

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2019

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-34822

MRI Interventions, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation or Organization)

58-2394628
(IRS Employer
Identification Number)

5 Musick
Irvine, California
(Address of Principal Executive Offices)

92618
(Zip Code)

(949) 900-6833

(Registrant's Telephone Number, Including Area Code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.)

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller Reporting Company
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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 7, 2019, there were 15,205,867 shares of common stock outstanding.

MRI INTERVENTIONS, INC.

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Trademarks, Trade Names and Service Marks

ClearPoint[®], *ClearTrace*[®] and *MRI Interventions*[®] are trademarks of MRI Interventions, Inc. Any other trademarks, trade names or service marks referred to in this Quarterly Report on Form 10-Q (this “Quarterly Report”) are the property of their respective owners. As used in this Quarterly Report, Brainlab refers to Brainlab AG and its affiliates.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains “forward-looking statements” as defined under the United States federal securities laws. The forward-looking statements are contained principally in the section of this Quarterly Report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements, expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- future revenues from sales of ClearPoint system products;
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products; and
- estimates regarding the sufficiency of our cash resources and our ability to obtain additional financing, to the extent necessary or advisable.

In some cases, you can identify forward-looking statements by terms such as “anticipates,” “believes,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

You should refer to the section titled “Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which we filed with the SEC on April 1, 2019 (the “2018 Form 10-K”), for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Quarterly Report, except to the extent required by applicable securities laws.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

MRI INTERVENTIONS, INC.
Condensed 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	<u>11,908,776</u>	<u>6,654,689</u>
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	<u>\$ 13,388,798</u>	<u>\$ 7,856,833</u>
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	<u>4,278,833</u>	<u>2,007,690</u>
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	<u>7,380,842</u>	<u>6,345,831</u>
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	<u>6,007,956</u>	<u>1,511,002</u>
Total liabilities and stockholders' equity	<u>\$ 13,388,798</u>	<u>\$ 7,856,833</u>

See accompanying notes to Condensed Consolidated Financial Statements.

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	\$ (1,122,968)	\$ (1,428,076)
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>

See accompanying notes to Condensed Consolidated Financial Statements.

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

	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	8,006,382	5,076,744
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	(3,175,896)	(4,268,744)
Other income (expense):		
Gain from change in fair value of derivative liabilities	-	64,318
Other income, net	8,100	1,284
Interest expense, net	(726,292)	(742,387)
Net loss	\$ (3,894,088)	\$ (4,945,529)
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.31)	\$ (0.45)
Weighted average shares outstanding:		
Basic and diluted	12,477,790	10,903,675

See accompanying notes to Condensed Consolidated Financial Statements.

MRI INTERVENTIONS, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

For The Nine Months Ended September 30, 2019

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2019	11,018,364	\$ 110,183	\$ 108,600,405	\$ (107,199,586)	\$ 1,511,002
Cumulative adjustment for adoption of new accounting standard	-	-	-	(244)	(244)
Issuances of common stock:					
Share-based compensation	28,462	285	152,301	-	152,586
Cashless warrant exercises	20,381	204	(204)	-	-
Net loss for the period	-	-	-	(1,220,725)	(1,220,725)
Balances, March 31, 2019	11,067,207	110,672	108,752,502	(108,420,555)	442,619
Issuances of common stock:					
Share-based compensation	3,251	32	203,962	-	203,994
Warrant exercises	189,407	1,894	381,182	-	383,076
May 2019 private placement, net of offering costs of \$94,162	2,426,455	24,265	7,403,583	-	7,427,848
Net loss for the period	-	-	-	(1,550,395)	(1,550,395)
Balances, June 30, 2019	13,686,320	136,863	116,741,229	(109,970,950)	6,907,142
Issuances of common stock:					
Share-based compensation	157,169	1,571	217,861	-	219,432
Cashless warrant exercises	1,145,903	11,459	(11,459)	-	-
Stock option exercise	2,500	25	4,325	-	4,350
Net loss for the period	-	-	-	(1,122,968)	(1,122,968)
Balances, September 30, 2019	14,991,892	\$ 149,918	\$ 116,951,956	\$ (111,093,918)	\$ 6,007,956

For The Nine Months Ended September 30, 2018

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2018	10,693,851	\$ 106,937	\$ 106,757,920	\$ (101,036,117)	\$ 5,828,740
Issuances of common stock:					
Share-based compensation	9,298	93	247,372	-	247,465
Under contractual arrangements	25,000	250	77,250	-	77,500
Warrant exercises	97,747	978	235,620	-	236,598
Net loss for the period	-	-	-	(1,640,917)	(1,640,917)
Balances, March 31, 2018	10,825,896	\$ 108,258	\$ 107,318,162	\$ (102,677,034)	\$ 4,749,386
Issuances of common stock:					
Share-based compensation	31,977	320	359,339	-	359,659
Warrant exercises	148,566	1,486	325,360	-	326,846
Net loss for the period	-	-	-	(1,876,536)	(1,876,536)
Balances, June 30, 2018	11,006,439	110,064	108,002,861	(104,553,570)	3,559,355
Issuances of common stock:					
Share-based compensation	15,933	159	361,204	-	361,363
Net loss for the period	-	-	-	(1,428,076)	(1,428,076)
Balances, September 30, 2018	11,002,372	\$ 110,223	\$ 108,364,065	\$ (105,981,646)	\$ 2,492,642

See accompanying notes to Condensed Consolidated Financial Statements.

MRI INTERVENTIONS, INC.
Condensed 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

NON-CASH TRANSACTIONS:

- On January 1, 2019, the Company adopted the provisions of Topic 842 within the Accounting Standards Codification, which resulted in the establishment of operating lease right-of-use assets and operating lease liabilities, each in the aggregate amount of \$480,395 (see Notes 2 and 6).
- During the nine months ended September 30, 2019 and 2018, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of \$191,647 and \$72,746, respectively, from loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets, to inventory.

