

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 June 30, 2016

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: 000-54575

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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files.)

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if smaller reporting company)

Smaller Reporting Company

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 August 1, 2016, there were 2,401,401 shares of common stock outstanding.

MRI INTERVENTIONS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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:

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

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, 2015, which we filed with the SEC on March 25, 2016, 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
(Unaudited)

	<u>June 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,015,982	\$ 5,408,523
Accounts receivable	769,723	1,218,043
Inventory, net	1,644,095	1,807,895
Prepaid expenses and other current assets	258,801	97,249
Total current assets	<u>4,688,601</u>	<u>8,531,710</u>
Property and equipment, net	539,747	440,606
Software license inventory	976,900	937,100
Other assets	238,210	27,306
Total assets	<u>\$ 6,443,458</u>	<u>\$ 9,936,722</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,097,503	\$ 697,807
Accrued compensation	516,913	557,784
Other accrued liabilities	718,223	1,398,707
Derivative liabilities	1,085,414	658,286
Deferred product and service revenues	222,637	116,009
Senior secured note payable, net of unamortized discount of \$64,835 at December 31, 2015	-	4,224,609
Total current liabilities	<u>3,640,690</u>	<u>7,653,202</u>
Accrued interest	715,125	542,500
Senior secured note payable	2,000,000	-
2014 junior secured notes payable, net of unamortized discount and deferred issuance costs of \$244,944 and \$467,611 at June 30, 2016 and December 31, 2015, respectively	3,480,056	3,257,389
2010 junior secured notes payable, net of unamortized discount of \$2,427,789 and \$2,535,230 at June 30, 2016 and December 31, 2015, respectively	572,211	464,770
Total liabilities	<u>10,408,082</u>	<u>11,917,861</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 2,401,401 shares issued and outstanding at June 30, 2016; and 2,284,537 issued and outstanding at December 31, 2015	24,014	22,845
Additional paid-in capital	85,636,016	83,722,596
Accumulated deficit	<u>(89,624,654)</u>	<u>(85,726,580)</u>
Total stockholders' deficit	<u>(3,964,624)</u>	<u>(1,981,139)</u>
Total liabilities and stockholders' deficit	<u>\$ 6,443,458</u>	<u>\$ 9,936,722</u>

See accompanying notes.

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

	For The Three Months Ended	
	June 30,	
	2016	2015
Revenues:		
Product revenues	\$ 1,066,551	\$ 774,054
Other service revenues	37,330	29,249
Development services revenues	-	22,438
Total revenues	<u>1,103,881</u>	<u>825,741</u>
Cost of product revenues	520,987	394,821
Research and development costs	749,942	426,931
Selling, general, and administrative expenses	1,888,056	2,187,393
Restructuring charges	-	499,184
Operating loss	<u>(2,055,104)</u>	<u>(2,682,588)</u>
Other income (expense):		
Gain (loss) from change in fair value of derivative liabilities	263,927	(186,304)
Gain from debt restructuring	121,224	-
Other income, net	139,239	115,522
Interest income	2,125	4,744
Interest expense	<u>(253,375)</u>	<u>(311,525)</u>
Net loss	<u>\$ (1,781,964)</u>	<u>\$ (3,060,151)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (0.90)	\$ (2.08)
Weighted average shares outstanding:		
Basic and diluted	1,971,071	1,472,998

See accompanying notes.

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

	For The Six Months Ended	
	June 30,	
	2016	2015
Revenues:		
Product revenues	\$ 2,432,705	\$ 1,750,925
Other service revenues	65,311	62,781
Development service revenues	-	22,438
Total revenues	<u>2,498,016</u>	<u>1,836,144</u>
Cost of product revenues	1,217,533	780,430
Research and development costs	1,407,134	954,443
Selling, general, and administrative expenses	3,862,305	4,476,053
Restructuring charges	-	1,252,584
Operating loss	<u>(3,988,956)</u>	<u>(5,627,366)</u>
Other income (expense):		
Gain (loss) from change in fair value of derivative liabilities	424,045	(969,106)
Gain from debt restructuring	121,224	-
Other income, net	214,380	198,209
Interest income	6,458	12,195
Interest expense	<u>(602,933)</u>	<u>(619,337)</u>
Net loss	<u>\$ (3,825,782)</u>	<u>\$ (7,005,405)</u>
Net loss per share attributable to common stockholders:		
Basic and diluted	\$ (1.66)	\$ (4.73)
Weighted average shares outstanding:		
Basic and diluted	2,309,537	1,481,021

See accompanying notes.

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

	For The Six Months Ended	
	June 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (3,825,782)	\$ (7,005,405)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	88,678	137,356
Share-based compensation	498,881	1,152,309
Expenses paid through the issuance of common stock	230,397	72,326
Gain (loss) from change in fair value of derivative liabilities	(424,045)	969,106
Amortization of debt issuance costs and original issue discounts	234,943	223,739
Loss from retirement of fixed assets	1,689	
Gain from debt restructuring	(121,224)	
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	448,320	(18,154)
Inventory	51,483	(188,079)
Prepaid expenses and other current assets	(161,552)	(128,130)
Other assets	(227,570)	(16,715)
Accounts payable and accrued expenses	(193,063)	(885,757)
Deferred revenue	106,628	(29,490)
Net cash flows from operating activities	<u>(3,292,217)</u>	<u>(5,716,894)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(100,324)	(7,377)
Net cash flows from investing activities	<u>(100,324)</u>	<u>(7,377)</u>
Cash flows from financing activities:		
Offering costs	-	-
Net cash flows from financing activities	<u>-</u>	<u>-</u>
Net change in cash and cash equivalents	(3,392,541)	(5,724,271)
Cash and cash equivalents, beginning of period	5,408,523	9,244,006
Cash and cash equivalents, end of period	<u>\$ 2,015,982</u>	<u>\$ 3,519,735</u>

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:		
Income taxes	\$ -	\$ -
Interest	<u>\$ 739,323</u>	<u>\$ -</u>

See accompanying notes.

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

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- During the six months ended June 30, 2016, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of \$89,184 from inventory to loaned systems, which are included in property and equipment in the accompanying condensed consolidated balance sheets. During the six months ended June 30, 2015, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of \$63,196 from loaned systems to inventory.

- As more fully described in Note 5, on June 30, 2016, the Company entered into amendments with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes (collectively, the “Noteholders”), that provided for, among other items, a reduction of the exercise prices of warrants held by the Noteholders in the event the Company closes a qualified public offering (as defined in the amendments). This provision created down round strike price protection with respect to the warrants, thus requiring that the warrants be accounted for as derivatives. The fair value of the derivatives, amounting to \$192,173, was established as a liability with a corresponding charge to stockholders’ deficit.

See accompanying notes.

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 was incorporated in the state of Delaware in March 1998. The Company’s principal executive office and principal operations are located in Irvine, California. The Company established MRI Interventions (Canada) Inc., a wholly-owned subsidiary incorporated in Canada, in August 2013. This subsidiary was established primarily for the purpose of performing software development, and its activities are reflected in these condensed consolidated financial statements.

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 under development 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 suspended its efforts to commercialize the ClearTrace system.

Liquidity and Management’s Plans

The cumulative net loss from the Company’s inception through June 30, 2016 was \$89.6 million. Net cash used in operations was \$3.3 million and \$5.7 million for the six months ended June 30, 2016 and 2015, respectively. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent financing activities consist of: (i) a December 2015 private placement of equity, which resulted in net proceeds of \$4.7 million; (ii) a December 2014 private placement of equity, which resulted in net proceeds of \$9.4 million; and (iii) a March 2014 private placement of debt and warrants, which resulted in net proceeds of \$3.5 million.

