017, an increase of 5%.

Sales and marketing expenses were $765,000 for the three months ended September 30, 2018, compared to $899,000 for the same period in 2017, a decrease of 15%.

General and administrative expenses were $1.1 million for the three months ended September 30, 2018, compared to $867,000 for the same period in 2017, an increase of 20%. The increase was due primarily to increases in stock-based compensation, legal fees and directors’ compensation, and to a decrease in activity-based cost allocation to other departments.

Net interest expense for the three months ended September 30, 2018 was $247,000, compared with $211,000 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 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 19, 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 www.mriinterventions.com, 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 which has been filed with the Securities and Exchange Commission, and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which the company intends to file with the Securities and Exchange Commission on or about November 13, 2018.

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

	For The Three Months Ended September 30,	
	2018	**2017**
Revenues:		
Product revenues	$ 1,739,804	$ 1,628,435
Service and other revenues	67,238	88,635
Total revenues	1,807,042	1,717,070
Cost of revenues	553,221	688,847
Research and development costs	617,241	589,716
Sales and marketing expenses	764,599	899,103
General and administrative expenses	1,078,171	866,727
Operating loss	(1,206,190)	(1,327,323)
Other income (expense):		
Gain from change in fair value of derivative liabilities	22,295	109,803
Other income, net	2,643	3,363
Interest expense, net	(246,824)	(211,362)
Net loss	$ (1,428,076)	$ (1,425,519)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.13)	$ (0.14)
Weighted average shares outstanding:		
Basic and diluted	11,006,959	10,339,210

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

	For The Nine Months Ended September 30,	
	2018	**2017**
Revenues:		
Product revenues	$ 4,691,002	$ 5,443,287
Service and other revenues	385,472	256,860
Total revenues	5,076,744	5,700,147
Cost of revenues	1,743,981	2,239,808
Research and development costs	1,828,846	2,231,616
Sales and marketing expenses	2,653,044	2,945,263
General and administrative expenses	3,119,617	2,786,698
Operating loss	(4,268,744)	(4,503,238)
Other income (expense):		
Gain from change in fair value of derivative liabilities	64,318	48,064
Other income, net	1,284	6,774
Interest expense, net	(742,387)	(637,270)
Net loss	$ (4,945,529)	$ (5,085,670)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.45)	$ (0.75)
Weighted average shares outstanding:		
Basic and diluted	10,903,675	6,783,605

MRI INTERVENTIONS, INC.
Consolidated Balance Sheets
(Unaudited)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,710,947	$ 9,289,831
Accounts receivable, net	1,055,327	949,415
Inventory, net	2,498,109	2,314,184
Prepaid expenses and other current assets	261,856	192,727
Total current assets	7,526,239	12,746,157
Property and equipment, net	321,858	267,667
Software license inventory	819,400	871,900
Other assets	10,640	11,641
Total assets	$ 8,678,137	$ 13,897,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 700,485	$ 759,445
Accrued compensation	643,734	806,445
Other accrued liabilities	252,820	480,159
Derivative liabilities	–	95,786
Deferred revenue	421,432	256,178
Senior secured note payable	–	2,000,000
Total current liabilities	2,018,471	4,398,013
Accrued interest	839,625	752,500
2014 junior secured notes payable, net	1,934,828	1,874,570
2010 junior secured notes payable, net	1,392,571	1,043,542
Total liabilities	6,185,495	8,068,625
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2018 and December 31, 2017	–	–
Common stock, $0.01 par value; 200,000,000 shares authorized; 11,022,372 shares issued and outstanding at September 30, 2018; and 10,693,851 issued and outstanding at December 31, 2017	110,223	106,937
Additional paid-in capital	108,364,065	106,757,920
Accumulated deficit	(105,981,646)	(101,036,117)
Total stockholders' equity	2,492,642	5,828,740
Total liabilities and stockholders' equity	$ 8,678,137	$ 13,897,365

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

	For The Nine Months Ended September 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (4,945,529)	$ (5,085,670)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	81,206	92,656
Share-based compensation	968,488	616,007
Expenses paid through the issuance of common stock	77,500	502,032
Gain from change in fair value of derivative liabilities	(64,318)	(48,064)
Amortization of debt issuance costs and original issue discounts	409,287	301,865
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(105,911)	2,185
Inventory, net	(204,171)	(311,637)
Prepaid expenses and other current assets	(69,130)	(104,329)
Other assets	1,000	–
Accounts payable and accrued expenses	(361,886)	(270,535)
Deferred revenue	165,254	58,709
Net cash flows from operating activities	(4,048,210)	(4,246,781)
Cash flows from investing activities:		
Purchases of property and equipment	(62,651)	(24,515)
Net cash flows from investing activities	(62,651)	(24,515)
Cash flows from financing activities:		
Proceeds from private offering, net of offering costs	–	11,984,495
Proceeds from warrant exercises	531,977	–
Repayment of senior secured note payable	(2,000,000)	–
Net cash flows from financing activities	(1,468,023)	11,984,495
Net change in cash and cash equivalents	(5,578,884)	7,713,199
Cash and cash equivalents, beginning of period	9,289,831	3,315,774
Cash and cash equivalents, end of period	$ $3,710,947	$ 11,028,973
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ –	$ –
Interest	$ 92,222	$ 146,611