See accompanying notes to Condensed Consolidated Financial Statements.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business and Liquidity

MRI Interventions, Inc. (the “Company”) is a medical device company focused on the development and commercialization of technology that enables physicians to see inside the brain and heart using direct, intra-procedural magnetic resonance imaging (“MRI”) guidance while performing minimally invasive surgical procedures.

The Company’s ClearPoint system, an integrated system comprised of reusable and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The Company received 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) in 2010 to market the ClearPoint system in the United States for general neurological interventional procedures. The Company’s ClearTrace system is a product candidate that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. Although still a product candidate, the Company has reduced its efforts to commercialize the ClearTrace system.

Liquidity and Management’s Plans

The Company has incurred net losses since its inception which has resulted in a cumulative deficit at September 30, 2019 of \$111 million. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable, product and service contracts and license arrangements.

The Company’s plans for the next twelve months reflect management’s anticipation of: (a) increases in revenues from sales of the ClearPoint System and related disposable products resulting from greater utilization at existing installed sites and the installation of the ClearPoint system at new sites, and from expansion of its product and service platforms; (b) growth in operating expenses that will be modest in comparison to the anticipated growth in revenues, with resulting decreases in loss from operations and in cash used in operations, albeit continuing to result in operations consuming cash over at least the next twelve months; and (c) financing activities to support repayment of debt obligations maturing in 2020 as discussed in Note 5. In management’s opinion, cash and cash equivalent balances at September 30, 2019, when combined with the Company’s operational and financing plans as set forth herein, are sufficient to support the Company’s operations and meet its obligations for at least the next twelve months. There is no assurance, however, that the Company will be able to achieve the objectives set forth in such plans.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

In the opinion of management, the accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company’s December 31, 2018 audited consolidated financial statements, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth therein. These condensed consolidated financial statements have been prepared in accordance with United States (“U.S.”) Securities and Exchange Commission (“SEC”) rules for interim financial information, and, therefore, omit certain information and footnote disclosures necessary to present such statements in accordance with generally accepted accounting principles in the U.S. (“GAAP”). The preparation of these condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s 2018 Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and nine months ended September 30, 2019 may not be indicative of the results to be expected for the entire year or any future periods.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Inventory

Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. Items in inventory relate predominantly to the Company's ClearPoint system. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying condensed consolidated balance sheets. All other software license inventory is classified as a non-current asset. The Company periodically reviews its inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

Intangible Assets

In June 2019, the Company entered into an Exclusive License Agreement (the "License Agreement") that provides exclusive rights to the Company for the development and commercialization of products in the functional neurosurgery field. Under the terms of the License Agreement, the Company paid \$150,000 to the licensor upon execution of the License Agreement and will make future payments based on the achievement of regulatory and commercialization milestones as defined in the License Agreement.

In conformity with Accounting Standards Codification Section 350, "Intangibles – Goodwill and Other," the Company amortizes its investment in the license rights described above over an expected useful life of 10 years.

Revenue Recognition

The Company's revenues are comprised primarily of: (1) product revenues resulting from the sale of functional neurosurgical products, and drug delivery and biologic products; (2) product revenues resulting from the sale of ClearPoint capital equipment; (3) functional neurosurgery and related service revenues resulting from the performance of product line commercialization planning and execution for a third party; (4) clinical case support revenues in connection with customer-sponsored clinical trials; and (5) revenues resulting from the rental, service, installation, training and shipping related to ClearPoint capital equipment. The Company recognizes revenue when control of the Company's products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Lines of Business; Timing of Revenue Recognition

- *Functional neurosurgery product, biologics and drug delivery systems product, and therapy product sales:* Revenues from the sale of functional neurosurgery products (consisting of disposable products sold commercially and related to cases utilizing the Company's ClearPoint system), biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing the ClearPoint system), and therapy products (consisting of disposable laser applicators), are generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are generally recognized at the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.
- *Capital equipment sales*
 - *Capital equipment sales preceded by evaluation periods:* The predominance of capital equipment sales (consisting of integrated computer hardware and software that are integral components of the Company's ClearPoint system) are preceded by customer evaluation periods of generally 90 days. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, revenue from capital equipment sales following such evaluation periods is recognized at the point in time the Company is in receipt of an executed purchase agreement or purchase order.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

- *Capital equipment sales not preceded by evaluation periods:* Revenue from sales of capital equipment not having been preceded by an evaluation period is recognized at the point in time that the equipment has been delivered to the customer.

For both types of capital equipment sales described above, the Company's determination of the point in time at which to recognize revenue represents that point at which the customer has legal title, physical possession, and the risks and rewards of ownership, and the Company has a present right to payment.