In addition, as more fully discussed in Note 5, on April 4, 2016 the Company and Brainlab AG (“Brainlab”) finalized a securities purchase agreement (the “2016 Purchase Agreement”) that provided, among other items, for the restructuring of a senior secured note payable to Brainlab, which was originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 (the “Brainlab Note”). The restructuring of the Brainlab Note resulted in a reduction of the principal amount outstanding under the Brainlab Note, which is reflected in a new, amended and restated note payable to Brainlab that matures on December 31, 2018.

The Company’s plans for the next twelve months reflect management’s anticipation of increases in revenues from sales of the ClearPoint system and related disposable products as a result of greater utilization at existing installed sites and the installation of the ClearPoint system at new sites. Management also anticipates maintaining recurring operating expenses at historical levels, with expected decreases in general and administrative expenses resulting primarily from the 2015 operational restructuring, discussed in Note 4, being offset by increases in selling and marketing expenses associated with the anticipated growth in revenues. However, there is no assurance that the Company will be able to achieve its anticipated results, and even in the event such results are achieved, the Company expects to continue to consume cash in its operations over at least the next twelve months.

As a result of the foregoing, the Company believes it will be necessary to seek additional financing from the sale of equity or debt securities, which would result in dilution to the Company’s current stockholders, the establishment of a credit facility, or the entry into an agreement with a strategic partner of some other form of collaborative relationship. There is no assurance, however, that the Company will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing that the Company does obtain will be sufficient to meet its needs. If the Company is not able to obtain the additional financing on a timely basis, the Company may be unable to achieve its anticipated results, and the Company may not be able to meet its other obligations as they become due. As such, there is substantial doubt as to the Company’s ability to continue as a going concern.

The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

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, 2015 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 financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the SEC on March 25, 2016. The accompanying unaudited condensed consolidated balance sheet as of December 31, 2015 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 six months ended June 30, 2016 may not be indicative of the results to be expected for the entire year or any future periods.

Reverse Stock Split

As more fully discussed in Note 8, on July 21, 2016, the Company's Board of Directors approved a 1-for-40 reverse stock split of its issued common stock, which was effectuated on July 26, 2016. All disclosure of common shares and per share data in the accompanying condensed consolidated financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

Derivative Liabilities

Derivative liabilities represent the fair value of conversion features of certain notes and of certain warrants to purchase common stock (see Note 7). These derivative liabilities are calculated utilizing the Monte Carlo simulation valuation method. Changes in the fair values of these warrants are recognized as other income or expense in the related condensed consolidated statements of operations.

Fair Value Measurements

The Company measures and records certain financial assets and liabilities at fair value on a recurring basis. GAAP provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority, referred to as Level 1, to quoted prices in active markets for identical assets and liabilities. The next priority, referred to as Level 2, is given to quoted prices for similar assets or liabilities in active markets or quoted prices for identical or similar assets or liabilities in markets that are not active; that is, markets in which there are few transactions for the asset or liability. The lowest priority, referred to as Level 3, is given to unobservable inputs. The table below reflects the level of the inputs used in the Company's fair value calculations:

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
June 30, 2016				
Derivative liabilities - warrants	\$ -	\$ -	\$ 440,562	\$ 440,562
Derivative liabilities - debt conversion feature	\$ -	\$ -	\$ 644,852	\$ 644,852
December 31, 2015				
Derivative liabilities - warrants	\$ -	\$ -	\$ 658,286	\$ 658,286

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

Inputs used in the Company's Level 3 calculation of fair value include the assumed dividend rate on our common stock, risk-free interest rates and stock price volatility, all of which are further discussed in Note 7.

Carrying amounts of the Company's cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to their short maturities.

The table below reflects the carrying values and the estimated fair values, based on Level 3 inputs, of the Company's outstanding notes payable, including the related accrued interest, at June 30, 2016:

	<u>Carrying Values</u>	<u>Estimated Fair Values</u>
Senior secured note payable, including accrued interest	\$ 2,000,000	\$ 2,000,000
2014 junior secured notes payable, including accrued interest	3,600,181	3,845,125
2010 junior secured notes payable, including accrued interest	1,167,211	1,167,211

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 that is not expected to be utilized within the next twelve months 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.

Revenue Recognition

The Company's revenues are comprised of: (1) product revenues resulting from the sale of ClearPoint system reusable products and disposable products; and (2) other service revenues. The Company recognizes revenue when persuasive evidence of an arrangement exists, the selling price or fee is fixed or determinable, collection is reasonably assured, and, for product revenues, risk of loss has transferred to the customer. For all sales, the Company requires either a purchase agreement or a purchase order as evidence of an arrangement. The Company analyzes revenue recognition on a case-by-case basis. The Company determines if the deliverables under the arrangement represent separate units of accounting as defined by GAAP. Application of GAAP regarding multiple-element arrangements requires the Company to make subjective judgments about the values of the individual elements and whether delivered elements are separable from the other aspects of the contractual relationship.

(1) *Product Revenues*

Sales of ClearPoint system reusable products: The predominance of ClearPoint system reusable product sales (consisting primarily of integrated computer hardware and software) are preceded by customer evaluation periods, generally with 90-day terms. 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, reusable product sales following such evaluation periods are recognized on the basis of an executed purchase agreement or purchase order that provide for risk of loss to pass to the customer. Sales of reusable products not having been preceded by an evaluation period are recognized on an individual agreement basis as described in the preceding paragraph above.

Sales of ClearPoint system disposable products: Revenues from the sale of disposable products, including ClearPoint system disposable products, are recognized at the time risk of loss passes to the customer, which is generally at the shipping point or upon delivery to the customer's location, depending on the agreed upon terms with the customer.

(2) *Other Service Revenues*

Other service revenues are comprised of installation fees, training fees, shipping fees and service fees charged in connection with ClearPoint system installations and ClearPoint system service agreements. Typically, the Company bills upfront for service agreements, which have terms ranging from one to three years. These amounts are recognized as revenue ratably over the term of the related service agreement

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 6, 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 June 30, 2016, the Company had \$130,104 in bank balances that were in excess of the insured limits.

At June 30, 2016, one customer represented 13% of the Company's accounts receivable balance. At December 31, 2015, three customers represented 14%, 14% and 12% of the Company's accounts receivable balance. No other customer represented more than 9% of total accounts receivable at each of June 30, 2016 and December 31, 2015.

For the three months ended June 30, 2016, sales to one customer represented 12% of product revenues, and for the six months ended June 30, 2016, sales to one customer represented 11% of product revenues. For the three months ended June 30, 2015, sales to three customers represented 12%, 10% and 10% of product revenues, and for the six months ended June 30, 2015 sales to one customer represented 10% of product revenues. No other single customer represented more than 8% and 9% of product revenues for the three months ended June 30, 2016 and 2015, respectively, and no other single customer represented more than 8% and 9% for the six months ended June 30, 2016 and 2015, respectively. 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 at June 30, 2016 and December 31, 2015 was \$25,000 and \$28,000, respectively.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2014-15, "Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern," which provides guidance on determining when and how to disclose going-concern uncertainties in financial statements. The new standard requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued. An entity must provide certain disclosures if conditions or events raise substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 applies to all entities and is effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the impact of this update on future disclosures concerning its liquidity position.

In July 2015, the FASB issued ASU 2015-11, "Simplifying the Measurement of Inventory," which requires an entity to measure inventory at the lower of cost or net realizable value, as opposed to the current requirement to measure inventory at the lower of cost or market, where market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016 and interim periods within fiscal years beginning after December 15, 2017. ASU 2015-11 is to be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company believes that adoption of ASU 2015-11 will not have a material effect on its consolidated financial statements.

In August 2015, the FASB issued ASU 2015-14 as an amendment to ASU 2014-09, "Revenue from Contracts with Customers," which created a new Topic, Accounting Standards Codification ("ASC") Topic 606. The standard is principle-based and provides a five-step model to determine when and how revenue is recognized. The core principle is that an entity should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard, and ASUs 2016-10 and 2016-12 discussed below, are effective for the Company beginning in 2018. Earlier application is permitted only as of 2017.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

In April 2016, the FASB issued ASU 2016-10, “Revenues from Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing,” which clarified guidance related to identifying performance obligations and licensing implementation guidance contained in ASC Topic 606 as promulgated by ASU 2015-14 discussed above.

