August 14, 2018

MRI Interventions Reports Second Quarter Results

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

IRVINE, Calif., Aug. 14, 2018 (GLOBE NEWSWIRE) -- 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;
- 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® 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™ 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 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 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 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 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, 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.

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

	For The Three Months Ended 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	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
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ -	$ -
Interest	$ 146,000	$ 146,611

Primary Logo

Source: MRI Interventions, Inc.