- *Functional neurosurgery and related services:* Revenues from functional neurosurgery and related services are recognized over the period of time such services are rendered.
- *Biologics and drug delivery services:*
 - *Outsourced recruitment and/or designation of a clinical services liaison between Company and its customer:* The Company recognizes revenue at the point in time that the liaison is either recruited or designated, which is the point at which the customer is able to direct, and obtain benefit from, use of the liaison. The Company made this determination based on the decision made by the customer to outsource this function to the Company, rather than to incur its own recruiting costs. Upon such recruitment or designation, the liaison becomes the customer's outsourced clinical support services coordinator.
 - *Outsourced technical clinical support of cases performed pursuant to customer-sponsored clinical trials:* The Company recognizes revenue at the point in time a clinical trial case is performed based on the allocated per-case transaction price.
 - *Other related services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.
- *Capital equipment-related services*
 - *Rental and equipment service:* Revenue from rental of ClearPoint capital equipment is recognized ratably on a monthly basis over the term of the rental agreement, which is less than one year. Revenue from service of ClearPoint capital equipment previously sold to customers is based on agreements with terms ranging from one to three years and revenue is recognized ratably on a monthly basis over the term of the service agreement. A time-elapsing output method is used for rental and service revenues because the Company transfers control evenly by providing a stand-ready service.
 - *Installation, training and shipping:* Consistent with the Company's recognition of revenue for capital equipment sales as described above, fees for installation, training and shipping fees in connection with sales of capital equipment that have been preceded by customer evaluation periods are recognized as revenue at the point in time the Company is in receipt of an executed purchase order for the equipment. Installation, training and shipping fees related to capital equipment sales not having been preceded by an evaluation period are recognized as revenue at the point in time that the related services are performed.

The Company operates in one industry segment, and substantially all its sales are to U.S.-based customers.

Payment terms under contracts with customers generally are in a range of 30-60 days after the customers' receipt of the Company's invoices.

The Company provides a one-year warranty on its functional neurosurgery products, biologics and drug delivery systems products, and capital equipment products that are not otherwise covered by a third-party manufacturer's warranty. The Company's contracts with customers do not provide for a right of return other than for product defects.

See Note 3 for additional information regarding revenue recognition.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Net Loss Per Share

The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which comprise the entire amount of the Company's outstanding common stock options and warrants as described in Note 7, would be anti-dilutive.

Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At September 30, 2019, the Company had approximately \$280,000 in bank balances that were in excess of the insured limits.

No customer accounted for sales in excess of 10% of total sales in any of the nine-month or three-month periods ended September 30, 2019 or 2018.

At September 30, 2019, an account receivable, related to the Letter of Intent discussed in Note 3, comprised 28% total accounts receivable at that date. Information with respect to accounts receivable from those customers who comprised more than 10% of accounts receivable at December 31, 2018 is as follows:

Customer – 1	17%
Customer – 2	12%

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts was approximately \$45,000 and \$38,000 at September 30, 2019 and December 31, 2018, respectively.

The Company is subject to risks common to emerging companies in the medical device industry, including, but not limited to: new technological innovations; acceptance and competitiveness of its products; dependence on key personnel; dependence on key suppliers; changes in general economic conditions and interest rates; protection of proprietary technology; compliance with changing government regulations; uncertainty of widespread market acceptance of products; access to credit for capital purchases by customers; and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Adoption of New Accounting Standard – Leases

Effective January 1, 2019, the Company adopted the provisions of Accounting Standards Update ("ASU") 2016-02, "Leases," which created a new Topic 842 within the Accounting Standards Codification. Topic 842 established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments that arise from leases.

See Note 6 for additional information regarding leases.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
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3. Revenue Recognition

Revenue by Service Line

	Three Months Ended September 30,	
	2019	2018
Products:		
Disposable products:		
Functional neurosurgery	\$ 1,854,251	\$ 1,448,850
Biologics and drug delivery	491,257	190,993
Therapy	64,095	-
Capital equipment	184,825	99,961
Total product revenue	<u>2,594,428</u>	<u>1,739,804</u>
Services:		
Capital equipment and other	210,538	62,238
Biologics and drug delivery	72,500	5,000
Therapy	50,000	-
Total service revenue	<u>333,038</u>	<u>67,238</u>
Total revenue	<u>\$ 2,927,466</u>	<u>\$ 1,807,042</u>
	Nine Months Ended September 30,	
	2019	2018
Products:		
Disposable products:		
Functional neurosurgery	\$ 5,212,460	\$ 3,787,712
Biologics and drug delivery	957,673	483,251
Therapy	81,925	-
Capital equipment	700,517	420,039
Total product revenue	<u>6,952,575</u>	<u>4,691,002</u>
Services:		
Capital equipment and other	515,695	218,742
Biologics and drug delivery	335,500	167,000
Therapy	202,612	-
Total service revenue	<u>1,053,807</u>	<u>385,742</u>
Total revenue	<u>\$ 8,006,382</u>	<u>\$ 5,076,744</u>

Contract Balances

- *Contract assets* – Substantially all the Company’s contracts with customers are based on customer-issued purchase orders for distinct products or services. Customers are billed upon delivery of such products or services, and the related contract assets comprise the accounts receivable balances included in the accompanying condensed consolidated balance sheets.
- *Contract liabilities* – The Company generally bills and collects capital equipment-related service fees at the inception of the service agreements, which have terms ranging from one to three years. The unearned portion of such service fees are classified as deferred revenue.

During the three and nine months ended September 30, 2019, the Company recognized capital equipment-related service revenue of \$38,093 and \$173,247, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2018.

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In September 2019, the Company entered into a Development Services Agreement with a customer under which the Company was entitled to bill the customer for an upfront payment of \$127,600, which the Company received in September 2019 and which is included in accounts receivable and deferred revenue in the accompanying consolidated balance sheet. Also, in September 2019, the Company entered into a Letter of Intent (the "LOI") with a customer who is a stockholder and whose Chief Operating Officer is a member of the Company's Board of Directors. The purpose of the LOI is to permit the commencement of a product development project in anticipation of negotiating a detailed Statement of Work (as described in the LOI) by December 31, 2019. Under the terms of the LOI, the Company was entitled to bill the customer for an upfront, nonrefundable payment of \$500,000, which amount is included in accounts receivable and deferred revenue in the accompanying September 30, 2019 condensed consolidated balance sheet. The Company intends to recognize each of the upfront payments described in this paragraph in proportional relationship to the transaction prices of the performance obligations contained in the related agreements.

