

MRI Interventions Reports 36% Increase in Fourth Quarter Revenue and Record Quarterly ClearPoint® Cases

Fourth Quarter Cash Burn from Operations Reduced to \$600,000

IRVINE, Calif., March 11, 2019 (GLOBE NEWSWIRE) -- MRI Interventions, Inc. (OTCQB: MRIC) (the "Company") today announced financial results for its fourth fiscal quarter and full year ended December 31, 2018.

Fourth Quarter 2018 Highlights

- Increased fourth quarter revenue 36% year-over-year to a record \$2.3 million.
- Reported a record \$1.6 million in quarterly functional neurosurgery revenue, an increase of 21% over the prior year fourth quarter.
- Increased gross margin to 70%, compared with 61% in the prior year fourth guarter.
- Completed a record 188 procedures across the Company's product portfolio, an increase of 18% over the prior year fourth guarter.
- Secured five additional hospital evaluations of the ClearPoint platform.
- Achieved FDA clearance for the ClearPoint 2.0 software platform and the ClearPoint PURSUIT[™] Neuro Aspiration System.
- Acquired a license to the CLS Tranberg[®] Therma Therapy System and laser applicators for use in neuro and spine, and commenced co-development efforts.
- Participated in the first patient cases in Voyager Therapeutics' Phase 2 VY-AADC Gene Therapy Trial for treatment of Parkinson's disease.
- Participated in the first patient dosing in Axovant Sciences' clinical study of AXO-Lenti-PD as a gene therapy for treatment of Parkinson's disease.
- Reduced cash used in operations to \$600,000, below the previous estimate of \$800,000.

Joe Burnett, President and Chief Executive Officer of MRI Interventions, Inc., said, "We produced a record fourth quarter including 36% growth in total revenue, a record 188 ClearPoint cases, a record \$1.6 million in functional neurosurgery revenue and a 70% gross margin while reducing cash used in operations to \$600,000. These results reflect diligent focus on our four-pillar growth strategy by our entire team and set the stage for an even more exciting year ahead. This is reflected in our 2019 expectations, which call for 800 to 850 cases using our ClearPoint system and revenue of \$9.5 to \$10.5 million.

"In pillar one, functional neurosurgery, we again reported record case volumes and record revenue in the quarter. We also commenced evaluation at five new ClearPoint sites and increased the number of sites using our multiple procedures per day protocol to seven. The increase in case volume reflected resolution in late 2018 of the FDA actions that affected third-party providers in the laser ablation space and overall momentum for ClearPoint guided procedures. We also received FDA clearance in November for our ClearPoint 2.0 next-generation software platform and expect it will be available for purchase by all new and existing ClearPoint customers in the first half of 2019.

"In biologics and drug delivery, our second pillar, we are supporting multiple new gene therapy trials using a variety of combinations of our products and clinical support services. This includes commencement of services under our expanded agreement with Voyager as part of its Phase 2 and 3 VY-AADC clinical trial.

"In pillar three, therapy, we announced an agreement with CLS to co-develop hardware, disposables and software to make the ClearPoint platform work together with the FDA-cleared Tranberg Therma Therapy System in a single, coordinated and efficient workflow. We believe that adding laser therapy to our portfolio has the potential to turn our lowest revenue and margin procedure into our highest. We also received clearance for our ClearPoint PURSUIT Neuro Aspiration System designed in collaboration with the Mayo Clinic. The PURSUIT device allows surgeons to identify an aspiration target using real-time MRI guidance and monitor the aspiration during surgery of the ventricular system or cerebrum.

"And in pillar four, gaining global scale, we entered into a distribution agreement with CLS for the distribution in the U.S. and Canada of its laser ablation system for non-neuro applications.

"We believe these outcomes demonstrate the success of our efforts to transform our company into a full-line neuro and spine therapy company, with products and partnerships for navigation, laser ablation, deep-brain stimulation, aspiration, gene therapy and more. We are excited to continue these efforts in 2019 and expect noteworthy increases in both cases and revenue as we continue to advance our initiatives."

2019 Outlook

The Company announced that it has raised its 2019 revenue expectation to be in a range of \$9.5 to \$10.5 million, representing year-over-year growth of 30% to 42%. The Company expects ClearPoint case volume to show similar growth in reaching an estimated range of 800 to 850 cases across its product portfolio.

Financial Results – Three Months Ended December 31, 2018

Functional neurosurgery revenue, which consists of disposable product sales and services related to cases utilizing the ClearPoint system, increased 21% to \$1.6 million for the three months ended December 31, 2018, from \$1.3 million for the same period in 2017. The increase was primarily due to an increase in ClearPoint case volume.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials and services, increased 1,029% to \$469,000 for the three months ended December 31, 2018, from \$42,000 for the same period in 2017.