In May 2016, the FASB issued ASU 2016-12, “Revenues from Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients,” which address narrow-scope improvements to the guidance on collectability, noncash consideration, and completed contracts at transition. Additionally, the amendments in this ASU provide a practical expedient for contract modifications at transition and an accounting policy election related to the presentation of sales taxes and other similar taxes collected from customers.

Based on a preliminary evaluation, the Company believes that adoption of ASC Topic 606 will not have a material effect on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,” which is intended to reduce the complexity in accounting for aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The Company believes that adoption of ASU 2016-09 will not have a material effect on its consolidated financial statement.

In November 2015, the FASB issued ASU 2015-17, “Balance Sheet Classification of Deferred Taxes,” which simplifies the presentation of deferred income taxes by requiring that deferred income tax liabilities and assets be classified as noncurrent in a classified balance sheet. Until implementation of this standard, deferred income tax liabilities and assets are required to be classified as current or noncurrent based on the classification of the related asset or liability for financial reporting purposes. Deferred tax liabilities and assets that are not related to an asset or liability for financial reporting are classified according to the expected reversal date of the temporary difference. This standard is effective for the Company beginning in 2017. Adoption will have no effect on the Company’s consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases,” which created a new Topic, ASC Topic 842 and 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. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard is effective for the Company beginning in 2019, and early application is permitted. Based on a preliminary evaluation, the Company believes that adoption of ASC Topic 842 will not have a material effect on its consolidated financial statements.

Adoption of New Accounting Standard

In April 2015, the FASB issued ASU 2015-03, “Simplifying the Presentation of Debt Issuance Costs,” which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 required retrospective adoption and became effective with respect to the Company’s financial statements on January 1, 2016. Prior to the effective date, such issuance costs were classified as assets and included as other assets in the Company’s balance sheet. Under the provisions of ASU 2015-03, such issuance costs are presented as a direct deduction from the carrying amount of the related debt (see Note 5) in the accompanying June 30, 2016 condensed consolidated balance sheet, and such issuance costs, amounting to \$166,080, have been reclassified in the December 31, 2015 condensed consolidated balance sheet to conform to the 2016 presentation.

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3. Inventory

Inventory consists of the following as of:

	June 30, 2016	December 31, 2015
Raw materials and work in process	\$ 870,091	\$ 853,034
Software licenses	122,500	179,400
Finished goods	<u>651,504</u>	<u>775,461</u>
Inventory included in current assets	1,644,095	1,807,895
Software licenses – non-current	<u>976,900</u>	<u>937,100</u>
	<u>\$ 2,620,995</u>	<u>\$ 2,744,995</u>

4. Restructuring Charges

In March 2015, the Company announced its plan to consolidate all major business functions into its Irvine, California headquarters and close its Memphis, Tennessee office. The Company completed this consolidation and closure in May 2015. The Company did not retain any of its Memphis-based employees. A total of seven employees were impacted by the consolidation, including three executives of the Company. In connection with this consolidation and closure, the Company recorded restructuring charges of \$499,184 and \$1,252,584 during the three and six months ended June 30, 2015, respectively, that related primarily to costs associated with severance and other compensation for the impacted employees.

5. Notes Payable

Senior Secured Note Payable

The indebtedness outstanding under the Brainlab Note at December 31, 2015 was approximately \$5.0 million and was to mature in April 2016. The indebtedness included approximately \$740,000 of accrued interest, which had accrued at a rate of 5.5% and was payable in a single aggregate installment upon maturity.

On April 4, 2016 (the “Closing Date”), the Company and Brainlab finalized the 2016 Purchase Agreement, as discussed below.

2016 Purchase Agreement

Under the 2016 Purchase Agreement, the Company: (i) paid to Brainlab all accrued and unpaid interest on the Brainlab Note, in the amount of approximately \$740,000; (ii) amended and restated the Brainlab Note on the terms described below; (iii) entered into a patent and technology license agreement with Brainlab (the “License Agreement”) for software relating to the Company’s SmartFrame device, in consideration for the cancellation of \$1.0 million of the principal amount of the Brainlab Note; (iv) issued to Brainlab, in consideration for the cancellation of approximately \$1.3 million of the principal amount of the Brainlab Note, 99,310 units, consisting of: (a) one share of the Company’s common stock; (b) warrants to purchase 0.4 share of common stock (the “2016 Series A Warrants”); and (c) warrants to purchase 0.3 shares of common stock (the “2016 Series B Warrants”) (collectively, the “Equity Units”); and (v) entered into a Registration Rights Agreement (the “2016 Registration Rights Agreement”), pursuant to which the Company agreed to file a registration statement with the SEC covering the resale of the shares of common stock issued to Brainlab under the 2016 Purchase Agreement, as well as the shares of common stock that are issuable upon exercise of the 2016 Series A Warrants and 2016 Series B Warrants (together, the “2016 Warrants”).

The 2016 Purchase Agreement contains covenants, representations and warranties by the Company and Brainlab (including indemnification from the Company in the event of breaches of its representations and warranties), which the Company believes are customary for transactions of this type.

As a result of the foregoing, on the Closing Date, the Company recorded a debt restructuring gain of approximately \$941,000 representing the difference between (a) the aggregate fair value of the License Agreement, which had no cost basis on the Company’s consolidated balance sheets, and the Equity Units, and (b) the aggregate principal amount of the Brainlab Note cancelled as consideration.

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2016 Registration Rights Agreement

The 2016 Registration Rights Agreement imposed deadlines by which the Company was required to file the 2016 Registration Statement to use its best efforts to have the 2016 Registration Statement declared effective. The 2016 Registration Statement was filed, and declared effective on June 20, 2016, within the deadlines imposed by the 2016 Registration Rights Agreement. Pursuant to the 2016 Registration Rights Agreement, if the Company fails to continuously maintain the effectiveness of the 2016 Registration Statement (with certain permitted exceptions), the Company will incur certain liquidated damages in a range of 2%-10%, depending on the duration of such failure, of the approximately \$1.3 million principal reduction of the Brainlab Note as described above. The 2016 Registration Rights Agreement also contains mutual indemnifications by the Company and Brainlab, which the Company believes are customary for transactions of this type.

2016 Warrants

The 2016 Series A Warrants and 2016 Series B Warrants are exercisable, in full or in part, at any time prior to the fifth anniversary of their issuance, at an exercise price of \$16.23 per share (before giving effect to the Note Conversion as defined below) and \$21.10 per share, respectively. The 2016 Warrants provide for certain adjustments that may be made to the exercise price and the number of shares issuable upon exercise due to future corporate events or otherwise. In the case of certain fundamental transactions affecting the Company, the holder of such 2016 Warrants, upon exercise of such warrants after such fundamental transaction, will have the right to receive, in lieu of shares of the Company's common stock, the same amount and kind of securities, cash or property that such holder would have been entitled to receive upon the occurrence of the fundamental transaction, had the 2016 Warrants been exercised immediately prior to such fundamental transaction. The 2016 Warrants contain a "cashless exercise" feature that allows the holders to exercise the warrants without a cash payment to the Company upon the terms set forth in the respective 2016 Warrant agreements.

Amended and Restated Promissory Note

On the Closing Date and pursuant to the 2016 Purchase Agreement, the Company issued Brainlab an unregistered, amended and restated secured note (the "New Brainlab Note"), which has the same terms and conditions as the Brainlab Note, except that: (i) the principal amount of the New Brainlab Note is \$2 million; (ii) interest will be paid quarterly in arrears; and (iii) the maturity date of the New Brainlab Note is December 31, 2018.