During the three and nine months ended September 30, 2019, the Company offered an upgraded version of its software at no additional charge to customers purchasing a three-year systems service agreement. The transaction prices of the software and the service agreement were determined through an allocation of the service agreement price based on the standalone prices of the software and the service agreements. The transaction price of the software was recognized as revenue upon its installation and comprised approximately \$113,000 of unbilled accounts receivable at September 30, 2019.

Remaining Performance Obligations

The Company's contracts with customers, other than capital equipment-related service agreements discussed below, are predominantly of terms less than one year. Accordingly, the transaction price of remaining performance obligations related to such contracts at September 30, 2019 are not material.

Revenue with respect to remaining performance obligations related to capital equipment-related service agreements with original terms in excess of one year amounted to \$398,943 at September 30, 2019. The Company expects to recognize this revenue within the next three years.

4. Inventory

Inventory consists of the following as of:

	September 30, 2019	December 31, 2018
Raw materials and work in process	\$ 1,624,342	\$ 1,219,753
Software licenses	402,500	122,500
Finished goods	<u>1,153,408</u>	<u>763,723</u>
Inventory, net, included in current assets	3,180,250	2,105,976
Software licenses – non-current	<u>451,900</u>	<u>801,900</u>
Total	<u>\$ 3,632,150</u>	<u>\$ 2,907,876</u>

5. Notes Payable

Senior Secured Note Payable

On September 25, 2018, the Company repaid in full all the outstanding debt, together with accrued and unpaid interest, under the senior secured note payable to Brainlab (the "Brainlab Note"). The Brainlab Note had a maturity date of December 31, 2018, and interest was payable quarterly in arrears at an annual rate of 5.5%. In connection with the repayment, the security agreement under which the Brainlab Note had been collateralized by all the assets of the Company was terminated.

2014 Junior Secured Notes Payable

On June 6, 2019, the Company repaid in full all the outstanding principal, which, together with accrued and unpaid interest, totaled approximately \$2.0 million, of its 12% Second-Priority Secured Non-Convertible Promissory Notes due 2019, as amended (the "2014 Secured Notes"). The 2014 Secured Notes had a maturity date of September 30, 2020, and interest was payable semi-annually in arrears. In connection with the repayment, the security agreement under which the 2014 Secured Note had been collateralized by all the assets of the Company was terminated.

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2010 Junior Secured Notes Payable

The Junior Secured Promissory Notes Due 2020 (the “2010 Secured Notes”) accrue interest at an annual rate of 3.5% and are collateralized by a security interest in all the Company’s assets, which, subsequent to the repayments of the Brainlab Notes and the 2014 Secured Notes described above, is the senior such interest. All outstanding principal and interest on the 2010 Secured Notes will be due and payable upon maturities in October and November 2020.

The carrying amount of the 2010 Secured Notes in the accompanying condensed consolidated balance sheets is presented net of a discount arising from shares issued to the noteholders at issuance of the 2010 Secured Notes. The unamortized discount at September 30, 2019 and December 31, 2018 was \$970,390 and \$1,459,209, respectively. This discount is being amortized to interest expense over the term of the notes using the effective interest method.

At each of September 30, 2019 and December 31, 2018, the Company’s Chairman and one of the Company’s officers held 2010 Secured Notes purchased at the date of original issuance having an aggregate principal balance of \$197,000.

In July 2019, the Company repaid, at a negotiated discount, two of the 2010 Secured Notes having an aggregate principal amount of approximately \$162,000, at the request of the holders of such 2010 Secured Notes.

Scheduled Notes Payable Maturities

Scheduled principal payments as of September 30, 2019 with respect to notes payable are summarized as follows:

Years ending December 31,	
2019	\$ -
2020	2,837,655
Total scheduled principal payments	2,837,655
Less: Unamortized discount	(970,390)
Total	\$ 1,867,265

6. Leases

The Company leases office space in Irvine, California that houses its headquarters and manufacturing facility under a non-cancellable operating lease. The lease term commenced on October 1, 2018 and expires in September 2023. The Company has the option to renew the lease for two additional periods of five years each. The Company also leases office space in Mississauga, Ontario, Canada for its software development personnel. The lease term commenced on August 1, 2018, was set to expire in July 2019, was renewed for a one-year period at the Company’s option, and provides for automatic one-year renewals at the Company’s option. Both office leases are classified as operating leases in conformity with the provisions of Topic 842.

The lease cost, included in general and administrative expense, was \$27,468 and \$82,405 for the three and nine months ended September 30, 2019, respectively.

At September 30, 2019, the weighted average discount rate was 6.7% and the weighted average remaining lease term was 47.36 months with respect to the leases described above.

The assumptions used in determining the foregoing information are as follows:

- Lease term – Topic 842 provides that the lease term consists of: (a) the non-cancelable period of the Irvine and Mississauga office leases; and (b) the period covered by the Company option to extend each office lease for which the Company is reasonably certain to do so. Based on the foregoing, management determined the lease term to extend to September 2023 for the Irvine office lease, and to July 2020 for the Mississauga office lease.
- Discount rate – Topic 842 provides that the discount rate is the rate implicit in the lease unless that rate cannot be determined, in which case the lessee’s incremental borrowing rate shall be used. Because neither the rate implicit in the lease nor the Company’s incremental borrowing rate were determinable, discount rates were obtained with reference to published U.S. High Yield CCC corporate bond rates at the inception dates of each of the leases, which, with respect to the Irvine office lease was 6.7%, and with respect to the Mississauga office lease was 6.9%.