Capital equipment and related service revenue, consisting of sales of ClearPoint reusable hardware and software and related services, decreased to \$174,000 for the three months ended December 31, 2018, from \$290,000 for the same period in 2017, due primarily to a decrease in sales of ClearPoint systems, which, as previously noted, historically have varied from quarter to quarter. The decrease in systems sales was partially offset by a 79% increase in capital equipment-related service revenues for the three months ended December 31, 2018 from the same period in 2017.

Gross margin for the three months ended December 31, 2018 improved to 70% from 61% in the same period in 2017, due primarily to favorable product mix of higher margin disposable products and services.

Research and development costs were \$481,000 for three months ended December 31, 2018, compared to \$582,000 for the same period in 2017, a decrease of 17%. Sales and marketing expenses were \$879,000 for the three months ended December 31, 2018, compared to \$1.0 million for the same period in 2017, a decrease of 13%. General and administrative expenses were \$1.2 million for the three months ended December 31, 2018, compared to \$1.3 million for the same period in 2017, a decrease of 4%.

Financial Results – Year Ended December 31, 2018

Functional neurosurgery revenue decreased 2% to \$5.4 million from \$5.5 million in 2017. The decrease was due primarily to two factors: (a) FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space until resolutions were accepted by the FDA in the 2018 fourth quarter; and (b) a third-party provider introduced a new deep brain stimulation system that did not have approval for use in the MRI suite for most of 2018, which was resolved in the 2018 third quarter. In spite of these factors, cases continued to climb year-over-year, to 670 cases in 2018, compared with 629 in 2017.

Biologics and drug delivery revenue increased 177% to \$1.1 million for 2018, from \$405,000 in 2017. This increase was due primarily to the commencement of additional services during 2018, and to an increase in biologics and drug delivery product sales.

Capital equipment and related service revenue decreased to \$813,000 for 2018, from \$1.5 million in 2017, due primarily to a decrease in sales of ClearPoint systems, which, as previously noted, historically have varied from quarter to quarter. The decrease in systems sales was partially offset by a 12% increase in capital equipment-related service revenues for the year ended December 31, 2018, as compared to 2017.

Gross margin for the year ended December 31, 2018 improved to 67% from 61% in 2017. The increase was due primarily to increased contribution from higher margin disposables and services revenue.

Research and development costs were \$2.3 million in 2018, compared to \$2.8 million in 2017, a decrease of \$504,000, or 18%. Sales and marketing expenses were \$3.5 million for the year ended December 31, 2018, compared to \$4.0 million in 2017, a decrease of \$424,000, or 11%. General and administrative expenses were \$4.3 million for 2018, compared to \$4.0 million for in 2017, an increase of \$279,000, or 7%.

Teleconference Information

Investors and analysts are invited to listen to a live broadcast review of the Company's 2018

fourth quarter and full year 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 March 25, 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.

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 for the guarter ended September 20, 2018, both of which have been filed with the Securities and Exchange Commission, and the Company's Annual Report on Form 10-K for the year ended December 31, 2018, which the company intends to file with the Securities and Exchange Commission on or about April 1, 2019.

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Consolidated Statements of Operations

	Three Months Ended December 31,		
	2018	2017	
Revenues: Product revenues	\$ 1,994,019	\$ 1,580,723	
Service and other revenues	282,504	98,655	
Total revenues	2,276,523	1,679,378	
Cost of revenues	689,088	659,000	
Research and development costs	481,293	582,158	
Sales and marketing expenses	878,997	1,011,193	
General and administrative expenses	1,206,169	1,259,848	
Operating loss	(979,024	(1,832,821)	
Other income (expense):			
Gain (loss) on change in fair value of derivative liabilities	-	(23,336)	
Other income (loss), net	(920) 10,130	
Interest expense, net	(237,996	(235,656)	
Net loss	\$ (1,217,940) \$ (2,081,683)	
Net loss per share attributable to common stockholders:		<u> </u>	
Basic and diluted	\$ (0.11) \$ (0.20)	
Weighted average shares outstanding:			
Basic and diluted	11,012,208	10,571,422	

MRI INTERVENTIONS, INC.

Consolidated Statements of Operations

	Years Ended [Years Ended December 31,		
	2018	2017		
Revenues:				
Product revenues	\$ 6,685,020	\$ 7,024,010		
Service and other revenues	668,246	355,515		
Total revenues	7,353,266	7,379,525		
Cost of revenues	2,433,069	2,898,808		
Research and development costs	2,310,139	2,813,733		
Sales and marketing expenses	3,532,040	3,956,455		
General and administrative expenses	4,325,786	4,046,366		
Operating loss	(5,247,768)	(6,335,837)		
Other income (expense):				
Gain on change in fair value of derivative liabilities	64,318	24,728		
Other income, net	364	16,682		
Interest expense, net	(980,383_)	(872,926)		
Net loss	\$ (6,163,469)	\$ (7,167,353)		
Net loss per share attributable to common stockholders:				
Basic and diluted	\$ (0.56)	\$ (0.93)		
Weighted average shares outstanding:				
Basic and diluted	10,928,213	7,738,343		

MRI INTERVENTIONS, INC.