Non-Exclusive License Agreement

On the Closing Date and pursuant to the 2016 Purchase Agreement, the Company and Brainlab entered into the License Agreement, for software relating to our SmartFrame device, for use in neurosurgery. The License Agreement does not affect the Company's ability to continue to independently develop, market and sell its own software for the SmartFrame device.

Based on the foregoing, the New Brainlab Note was classified as a non-current liability in the accompanying June 30, 2016 condensed consolidated balance sheet.

The New Brainlab Note is collateralized by a senior security interest in the assets of the Company.

2014 Junior Secured Notes Payable

In March 2014, the Company entered into securities purchase agreements for the private placement of: (i) second-priority secured non-convertible promissory notes (the "2014 Secured Notes"); and (ii) warrants to purchase 0.01 shares of the Company's common stock for each dollar in principal amount of the 2014 Secured Notes sold by the Company. Pursuant to those securities purchase agreements, the Company sold 2014 Secured Notes in a total aggregate principal amount of \$3,725,000, together with warrants to purchase up to 27,937 shares of common stock, for aggregate gross proceeds of \$3,725,000, before placement agent commissions and other expenses.

The 2014 Secured Notes have a five-year term and bear interest at a rate of 12% per year, payable semi-annually, in arrears. The 2014 Secured Notes are not convertible into shares of the Company's common stock. Following the third anniversary of the issuance date, the 2014 Secured Notes may be prepaid, without penalty or premium, provided that all principal and unpaid accrued interest under all 2014 Secured Notes is prepaid at the same time. Prior to the third anniversary of the issuance date, the Company may prepay all, but not less than all, of the principal and unpaid accrued interest under the 2014 Secured Notes at any time, subject to the Company's payment of the additional prepayment premium stated in the notes. The 2014 Secured Notes are collateralized by a security interest in the Company's property and assets, which security interest is junior and subordinate to the security interest that collateralizes the New Brainlab Note.

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The warrants issued to the investors are exercisable, in full or in part, at any time prior to the fifth anniversary of the issuance date, at an exercise price of \$70.00 per share, subject to adjustment from time-to-time for stock splits or combinations, stock dividends, stock distributions, recapitalizations and other similar transactions. Assumptions used in calculating the fair value of the warrants using the Black-Scholes valuation model were:

Dividend yield	0%
Expected volatility	47.5% – 47.7%
Risk free interest rates	1.73% – 1.76%
Expected life (in years)	5.0

Under GAAP, the Company allocated the \$3,725,000 in proceeds proportionately between the 2014 Secured Notes and the warrants issued to investors based on their relative fair values, with \$413,057 being allocated to the fair value of the warrants, recorded as equity. The 2014 Secured Notes were recorded at the principal amount, less a discount equal to \$413,057. The unamortized discount at June 30, 2016 and December 31, 2015 was \$263,721 and \$301,531, respectively. This discount is being amortized to interest expense over the five-year term of the 2014 Secured Notes using the effective interest method. The carrying amount of the 2014 Secured Notes in the accompanying condensed consolidated balance sheets is also presented net of issuance costs, as discussed further below.

Non-employee directors of the Company purchased a total of \$1,100,000 of the 2014 Secured Notes, either directly or through a trust. The Company’s placement agents earned cash commissions of \$145,500 as well as warrants to purchase 1,818 shares of the Company’s common stock. The placement agent warrants have the same terms and conditions as the investor warrants.

The placement agent cash commissions, the \$30,210 fair value of the placement agent warrants, and other offering expenses, aggregating \$76,186, were recorded as deferred financing costs and are presented as reductions of the carrying amount of the 2014 Secured Notes in the accompanying condensed consolidated balance sheets. These deferred financing costs, having an unamortized balance of \$141,223 and \$166,080 at June 30, 2016 and December 31, 2015, are being amortized to interest expense over the term of the 2014 Secured Notes using the effective interest method.

2010 Junior Secured Notes Payable

In November 2010, the Company issued units consisting of a junior secured note (the “2010 Secured Notes”) and one share of the Company’s common stock. An aggregate of 267,857 units were issued, and the Company received proceeds of \$3,000,000 representing the aggregate principal amount of the 2010 Secured Notes. The 2010 Secured Notes mature in November 2020, accrue interest at the rate of 3.5% per year, and are collateralized by a security interest in the assets of the Company, which security interest is junior and subordinate to the security interests that collateralize the Brainlab Note and the 2014 Secured Notes. All outstanding principal and interest on the 2010 Secured Notes will be due and payable in a single payment upon maturity.

Under GAAP, the Company allocated the \$3,000,000 in proceeds from the sale of the units between the 2010 Secured Notes and the shares of common stock based on their relative fair values, with the fair value of the notes being estimated based on an assumed market interest rate for notes of similar terms and risk, and the fair value of the Company’s common stock being estimated by management using a market approach, with input from a third-party valuation specialist. The allocation of such relative fair values resulted in \$2,775,300 being allocated to the value of the shares of common stock, which was recorded as equity. The 2010 Secured Notes were recorded at the principal amount of \$3,000,000, less a discount equal to \$2,775,300. The unamortized discount at June 30, 2016 and December 31, 2015 was \$2,427,789 and \$2,535,230, respectively. This discount is being amortized to interest expense over the 10-year term of the notes using the effective interest method.

Four then-serving officers of the Company purchased an aggregate of 22,068 units in the offering for \$247,164. In addition, three non-employee directors of the Company also purchased an aggregate of 14,180 units in the offering for \$158,816.

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Note Conversions

On June 30, 2016, the Company entered into amendments (the “Amendments”) with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes, one of whom is a trust for which one of the Company’s non-employee directors serves as a trustee. Pursuant to the Amendments, the parties agreed that, in the event the Company closes a qualified public offering: (i) \$2,000,000 of the principal balance of those notes, plus all unpaid accrued interest on that amount, will automatically convert into the security offered in the qualified public offering, based on the public offering price of that security; and (ii) the exercise price for 46,207 shares of common stock underlying warrants issued in connection with those notes will be reduced to equal the greater of (x) the public offering price of the security offered in the qualified public offering, or (y) if the security offered in the qualified public offering is or includes convertible stock or common stock warrants, the highest price per whole share for which the Company’s common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. These provisions create: (a) a conversion feature allowing for the principal balance described above, plus all unpaid related accrued interest, to be converted 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 the warrants, both of which, under GAAP, are required to be accounted for as derivatives, the calculation and accounting for which is described in Note 7.

In addition, based on the provisions of the Amendments, on June 30, 2016, the Company recorded a debt restructuring loss of approximately \$820,000 resulting from the restructuring of the New Brainlab Note and those 2014 Secured Notes subject to the Amendments.

Scheduled Notes Payable Maturities

Scheduled principal payments as of June 30, 2016 with respect to notes payable are summarized as follows:

Years ending December 31.	
2018	\$ 2,000,000
2019	3,725,000
2020	<u>3,000,000</u>
Total scheduled principal payments	8,725,000
Less unamortized discounts	(2,539,510)
Less unamortized deferred financing costs	(133,223)
	<u>\$ 6,052,267</u>

6. Stockholders’ Equity

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) the fees otherwise payable to each director in cash, times (ii) the percentage of fees the director elected to receive in shares of common stock, by (iii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the three months ended June 30, 2016 and 2015, 2,824 shares and 939 shares, respectively, were issued to directors as payment for director fees in lieu of cash. During the six months ended June 30, 2016 and 2015, 6,374 shares and 5,744 shares, respectively, were issued to directors as payment for director fees in lieu of cash.

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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.