MRI Interventions, Inc.
Notes to Condensed Consolidated Financial Statements
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7. Stockholders' Equity

2019 Private Placement

On May 9, 2019, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors (collectively, the "Investors") for the private placement of 2,426,455 shares of the Company's common stock at \$3.10 per share (the "2019 PIPE"). The Company received aggregate gross proceeds of approximately \$7.5 million, before deducting offering expenses aggregating approximately \$94,000.

The Purchase Agreement also contains representations and warranties by the Company and the Investors and covenants of the Company and the Investors (including indemnification from the Company in the event of breaches of its representations and warranties), certain information rights and other rights, obligations and restrictions, which the Company believes are customary for transactions of this type.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Director fees, whether paid in cash or in shares of common stock, are payable quarterly on the last day of each fiscal quarter. The number of shares of common stock issued to directors is determined by dividing the product of: (i)(a) the fees otherwise payable to each director in cash, times (b) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. Following is information regarding the number of shares issued to directors as payment for director fees in lieu of cash:

Three Months Ended September 30,	
2019	2018
5,720	15,933

Nine Months September 30,	
2019	2018
23,459	38,341

Stock Incentive Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans") under which it has granted share-based awards, such as stock grants, and incentive and non-qualified stock options, to employees, directors, consultants and advisors. Awards may be subject to a vesting schedule as set forth in individual award agreements. Certain of the Plans also have provided for cash-based performance bonus awards.

Since October 2017, the Company has granted share-based awards under the MRI Interventions, Inc. Second Amended and Restated 2013 Incentive Compensation Plan (the "2013 Plan"). Under the 2013 Plan, a total of 1,956,250 shares of the Company's common stock are reserved for issuance. Of this amount, stock grants of 387,975 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 1,042,166 shares were outstanding as of September 30, 2019. Accordingly, 523,609 shares remained available for grants under the 2013 Plan as of that date.

MRI Interventions, Inc.
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Stock option activity under all of the Company's Plans during the nine months ended September 30, 2019 is summarized below:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2019	1,386,396	\$ 11.09
Granted	216,046	3.34
Exercised	(2,500)	1.74
Expired / forfeited	(12)	385.60
Outstanding at September 30, 2019	<u>1,599,930</u>	<u>\$ 9.79</u>

As of September 30, 2019, there was unrecognized compensation expense of \$587,431 related to outstanding stock options, which is expected to be recognized over a weighted average period of 1.7 years.

Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the nine months ended September 30, 2019 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2019	8,676,481	\$ 4.17
Exercised	(2,437,755)	2.20
Expired / Terminated	(29,754)	41.55
Outstanding at September 30, 2019	<u>6,208,972</u>	<u>\$ 4.76</u>

8. Derivative Liabilities

Derivative liabilities arose from an amendment the Company entered into with Brainlab, with respect to the Brainlab Note and related warrants (the "Brainlab warrants"), the provisions of which created: (a) a conversion feature allowing for \$500,000 the principal balance of the Brainlab Note to be converted in a Qualified Public Offering, as defined in the amendment, at a public offering price that may be less than market value per share of the Company's common stock; and (b) down round strike price protection with respect to Brainlab warrants. The conversion feature and the Brainlab warrants described herein terminated unexercised pursuant to the Company's September 2018 repayment of the Brainlab Note as discussed in Note 5, and, accordingly, the Company had no derivative liabilities thereafter.

The fair values and the changes in fair values of derivative liabilities during the nine months ended September 30, 2018 are as follows:

Balance, January 1, 2018	\$ 95,786
Reduction from warrant exercise	(31,468)
Gain on change in fair value for the period	(64,318)
Balance, September 30, 2018	<u>\$ -</u>

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the unaudited condensed financial statements and the notes thereto appearing in Part I, Item 1 of this Quarterly Report. Historical results and trends that might appear in this Quarterly Report should not be interpreted as being indicative of future operations.

Overview

We are a medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain under direct, intra-procedural MRI guidance. We have two product platforms. Our principal product platform is our ClearPoint system, which is in commercial use and is used to perform minimally invasive surgical procedures in the brain. The ClearPoint system utilizes intra-procedural MRI to guide the procedures and is designed to work in a hospital's existing MRI suite. We believe that this product platform will deliver better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system. In addition, we have the ClearTrace product candidate that is designed to allow catheter-based minimally invasive procedures in the heart to be performed in an MRI suite. Although still a product candidate, the Company has reduced its efforts to commercialize the ClearTrace system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the U.S. for general neurological procedures. In addition, in 2011, we obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. Substantially all our product revenues for the three and nine months ended September 30, 2019 relate to sales of our ClearPoint system products. We have financed our operations and internal growth primarily through the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of September 30, 2019, we had accumulated losses of approximately \$111 million. We may continue to incur operating losses as we expand our ClearPoint system platform and our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors that may influence our future results of operations, and that we believe are important to an understanding of our business and results of operations.

Revenues

In 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. for general neurological procedures. Future revenues from sales of our ClearPoint system products are difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses.

Generating recurring revenues from the sale of functional neurosurgical products is an important part of our business model for our ClearPoint system. We anticipate that, over time, recurring revenues will constitute an increasing percentage of our total revenues as we leverage installations of our ClearPoint system to generate recurring sales of our functional neurosurgical products. Our product revenues were approximately \$2.6 million and \$7.0 million for the three and nine months ended September 30, 2019, respectively, and predominantly related to our ClearPoint system.

Our revenue recognition policies are more fully described in Note 2 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Cost of Revenues

Cost of revenues includes the direct costs associated with the assembly and purchase of components for functional neurosurgical products, drug delivery and biologic products, and ClearPoint capital equipment which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of revenues also includes the allocation of manufacturing overhead costs and depreciation of loaned systems installed under our ClearPoint placement program, as well as provisions for obsolete, impaired, or excess inventory.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products. Such costs include salaries, travel, and benefits for research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; consultant costs; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development costs may increase as we: (i) continue to develop enhancements to our ClearPoint system; (ii) increase our ClearTrace system product development efforts; and (iii) seek to expand the application of our technological platforms. From our inception through September 30, 2019, we have incurred approximately \$55 million in research and development expenses.