Consolidated Balance Sheets

		December 31,		
		2018		2017
ASSETS	_			
Current assets:				
Cash and cash equivalents	\$	3,101,133	\$	9,289,831
Accounts receivable, net		1,233,896		949,415
Inventory, net		2,105,976		2,314,184
Prepaid expenses and other current assets		213,684		192,727
Total current assets		6,654,689		12,746,157
Property and equipment, net		377,706		267,667
Software license inventory		801,900		871,900
Other assets		22,538		11,641
Total assets	\$	7,856,833	\$	13,897,365
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	500,929	\$	759,445
Accrued compensation		764,960		806,445
Other accrued liabilities		390,838		480,159
Derivative liabilities		-		95,786
Deferred product and service revenues		350,963		256,178
Senior secured note payable		-		2,000,000
Total current liabilities		2,007,690		4,398,013
Accrued interest		857,500		752,500
2010 junior secured notes payable, net of unamortized discount of \$1,459,209 and		,,,,,,		,
\$1,956,458 at December 31, 2018 and 2017, respectively		1,540,791		1,043,542
2014 junior secured notes payable, net of unamortized discount and deferred issuance costs				
aggregating \$35,149 and \$100,430 at December 31, 2018 and 2017, respectively		1,939,850		1,874,570
Total liabilities		6,345,831		8,068,625
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.01 par value; 25,000,000 shares authorized at December 31, 2018 and				
2017; none issued and outstanding at December 31, 2018 and 2017				
		-		-
Common stock, \$0.01 par value; 200,000,000 shares authorized at December 31, 2018 and				
2017; 11,018,364 and 10,693,851 shares issued and outstanding at December 31, 2018 and		440 400		400.007
2017, respectively		110,183		106,937
Additional paid-in capital		108,600,405		106,757,920
Accumulated deficit	((107,199,586)	((101,036,117)
Total stockholders' equity		1,511,002		5,828,740
Total liabilities and stockholders' equity	\$	7,856,833	\$	13,897,365

MRI INTERVENTIONS, INC.

Consolidated Statements of Cash Flows

Cash flows from operating activities: Net loss Adjustments to reconcile net loss to net cash flows from operating activities: Depreciation and amortization Share-based compensation	2018 \$ (6,163,469) 109,439 1,231,379 77,500	\$ (7,167,353 116,454
Net loss Adjustments to reconcile net loss to net cash flows from operating activities: Depreciation and amortization Share-based compensation	109,439 1,231,379	•
Adjustments to reconcile net loss to net cash flows from operating activities: Depreciation and amortization Share-based compensation	109,439 1,231,379	•
Depreciation and amortization Share-based compensation	1,231,379	116,454
Share-based compensation	1,231,379	116,454
Share-based compensation		
·		1,245,601
Expenses paid through the issuance of common stock		502,032
Gain on change in fair value of derivative liabilities	(64,318)	(24,178
Amortization of debt issuance costs and original issue discounts	562,529	426,358
Increase (decrease) in cash resulting from changes in:	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	-,
Accounts receivable	(284,481)	(83,472
Inventory	122,220	(469,922
Prepaid expenses and other current assets	(20,957)	(57,731
Other assets	(10,897)	(999
Accounts payable and accrued expenses	(284,322)	(512,362
Deferred revenue	94,785	33,061
Net cash flows from operating activities	(4,630,592)	(5,992,511
Cash flows from investing activities:	 `	· · · · · · · · · · · · · · · · · · ·
Purchases of property and equipment	(63,490)	(26,752
Net cash flows from investing activities	(63,490)	(26,752
Cash flows from financing activities:		
Net proceeds from equity private placements and exercise of warrants	_	11,993,320
Exercise of warrants	505,384	-
Repayment of senior secured note	(2,000,000)	-
Net cash flows from financing activities	(1,494,616)	11,993,320
Net change in cash and cash equivalents	(6,188,698)	5,974,057
Cash and cash equivalents, beginning of year	9,289,831	3,315,774
Cash and cash equivalents, end of year	\$ 3,101,133	\$ 9,289,831
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SUPPLEMENTAL CASH FLOW INFORMATION Cash paid for:		
Income taxes	\$ -	\$ -
Interest	\$ 210,722	\$ 348,528
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Source: MRI Interventions, Inc.