In June 2013, the Company’s stockholders approved the 2013 Incentive Compensation Plan. Upon its approval, the Company ceased making awards under other previous Plans, although then-outstanding awards made under such other previous Plans remain outstanding in conformity with their original terms. At the 2015 Annual Meeting, the Company’s stockholders approved the adoption of the MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan (the “Amended 2013 Plan”). The material change effected in the Amended 2013 Plan was to increase the number of shares of the Company’s common stock available for awards thereunder by 125,000 shares, resulting in a total of 156,250 shares of the Company’s common stock being reserved for issuance under the Amended 2013 Plan. Of this amount, stock grants of 22,359 shares have been awarded and option grants of 81,616 shares were outstanding as of June 30, 2016. Accordingly, 52,275 shares remained available for grants under the Amended 2013 Plan as of that date.

Activity under all of the Company’s Plans during the six months ended June 30, 2016 is summarized below:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2015	298,282	\$ 48.80
Granted	11,500	11.57
Forfeited	(2,250)	43.04
Outstanding at June 30, 2016	307,532	\$ 49.18

The estimated grant date fair values of options granted during the three months ended June 30, 2016 were calculated using the Black-Scholes valuation model, based on the following assumptions:

Dividend yield	0%
Expected volatility	49.86% – 50.69%
Risk free interest rates	1.23% – 1.38%
Expected lives (in years)	6

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the three and six months ended June 30, 2016 and 2015, share-based compensation expense related to options was:

Three Months Ended June 30,	
2016	2015
\$ 238,312	\$ 774,417

Six Months Ended June 30,	
2016	2015
\$ 498,881	\$ 1,152,309

As of June 30, 2016, there was unrecognized compensation expense of \$1,356,187 related to outstanding stock options, which is expected to be recognized over a weighted average period of 1.61 years.

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Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the six months ended June 30, 2016 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2015	845,402	\$ 19.20
Issued	69,517	40.00
Terminated	-	-
Outstanding at June 30, 2016	<u>914,920</u>	<u>\$ 25.85</u>

7. Derivative Liabilities

On June 30, 2016, the Company entered into amendments with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes, the provisions of which create: (a) a conversion feature allowing for the principal balance described above to be converted 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 the warrants, both of which, under GAAP, are required to be accounted for as derivatives, thus requiring that the conversion feature and the warrants each be adjusted to estimated fair value at each balance sheet date and shown as liabilities in the accompanying condensed consolidated balance sheets.

In addition, warrants issued in 2012 and 2013 financing transactions contain either or both net-cash settlement and down round provisions. Under GAAP, such provisions require that these warrants be accounted for as derivatives, thus requiring that such warrants be adjusted to estimated fair value at each balance sheet date and shown as liabilities in the accompanying consolidated balance sheets. The fair value of such warrants was calculated using the Monte Carlo simulation valuation method.

Under GAAP, the provisions described above require that the conversion feature and the warrants be accounted for as derivatives, thus requiring that they each be adjusted to estimated fair value at each balance sheet date and shown as liabilities in the accompanying condensed consolidated balance sheets.

The fair values of the conversion feature and the warrants were calculated using the Monte Carlo simulation valuation method.

Assumptions used in calculating the fair value of the conversion feature at June 30, 2016 are as follows:

Risk free interest rates	0.65%
Volatility	60%

In addition to the assumptions above, the Company also estimates the likelihood of whether it will participate in a future round of a qualified public offering and, if so, the estimated timing and pricing of its offering of common stock.

Assumptions used in calculating the fair value of the warrants at June 30, 2016 are as follows:

Dividend yield	0%
Expected volatility	60% – 70%
Risk free interest rates	0.45% – 0.65%
Expected remaining term (in years)	1.01 – 1.57

In addition to the assumptions above, the Company also estimates the likelihood of whether it will participate in a future round of qualifying equity financing, as defined in either the amended note or warrant agreements, as applicable, that would trigger the conversion feature or the repricing of warrants, and, if so, the estimated timing and pricing of its offering of common stock.

The fair values and the changes in fair values of derivative liabilities during the six months ended June 30, 2016 are as follows:

Balance, December 31, 2015	\$ 658,286
Conversion of equity warrants to liabilities	192,173
Additions from debt restructuring	659,000
Gain on change in fair value for the period	(424,045)
Balance, June 30, 2016	<u>\$ 1,085,414</u>

8. Subsequent Events

On June 30, 2016, the Company's stockholders approved a reverse stock split of the Company's issued and outstanding shares of common stock at a ratio of 1-for-15, 1-for-20, 1-for-25, 1-for-30, 1-for-35 or 1-for-40, with the specific ratio and effective time of the reverse stock split to be determined by the Company's Board of Directors. On July 21, 2016, the Company's Board of Directors approved a 1-for-40 reverse stock split of its issued common stock, which was effectuated on July 26, 2016. The reverse stock split did

not cause an adjustment to the par value of the authorized shares of common stock. As a result of the reverse stock split, the share and per-share amounts under the Plans and warrants with third parties were adjusted. No fractional shares were issued in connection with the reverse stock split. In lieu of issuing fractional shares, the Company remitted approximately \$4,800 to affected stockholders. All disclosure of common shares and per share data in the accompanying condensed consolidated financial statements and related notes have been adjusted retroactively to reflect the reverse stock split for all periods presented.

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 and heart under direct, intra-procedural MRI guidance. We have two product platforms. Our ClearPoint system, which is in commercial use, is used to perform minimally invasive surgical procedures in the brain. We anticipate that our ClearTrace system, which is a product candidate still in development, will be used to perform minimally invasive surgical procedures in the heart. In 2015, we suspended development of the ClearTrace system so that we could focus our resources on the ClearPoint system. Both systems utilize intra-procedural MRI to guide the procedures and are designed to work in a hospital's existing MRI suite. We believe that our two product platforms, subject to appropriate regulatory clearance and approval, will deliver better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the U.S. for general neurological procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the European Union. Substantially all of our product revenues for the three and six months ended June 30, 2016 and 2015 relate to sales of our ClearPoint system products. We do not have regulatory clearance or approval to sell our ClearTrace system for commercial use. 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 June 30, 2016, we had an accumulated deficit of \$89.4 million. We expect to continue to incur operating losses as we commercialize our ClearPoint system products and expand our business.

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 June 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. We cannot sell our ClearTrace system for commercial use until we receive regulatory clearance or approval.

Generating recurring revenues from the sale of disposable 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 ClearPoint disposable products. Our product revenues were approximately \$1.1 million and \$774,000 for the three and six months ended June 30, 2016, respectively, and were almost entirely related to our ClearPoint system.

Our revenue recognition policies are more fully described in Note 2 to the condensed consolidated financial statements appearing in Part I, Item 1 of this Quarterly Report.

Cost of Product Revenues

Cost of product revenues includes the direct costs associated with the assembly and purchase of components for disposable products and ClearPoint system reusable products which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of product 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 and our ClearTrace system components (prior to the suspension of such development). 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; sponsored research and product development with third parties; 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) resume our ClearTrace system product development efforts; and (iii) expand our research to apply our technologies to additional product applications. From our inception through June 30, 2016, we have incurred approximately \$47 million in research and development costs.

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 the continuing development of our ClearTrace system for commercialization.

Selling, General and Administrative Expenses

Our selling, 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; medical device excise taxes; 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 selling, general and administrative 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

There have been no significant changes in our critical accounting policies during the six months ended June 30, 2016 as compared to the critical accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2015, which we filed with the SEC on March 25, 2016.

Results of Operations

Three Months Ended June 30, 2016 Compared to the Three Months Ended June 30, 2015

	Three Months Ended June 30,		
	2016	2015	Percentage Change
Product and other service revenues	\$ 1,103,881	\$ 803,303	37%
Development service revenues	-	22,438	NM
Cost of product revenues	520,987	394,821	32%
Research and development costs	749,942	426,931	76%
Selling, general and administrative expenses	1,888,056	2,187,393	(14)%
Restructuring charges	-	499,184	NM
Other income (expense):			
Gain (loss) from change in fair value of derivative liabilities	263,927	(186,304)	242%
Gain from debt restructuring	121,224	-	NM
Other income, net	139,239	115,522	21%
Interest expense, net	(251,250)	(306,781)	18%
Net loss	<u>\$ (1,781,964)</u>	<u>\$ (3,060,151)</u>	<u>42%</u>

NM= not meaningful

Product and Other Service Revenues. Product and other service revenues were \$1.1 million for the three months ended June 30, 2016, and \$803,000 for the same period in 2015, an increase of \$301,000, or 37%.