Product development timelines, likelihood of success, and total costs can vary widely by product candidate. There are also risks inherent in the regulatory clearance and approval process. At this time, we are unable to estimate with any certainty the costs that we will incur in either the further development of our ClearTrace system for commercialization, or in our efforts to expand the application of our technological platforms.

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for attorneys and outside accountants; occupancy costs; insurance; and other general and administrative expenses, which include, but are not limited to, corporate licenses, director fees, hiring costs, taxes, postage, office supplies and meeting costs. Our sales and marketing expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system and the increased headcount necessary to support growth in operations.

Critical Accounting Policies

As described in Note 2 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, effective January 1, 2019, we adopted the provisions of ASC Topic 842, "Leases."

There have been no other significant changes in our critical accounting policies during the three or nine months ended September 30, 2019 as compared to the critical accounting policies described in our 2018 Form 10-K.

Results of Operations

Three Months Ended September 30, 2019 Compared to the Three Months Ended September 30, 2018

	Three Months Ended September 30,		
	2019	2018	Percentage Change
Product revenues	\$ 2,594,428	\$ 1,739,804	49%
Service and other revenues	333,038	67,238	395%
Total revenues	2,927,466	1,807,042	62%
Cost of revenues	983,042	553,221	78%
Research and development costs	761,881	617,241	23%
Sales and marketing expenses	1,063,143	764,599	39%
General and administrative expenses	1,029,929	1,078,171	(4)%
Other income (expense):			
Gain from change in fair value of derivative liabilities	-	22,295	(100)%
Other income, net	728	2,643	(72)%
Interest expense, net	(213,167)	(246,824)	(14)%
Net loss	<u>\$ (1,122,968)</u>	<u>\$ (1,428,076)</u>	(21)%

Revenues. Total revenues were \$2.9 million for the three months ended September 30, 2019, and \$1.8 million for the three months ended September 30, 2018, an increase of \$1.1 million, or 62%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 28% to \$1.9 million for the three months ended September 30, 2019, from \$1.4 million for the same period in 2018. We believe this increase in volume is indicative of several factors, including: (a) an expanded customer base; (b) greater acceptance of the ClearPoint system; (c) more efficient utilization of MRI scanner availability by our existing customers; and (d) the resolution in late 2018 of FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space and, by extension, adversely affected customer orders of the ClearPoint system and related disposable products. There were no increases in functional neurosurgery product prices during the period between the three months ended September 30, 2019 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 188% to \$564,000 for the three months ended September 30, 2019, from \$196,000 for the same period in 2018. This increase was due primarily to: (a) an increase, during the quarter ended September 30, 2019, relative to the same period in 2018, in biologic and drug delivery product revenues. There were no increases in biologics and drug delivery product prices during the period between the three months ended September 30, 2018 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, increased 85% to \$185,000 for the three months ended September 30, 2019, from \$100,000 for the same period in 2018. Revenues from this product line historically have varied from quarter to quarter. This increase was due primarily to an increase from the third quarter of 2018 to the same period in 2019 in the number of ClearPoint systems sold. There were no increases in capital equipment product prices during the period between the three months ended September 30, 2019 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, increased 238% to \$211,000 for the three months ended September 30, 2019, from \$62,000 for the same period in 2018. The increase was due primarily to an increase in equipment service contracts. Also contributing to the increase were fees associated with the aforementioned increase in capital equipment sales.

Cost of Revenues. Cost of revenues was \$983,000, representing a gross margin of 66%, for the three months ended September 30, 2019, and was \$553,000, representing a gross margin of 69%, for the three months ended September 30, 2018. This decrease in gross margin was due primarily to: (a) a shift in the mix of revenues by line of business that resulted in functional neurosurgery disposable products and ClearPoint system software, which bear higher gross margins in comparison to other product lines, representing a lower percentage in total sales for the three months ended September 30, 2019, relative to the same period in 2018; (b) an increase in the average cost of disposable product components; and (c) an increase in indirect costs from the third quarter of 2018 to the same period in 2019.

Research and Development Costs. Research and development costs were \$762,000 for the three months ended September 30, 2019, compared to \$617,000 for the same period in 2018, an increase of \$145,000, or 23%. The increase was due primarily to increases in personnel and product development costs, with related increases in intellectual property and consulting costs, which were partially offset by decreases in professional fees and costs incurred in connection with sponsored research projects which had been undertaken during the quarter ended September 30, 2018, but which had been subsequently discontinued.

Sales and Marketing Expenses. 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 \$299,000, or 39%. This increase was primarily due to increases in personnel costs attributable to increases in: (a) incentive compensation consistent with the increase in revenues during the three months ended September 30, 2019 as compared to the same period in 2018; and (b) clinical personnel headcount during the three months ended September 30, 2019 as compared to the same period in 2018.

General and Administrative Expenses. 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 \$48,000, or 4%. This decrease was due primarily to a decrease in the accrual for directors' fees which was partially offset by increases in personnel costs and professional fees.