ClearPoint disposable product sales for the three months ended June 30, 2016 were \$1.0 million, compared with \$678,000 for the same period in 2015, representing an increase of \$350,000, or 52%. This increase was due primarily to a greater number of procedures performed using our ClearPoint system within a larger installed base for ClearPoint in the three months ended June 30, 2016, relative to the same period in 2015.

ClearPoint reusable product sales for the three months ended June 30, 2016 were \$39,000, compared with \$93,000 of such sales for the same period in 2015, representing a decrease of \$54,000, or 58%. Sales of our reusable products, which consist primarily of computer hardware and software bearing sales prices that are appreciably higher than those for disposable products, may vary, sometimes significantly, from quarter to quarter.

Cost of Product Revenues. Cost of product revenues was \$521,000 for the three months ended June 30, 2016, representing gross margin on product revenues of 51%, compared to \$395,000 for the same period in 2015, representing gross margin of 49%. The increase in gross margin was due primarily to a favorable product mix toward disposable product sales during the three months ended June 30, 2016, relative to the same period in 2015, as disposable products bear a higher margin relative to reusable products, and to a decrease in the provision for inventory obsolescence during the three months ended June 30, 2016, relative to the same period in 2015. These factors were partially offset by increases during the three months ended June 30, 2016, relative to the same period in 2015, in product scrap levels and in the allocation of indirect costs, amounting to \$112,000, to manufacturing in connection with our transition from a focus on research and development to commercial activities.

Research and Development Costs. Research and development costs were \$750,000 for the three months ended June 30, 2016, compared to \$427,000 for the same period in 2015, an increase of \$323,000, or 76%. The increase was due primarily to increases in the three months ended June 30, 2016, relative to the same period in 2015, in: (a) software development costs of \$104,000 incurred in connection with our development of the next generation of the ClearPoint operating system; (b) compensation of \$86,000 related primarily to an increase in headcount in January 2016; (c) regulatory fees of \$35,000; and (d) product development costs other than software of \$33,000.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$1.9 million for the three months ended June 30, 2016 as compared with \$2.2 million for the same period in 2015, a decrease of \$299,000, or 14%. This decrease was attributable primarily to decreases during the three months ended June 30, 2016, relative to the same period in 2015, in: (a) personnel costs, including share-based compensation and travel costs, of \$197,000; (b) the allocation of costs, amounting to \$51,000, to manufacturing in connection with our transition from a focus on research and development to commercial activities; (c) occupancy costs of \$25,000; and (d) medical device excise taxes, suspended by federal legislation for a two-year period beginning January 1, 2016, of \$14,000. These fluctuations were partially offset by increases in: (i) professional fees of \$44,000; and (b) public company and investor relations expenses of \$37,000.

Restructuring Charges. In March 2015, we announced the consolidation of all major business functions into our Irvine, California headquarters. In connection with this consolidation, we closed our Memphis, Tennessee office in May 2015. We did not retain any of our Memphis-based employees. A total of seven employees were impacted by the consolidation, including three of our executives, whose termination of employment triggered a modification in the terms of stock options previously granted to them. As a result of these modifications of option terms, we revalued such options and recorded related, one-time restructuring costs of \$493,000, constituting nearly all of the restructuring charges incurred during the three months ended June 30, 2015.

Other Income (Expense). During the three months ended June 30, 2016, we recorded a gain of \$264,000, and during the three months ended June 30, 2015, we recorded a loss of \$186,000, resulting from additions to, and changes in the fair value of, our derivative liabilities. For the three months ended June 30, 2016, such derivative liabilities related to: (a) the issuance of warrants in connection with 2012 and 2013 private placement transactions; and (b) the amendment, in June 2016, of certain notes to add contingent conversion terms and potential down round pricing protection of warrants issued in connection with such notes, both as more fully discussed in Note 5 to the condensed consolidated financial statements included elsewhere in the Quarterly Report. For the three months ended June 30, 2015, derivative liabilities were limited to the issuance of warrants in connection with the 2012 and 2013 private placement transactions.

In April 2016, we entered into the 2016 Purchase Agreement with Brainlab under which the Brainlab Note was restructured and, among other items, we: (i) entered into a patent and technology license agreement with Brainlab (the "License Agreement") for software relating to the Company's SmartFrame device, in consideration for the cancellation of \$1.0 million of the principal amount of the Brainlab Note; and (ii) issued to Brainlab, in consideration for the cancellation of approximately \$1.3 million of the principal amount of the Brainlab Note, 99,310 units, consisting of one share of the Company's common stock, a Series A Warrants to purchase 0.4 share of common stock and a Series B Warrants to purchase 0.3 shares of common stock. As a result of the foregoing, we recorded a gain of \$941,000 representing the difference between (a) the aggregate fair value of the License Agreement, which had no cost basis on our consolidated balance sheets, and the equity units, and (b) the aggregate principal amount of the Brainlab Note cancelled as consideration.

In June 2016, we entered into the Amendments with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes, one of whom is a trust for which one of our non-employee directors serves as a trustee. Pursuant to the Amendments, the parties agreed that, in the event we close a qualified public offering: (i) \$2,000,000 of the principal balance of those notes, plus all unpaid accrued interest on that amount, will automatically convert into the security offered in the qualified public offering, based on the public offering price of that security; and (ii) the exercise price for 46,207 shares of common stock underlying warrants issued in connection with those notes will be reduced, to equal the greater of (x) the public offering price of the security offered in the qualified public offering, or (y) if the security offered in the qualified public offering is or includes convertible stock or common stock warrants, the highest price per whole share for which our common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. Based on the provisions of the Amendments, on June 30, 2016, we recorded a debt restructuring loss of \$820,000 resulting from the restructuring of the New Brainlab Note and those 2014 Secured Notes subject to the Amendments.

Net other income did not materially fluctuate, amounting to \$139,000 and \$115,000 for the three months ended June 30, 2016 and 2015, respectively.

Net interest expense for the three months ended June 30, 2016 was \$251,000, compared with \$307,000 for the same period in 2015. The decrease was due primarily to the reduced principal balance of the New Brainlab Note resulting from the restructuring of the Brainlab Note described above.

Six Months Ended June 30, 2016 Compared to the Six Months Ended June 30, 2015

	Six Months Ended June 30,		
	2016	2015	Percentage Change
Product and other service revenues	\$ 2,498,016	\$ 1,813,706	38%
Development service revenues	-	22,438	NM
Cost of product revenues	1,217,533	780,430	56%
Research and development costs	1,407,134	954,443	47%
Selling, general and administrative expenses	3,862,305	4,476,053	(14)%
Restructuring charges	-	1,252,584	NM
Other income (expense):			
Gain (loss) from change in fair value of derivative liabilities	424,045	(969,106)	144%
Gain from debt restructuring	121,224	-	NM
Other income, net	214,380	198,209	8%
Interest expense, net	(596,475)	(607,142)	(2)%
Net loss	<u>\$ (3,825,782)</u>	<u>\$ (7,005,405)</u>	<u>45%</u>

NM= not meaningful

Product and Other Service Revenues. Product and other service revenues were \$2.5 million for the six months ended June 30, 2016, and \$1.8 million for the same period in 2015, an increase of \$684,000, or 38%.

ClearPoint disposable product sales for the six months ended June 30, 2016 were \$2.1 million, compared with \$1.5 million for the same period in 2015, representing an increase of \$614,000, or 40%. This increase was due primarily to a greater number of procedures performed using our ClearPoint system within a larger installed base for ClearPoint in the six months ended June 30, 2016, relative to the same period in 2015.