Other Income (Expense). Net interest expense for the three months ended September 30, 2019 was \$213,000, compared with \$247,000 for the same period in 2018. The decrease was primarily due to the repayment, in June 2019, of the 2014 Secured Notes as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Nine Months Ended September 30, 2019 Compared to the Nine Months Ended September 30, 2018

	Nine Months Ended September 30,		
	2019	2018	Percentage Change
Product revenues	\$ 6,952,575	\$ 4,691,002	48%
Service and other revenues	1,053,807	385,742	173%
Total revenues	8,006,382	5,076,744	58%
Cost of revenues	2,899,837	1,743,981	66%
Research and development costs	2,044,224	1,828,846	12%
Sales and marketing expenses	3,246,912	2,653,044	22%
General and administrative expenses	2,991,305	3,119,617	(4)%
Other income (expense):			
Gain from change in fair value of derivative liabilities	-	64,318	(100)%
Other income, net	8,100	1,284	531%
Interest expense, net	(726,292)	(742,387)	(2)%
Net loss	<u>\$ (3,894,088)</u>	<u>\$ (4,945,529)</u>	(21)%

Revenue. Total revenues were \$8.0 million for the nine months ended September 30, 2019, and \$5.1 million for the nine months ended September 30, 2018, an increase of \$2.9 million, or 58%.

Functional neurosurgery revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 38% to \$5.2 million for the nine months ended September 30, 2019, from \$3.8 million for the same period in 2018. We believe this increase in volume is indicative of several factors, including: (a) an expanded customer base; (b) greater acceptance of the ClearPoint system; (c) more efficient utilization of MRI scanner availability by our existing customers; and (d) the resolution in late 2018 of FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space and, by extension, adversely affected customer orders of the ClearPoint system and related disposable products. There were no increases in functional neurosurgery product prices during the period between the nine months ended September 30, 2019 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 99% to \$1.3 million for the nine months ended September 30, 2019, from \$650,000 for the same period in 2018. This increase was due primarily to an increase in biologic and drug delivery product revenues during the nine months ended September 30, 2019, relative to the same period in 2018, as well as to an increase, between the same periods, in services revenues due primarily to this service line not having commenced until the second fiscal quarter of 2018. There were no increases in biologics and drug delivery product prices during the period between the nine months ended September 30, 2018 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, increased 67% to \$701,000 for the nine months ended September 30, 2019, from \$420,000 for the same period in 2018. Revenues from this product line historically have varied from quarter to quarter. This increase was due primarily to an increase from the nine months ended September 30, 2018 to the same period in 2019 in the number of ClearPoint systems sold. There were no increases in capital equipment product prices during the period between the nine months ended September 30, 2019 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, increased 136% to \$516,000 for the nine months ended September 30, 2019, from \$219,000 for the same period in 2018. The increase was due primarily to an increase in equipment service contracts.

Cost of Revenues. Cost of revenues was \$2.9 million for the nine months ended September 30, 2019, representing a gross margin of 64%, and was \$1.7 million for the same period in 2018, representing gross margin of 66%. This decrease in gross margin was due primarily to: (a) a shift in the mix of revenues by line of business that resulted in functional neurosurgery disposable products and ClearPoint system software, which bear higher gross margins in comparison to other product lines, representing a lower percentage in total sales for the nine months ended September 30, 2019, relative to the same period in 2018; (b) an increase in the average cost of disposable product components; and (c) an increase in indirect costs from the nine months ended September 30, 2018 to the same period in 2019.

Research and Development Costs. Research and development costs were \$2.0 million for the nine months ended September 30, 2019, compared to \$1.8 million for the same period in 2018, an increase of \$215,000, or 12%. The increase was due primarily to increases in personnel and product development costs, and related intellectual property and consulting costs, which were partially offset by decreases in regulatory legal fees.

Sales and Marketing Expenses. Sales and marketing expenses were \$3.2 million for the nine months ended September 30, 2019, compared to \$2.7 million for the same period in 2018, an increase of \$600,000, or 22%. This increase was primarily due to an increase in personnel costs due to increases in headcount of clinical personnel and in incentive compensation which is consistent with increases in revenue for the nine months ended September 30, 2019 as compared to the same period in 2018.

General and Administrative Expenses. General and administrative expenses decreased 4% to \$3.0 million for the nine months ended September 30, 2019 and compared to \$3.1 million for the same period in 2019. This decrease was due primarily to decrease in personnel costs and an increase in activity-based cost allocations to other departments, which were partially offset by increases in license fees and taxes and insurance premiums.

Other Income (Expense). Net interest expense for the nine months ended September 30, 2019 was \$726,000, compared with \$742,000 for the same period in 2018. The decrease was primarily due to the repayment, in June 2019, of the 2014 Secured Notes, which was partially offset by increased amortization of the discount and deferred issuance costs associated with the 2014 Secured Notes and the 2010 Secured Notes, as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Liquidity and Capital Resources

At September 30, 2019, we had cash and cash equivalent balances aggregating \$6.2 million. Net cash used in operating activities was \$2.4 million for the nine months ended September 30, 2019.

Our plans for the next twelve months reflect our anticipation of: (a) increases in revenues from sales of the ClearPoint system and related disposable products resulting from greater utilization at existing installed sites and the installation of the ClearPoint system at new sites, and from expansion of our product and service platforms; (b) growth in operating expenses that will be modest in comparison to the anticipated growth in revenues, with resulting decreases in loss from operations and in cash used in operations, albeit continuing to result in operations consuming cash over at least the next twelve months; and (c) financing activities to support repayment of debt obligations maturing in 2020 as discussed in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report. In management's opinion, cash and cash equivalent balances at September 30, 2019, when combined with our operational and financing plans as set forth herein, are sufficient to support our operations and meet our obligations for at least the next twelve months. There is no assurance, however, that we will be able to achieve the objectives set forth in such plans.

Cash Flows

Cash activity for the nine months ended September 30, 2019 and 2018 is summarized as follows:

	Nine Months Ended September 30,	
	2019	2018
Cash used in operating activities	\$ (2,383,705)	\$ (4,048,210)
Cash used in investing activities	(160,190)	(62,651)
Cash provided (used) by financing activities	5,677,928	(1,468,023)
Net change in cash and cash equivalents	<u>\$ 3,134,035</u>	<u>\$ (5,578,884)</u>

Net Cash Flows from Operating Activities. We used \$2.4 million and \$4.0 million of cash for operating activities during the nine months ended September 30, 2019 and 2018, respectively.

During the nine months ended September 30, 2019, uses of cash in operating activities primarily consisted of: (i) our \$3.9 million net loss; (ii) increases in accounts receivable of \$895,000, inventory of \$908,000, and prepaid expenses and other current assets of \$151,000; and (iii) a decrease in lease liabilities of \$82,000. These uses were partially offset by: (a) a decrease in other assets of \$12,000; (b) increases in accounts payable and accrued expenses of \$1.5 million and in deferred revenue of \$747,000; and (c) net non-cash expenses included in our net loss aggregating \$1.3 million and consisting primarily of depreciation and amortization, share-based compensation, and amortization of debt issuance costs, original issue discounts on debt and lease rights-of-use, net of accretion in lease liabilities.

During the nine months ended September 30, 2018, uses of cash in operating activities primarily consisted of: (i) our \$4.9 million net loss; (ii) increases in accounts receivable of \$106,000, inventory of \$204,000 and prepaid expenses and other current assets of \$69,000; and (iii) a decrease in accounts payable and accrued expenses of \$362,000. These uses were partially offset by: (a) net non-cash expenses included in our net loss aggregating \$1.5 million and consisting primarily of depreciation and amortization, share-based compensation, expenses paid through the issuance of common stock, change in fair value of derivative liabilities and amortization of debt issuance costs and original issue discounts; and (b) a decrease in other assets of \$1,000 and an increase in deferred revenue of \$165,000.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the nine months ended September 30, 2019 were \$160,000 and consisted primarily of an acquisition of medical device license rights.

Net cash flows used in investing activities for the nine months ended September 30, 2018 was \$63,000 and consisted of equipment acquisitions.

Net Cash Flows from Financing Activities. Net cash flows from financing activities for the nine months ended September 30, 2019 consisted of: (a) net proceeds of \$7.4 million received from the sale of shares of our common stock under the terms of the 2019 PIPE as described in Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report; and (b) \$387,000 received from warrant exercises. These proceeds were partially offset by the \$2.0 million repayment, in June 2019, of the 2014 Secured Notes, and the \$162,000 repayment of certain of the 2010 Secured Notes, both as described in Note 5 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Net cash flows from financing activities for the nine months ended September 30, 2018 consisted of the \$2.0 million repayment of the Brainlab Note as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, net of cash proceeds received from warrant exercises of \$532,000.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our ClearPoint system products, develop our ClearTrace system, and pursue additional applications for our technology platforms. Our cash balances are primarily held in a variety of demand accounts with a view to liquidity and capital preservation.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical devices, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to successfully commercialize our ClearPoint system products, complete the development of our ClearTrace system and pursue additional applications for our technology platforms. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Off-Balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Interest Rate Risk

Our exposure to market risk is limited primarily to interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, because all our investments are in short-term bank deposits and institutional money market funds. The primary objective of our investment activities is to preserve principal while at the same time maximizing income we receive without significantly increasing risk. Due to the nature of our short-term investments, we believe that we are not subject to any material market risk exposure.

Foreign Currency Risk

To date, we have recorded no product sales in currencies other than U.S. dollars. We have only limited business transactions in foreign currencies. We do not currently engage in hedging or similar transactions to reduce our foreign currency risks, which at present, are not material. We believe we have no material exposure to risk from changes in foreign currency exchange rates at this time. We will continue to monitor and evaluate our internal processes relating to foreign currency exchange, including the potential use of hedging strategies.

ITEM 4. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"). Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2019 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2019.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2019, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

None.

ITEM 1A. RISK FACTORS.

Our business, future financial condition and results of operations are subject to a number of factors, risks and uncertainties, which are disclosed in Item 1A, “Risk Factors,” in Part I of our 2018 Form 10-K. Additional information regarding some of those risks and uncertainties is contained in the notes to the Condensed Consolidated Financial Statements appearing in Part I, Item 1 of this Quarterly Report, and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing in Part I, Item 2 of this Quarterly Report. The risks and uncertainties disclosed in our 2018 Form 10-K, our quarterly reports on Form 10-Q and other reports filed with the SEC are not necessarily all the risks and uncertainties that may affect our business, financial condition and results of operations in the future.

There have been no material changes to the risk factors as disclosed in our 2018 Form 10-K.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

The exhibits listed below are filed, furnished or incorporated by reference as part of this Quarterly Report.

Exhibit Number	Exhibit Description
<u>31.1*</u>	<u>Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u>
<u>31.2*</u>	<u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u>
<u>32+</u>	<u>Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code</u>
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation

* Filed herewith.

+ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350, and it is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 thereunto duly authorized.

Date: November 13, 2019

MRI INTERVENTIONS, INC.

By: /s/ Joseph M. Burnett

Joseph M. Burnett
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Harold A. Hurwitz

Harold A. Hurwitz
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Joseph M. Burnett, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2019, of MRI Interventions, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2019

/s/ Joseph M. Burnett

Joseph M. Burnett
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

I, Harold A. Hurwitz, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2019, of MRI Interventions, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2019

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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER
THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF
CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE**

Each of the undersigned, Joseph M. Burnett and Harold A. Hurwitz, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended September 30, 2019, of MRI Interventions, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2019

/s/ Joseph M. Burnett

Joseph M. Burnett
Chief Executive Officer

/s/ Harold A. Hurwitz

Harold A. Hurwitz
Chief Financial Officer