ClearPoint reusable product sales for the six months ended June 30, 2016 were \$301,000, compared with \$230,000 of such sales for the same period in 2015, representing an increase of \$71,000, or 31%. Sales of our reusable products, which consist primarily of computer hardware and software bearing sales prices that are appreciably higher than those for disposable products, may vary, sometimes significantly, from quarter to quarter.

Cost of Product Revenues. Cost of product revenues was \$1.2 million for the six months ended June 30, 2016, representing gross margin on product revenues of 50%, compared to \$780,000 for the same period in 2015, representing gross margin of 55%. The decrease in gross margin was due primarily to (a) an unfavorable product mix related to reusable product sales; and (b) the allocation of indirect costs, amounting to \$240,000, to manufacturing during the six months ended June 30, 2016 in connection with our transition from a focus on research and development to commercial activities.

Research and Development Costs. Research and development costs were \$1.4 million for the six months ended June 30, 2016, compared to \$954,000 for the same period in 2015, an increase of \$453,000, or 47%. The increase was due primarily to increases during the six months ended June 30, 2016, relative to the same period in 2015, in: (a) software development costs of \$168,000 incurred in connection with our development of the next generation of the ClearPoint operating system; (b) personnel costs, related primarily to additional headcount and related search commissions, of \$121,000; (c) regulatory fees of \$54,000; (d) license fees of \$52,000; and (e) other product development costs of \$52,000. Partially offsetting these increases was an allocation of departmental costs to manufacturing during the six months ended June 30, 2016, amounting to \$77,000, in connection with our transition from a focus on research and development to commercial activities.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$3.9 million for the six months ended June 30, 2016 as compared with \$4.5 million for the same period in 2015, a decrease of \$614,000, or 14%. This decrease was attributable primarily to decreases in: (a) personnel costs, including share-based compensation and travel, of \$484,000; (b) an allocation of departmental costs to manufacturing during the six months ended June 30, 2016, amounting to \$87,000, in connection with our transition from a focus on research and development to commercial activities; (c) occupancy costs of \$33,000; and (d) medical device excise taxes, suspended by federal legislation for a two-year period beginning January 1, 2016, of \$30,000. These fluctuations were partially offset by increases during the six months ended June 30, 2016, relative to the same period in 2015, in: (i) public company costs of \$105,000; and (ii) professional fees of \$45,000.

Restructuring Charges. In March 2015, we announced the consolidation of all major business functions into our Irvine, California headquarters. In connection with this consolidation, we closed our Memphis, Tennessee office in May 2015. We did not retain any of our Memphis-based employees. A total of seven employees were impacted by the consolidation, including three of our executives. As a result of we incurred expense of \$1.3 million primarily related to termination costs, including the modifications of option terms, during the six months ended June 30, 2015.

Other Income (Expense). During the six months ended June 30, 2016, we recorded a gain of \$424,000, and during the six months ended June 30, 2015, we recorded a loss \$969,000, resulting from additions to, and changes in the fair value of, our derivative liabilities. During the six months ended June 30, 2016, such derivative liabilities related to: (a) the issuance of warrants in connection with 2012 and 2013 private placement transactions; and (b) the amendment, in June 2016, of certain notes to add contingent conversion terms and potential down round pricing protection of warrants issued in connection with such notes, both as more fully discussed in Note 5 to the condensed consolidated financial statements included elsewhere in the Quarterly Report. For the three months ended June 30, 2015, derivative liabilities were limited to the issuance of warrants in connection with the 2012 and 2013 private placement transactions.

In April 2016, we entered into the 2016 Purchase Agreement with Brainlab under which the Brainlab note was restructured and, among other items, we: (i) entered into a patent and technology license agreement with Brainlab (the "License Agreement") for software relating to the Company's SmartFrame device, in consideration for the cancellation of \$1.0 million of the principal amount of the Brainlab Note; and (ii) issued to Brainlab, in consideration for the cancellation of approximately \$1.3 million of the principal amount of the Brainlab Note, 99,310 units, consisting of one share of the Company's common stock, a Series A Warrants to purchase 0.4 share of common stock and a Series B Warrants to purchase 0.3 shares of common stock. As a result of the foregoing, we recorded a gain of \$941,000 representing the difference between (a) the aggregate fair value of the License Agreement, which had no cost basis on our consolidated balance sheets, and the equity units, and (b) the aggregate principal amount of the Brainlab Note cancelled as consideration.

In June 2016, we entered into the Amendments with Brainlab, with respect to the New Brainlab Note, and with two holders of the 2014 Secured Notes, one of whom is a trust for which one of our non-employee directors serves as a trustee. Pursuant to the Amendments, the parties agreed that, in the event we close a qualified public offering: (i) \$2,000,000 of the principal balance of those notes, plus all unpaid accrued interest on that amount, will automatically convert into the security offered in the qualified public offering, based on the public offering price of that security; and (ii) the exercise price for 46,207 shares of common stock underlying warrants issued in connection with those notes will be reduced, to equal the greater of (x) the public offering price of the security offered in the qualified public offering, or (y) if the security offered in the qualified public offering is or includes convertible stock or common stock warrants, the highest price per whole share for which our common stock is issuable upon conversion of such convertible stock or upon exercise of such common stock warrants. Based on the provisions of the Amendments, on June 30, 2016, we recorded a debt restructuring loss of \$820,000 resulting from the restructuring of the New Brainlab Note and those 2014 Secured Notes subject to the Amendments.

Net other income did not materially fluctuate, amounting to \$214,000 and \$198,000 for the six months ended June 30, 2016 and 2015, respectively.

Net interest expense did not materially fluctuate, amounting to \$596,000 and \$607,000 for the six months ended June 30, 2016 and 2015, respectively.

Liquidity and Capital Resources

The cumulative net loss from our inception through June 30, 2016 was \$89.6 million. Net cash used in operating activities was \$3.3 million and \$5.7 million for the six months ended June 30, 2016 and 2015, respectively. Since inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent such financing activities consist of: (i) a December 2015 private placement of equity, which resulted in net proceeds of \$4.7 million; (ii) a December 2014 private placement of equity, which resulted in net proceeds of \$9.3 million; and (iii) a March 2014 private placement of debt and warrants, which resulted in net proceeds of \$3.5 million. In addition, in March 2014, we completed a transaction with Boston Scientific that resulted in the cancellation of \$4.3 million in related party convertible notes payable held by Boston Scientific, which were scheduled to mature in 2014.

In addition, as more fully discussed in Note 5 to the condensed consolidated unaudited financial statements included elsewhere in this Quarterly Report, on March 22, 2016 we entered into the 2016 Purchase Agreement with Brainlab that provided, among other items, for the restructuring of the Brainlab Note. The restructuring of the Brainlab Note was consummated on April 4, 2016 and resulted in a \$2.3 million reduction of the principal amount outstanding under the Brainlab Note, which is reflected in the New Brainlab Note that matures on December 31, 2018.

Our plans for the next twelve months reflect management's anticipation of increases in revenues from sales of the ClearPoint system and related disposable products as a result of greater utilization at existing installed sites and the installation of the ClearPoint system at new sites. Management also anticipates maintaining recurring operating expenses at historical levels, with expected decreases in general and administrative expenses, resulting primarily from the operational restructuring discussed in Note 4 to the condensed consolidated financial statements included elsewhere in this Quarterly Report being offset by increases in selling and marketing expenses associated with the anticipated growth in revenues. However, there is no assurance that we will be able to achieve our anticipated results, and even in the event such results are achieved, we expect to continue to consume cash in our operations over at least the next twelve months.

As a result of the foregoing, we believe it will be necessary to seek additional financing from the sale of equity or debt securities, which would result in dilution to our current stockholders, the establishment of a credit facility, or the entry into an agreement with a strategic partner or some other form of collaborative relationship. There is no assurance, however, that we will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing that we do obtain will be sufficient to meet our needs. If we are not able to obtain the additional financing on a timely basis, we may be unable to achieve our anticipated results, and we may not be able to meet our other obligations as they become due. As such, there is substantial doubt as to our ability to continue as a going concern.

Cash Flows

Cash activity for the six months ended June 30, 2016 and 2015 is summarized as follows:

	Six Months Ended	
	June 30,	
	2016	2015
Cash used in operating activities	\$ (3,292,217)	\$ (5,716,894)
Cash used in investing activities	(100,324)	(7,377)
Cash used in financing activities	-	-
Net decrease in cash and cash equivalents	<u>\$ (3,392,541)</u>	<u>\$ (5,724,271)</u>

Net Cash Flows from Operating Activities. We used \$3 million and \$5.7 million of cash for operating activities during the six months ended June 30, 2016 and 2015, respectively.

During the six months ended June 30, 2016, uses of cash in operating activities primarily consisted of: (i) our \$3.8 million net loss; (ii) the addition to net loss of the non-cash gains from debt restructuring and the change in fair value of derivative liabilities of \$121,000 and \$424,000, respectively; (iii) an increase in prepaid expenses and other current assets of \$162,000; (iv) an increase in other assets of \$228,000; and (v) a decrease in accounts payable and accrued expenses of \$193,000. These uses were partially offset by: (a) non-cash expenses included in our net loss aggregating \$966,000 and consisting of depreciation and amortization, share-based compensation, expenses paid through the issuance of common stock, loss from change in fair value of derivative liabilities, amortization of debt issuance costs and original issue discounts, and loss from retirement of fixed assets; (b) decreases in accounts receivable and inventory of \$448,000 and \$51,000, respectively; and (c) an increase in deferred revenue of \$107,000.

During the six months ended June 30, 2015, uses of cash in operating activities primarily consisted of (a) our \$7.0 million loss from operations (which included restructuring charges of \$753,000), (b) a reduction of accounts payable and accrued expenses of \$886,000, and (c) increases in inventory of \$188,000 and in prepaid expenses and other current assets of \$128,000. These uses were partially offset by non-cash expenses included in our loss from operations consisting of (x) an increase in the fair value of our derivative liabilities of \$969,000, (y) share-based compensation of \$707,000, and (z) amortization of debt issuance costs and original issue discounts of \$224,000.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the six months ended June 30, 2016 and 2015 were \$100,000 and \$7,000, respectively, and consisted of equipment acquisitions in both periods.

Net Cash Flows from Financing Activities. There were no cash flows from financing activities during either of the six months ended June 30, 2016 or 2015.

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 typically held in a variety of interest bearing instruments, including interest bearing demand accounts and certificates of deposit. Cash in excess of immediate requirements is invested primarily 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 and complete the development of our ClearTrace system. 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 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 (prior to the suspension of such development);
- 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 of 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 the 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, or 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 June 30, 2016 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 June 30, 2016.

During the quarter ended June 30, 2016, 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 Annual Report on Form 10-K for the year ended December 31, 2015, which we filed with the SEC on March 25, 2016. 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 Annual Report on Form 10-K, our quarterly reports on Form 10-Q and other reports filed with the SEC are not necessarily all of 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 Annual Report on Form 10-K for our year ended December 31, 2015, except as follows:

Our ClearTrace system remains a product candidate in development. We cannot be certain that we will be able to successfully complete development of, and obtain regulatory clearances or approvals for, our ClearTrace system in a timely fashion, or at all.

Our ClearTrace system is a product candidate in development, although we suspended our ClearTrace development program in 2015 to enable us to focus resources on our ClearPoint system. At the time we suspended our ClearTrace development work, we had conducted only animal studies and other preclinical work with respect to that product candidate. Our ClearTrace system will require substantial additional development and testing. There can be no assurance that we will resume our ClearTrace development program, or that, if resumed, our development efforts will be successfully completed, or that the ClearTrace system will have the capabilities we expect. If we resume our work, we may encounter significant difficulties and costs during the course of our development efforts and we may encounter significant additional delays. Even if we successfully complete development of our ClearTrace system, there can be no assurance that we will obtain the regulatory clearances or approvals to market and commercialize it. If we are unable to obtain regulatory clearances or approvals for our ClearTrace system, or otherwise experience delays in obtaining such regulatory clearances or approvals, the commercialization of the ClearTrace system will be delayed or prevented. Even if cleared or approved, the ClearTrace system may not be cleared or approved for the indications that are necessary or desirable for successful commercialization. Delays in developing our ClearTrace system or obtaining regulatory clearances or approvals may also result in the loss of potential competitive advantages that might otherwise be attained by bringing products to market earlier than our competitors. Any of these contingencies could adversely affect our business. Likewise, in lieu of resuming our ClearTrace development program and undertaking the remaining development work, we may explore collaborations with one or more third parties pursuant to which the technologies underlying our ClearTrace system would be further developed and potentially commercialized. If we enter into any such collaboration with a third party, we may have to relinquish valuable rights to our ClearTrace system and its underlying technologies.

We may not realize anticipated benefits from our collaborative agreement with Siemens regarding our ClearTrace system.

In February 2014, we entered into a development agreement with Siemens that relates to our ClearTrace system. That development agreement provides for certain commercial exclusivity in the field of MRI-guided catheter-based cardiac electrophysiology using catheters that are actively tracked by the MRI scanner. During the exclusivity period and within that particular exclusivity field, Siemens agreed not to engage in certain actions and activities, the intention being that we would have the exclusive opportunity to commercialize MRI-guided catheter-based cardiac electrophysiology with active catheter tracking with Siemens MRI systems. Likewise, during the exclusivity period and within the exclusivity field, we agreed not to sell or otherwise provide to any third party actively tracked catheters for commercial use that are intended to be used with a non-Siemens MRI system. However, the development agreement provides that, as a condition of continued exclusivity, we must release software and catheters for our ClearTrace system in the United States or European Union by the end of June 2016. Given the stage and status of our ClearTrace development program, we did not meet that milestone, and, as a result, Siemens may elect to terminate the exclusivity provisions of the agreement. If Siemens elects to terminate exclusivity, we may not realize some of the anticipated benefits from our development agreement with Siemens.

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 in the accompanying Exhibit Index are filed, furnished or incorporated by reference as part of this Quarterly Report.

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: August 15, 2016

MRI INTERVENTIONS, INC.

By: /s/ Francis P. Grillo

Francis P. Grillo
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Harold A. Hurwitz

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Certificate of Amendment of Certificate of Incorporation of MRI Interventions, Inc., filed with the Secretary of the State of Delaware on July 26, 2016 (Incorporated by reference to Exhibit 3.1 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on July 26, 2016)
4.1	Form of Series A Warrant (Incorporated by reference to Exhibit 4.1 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
4.2	Form of Series B Warrant (Incorporated by reference to Exhibit 4.2 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
4.3	Form of Amended and Restated 5.5% Promissory Note, Due December 31, 2018, issued to Brainlab AG by MRI Interventions, Inc. (Incorporated by reference to Exhibit 4.3 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
10.1	Securities Purchase Agreement, dated March 22, 2016, by and between MRI Interventions, Inc. and Brainlab AG (Incorporated by reference to Exhibit 10.1 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
10.2	Form of Registration Rights Agreement by and between MRI Interventions, Inc. and Brainlab AG (Incorporated by reference to Exhibit 10.2 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
10.3	Form of Patent and Technology License Agreement by and between MRI Interventions, Inc. and Brainlab AG (Incorporated by reference to Exhibit 10.3 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 000-54575) filed with the Securities and Exchange Commission on March 22, 2016)
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934
32+	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
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.

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

I, Francis P. Grillo, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended June 30, 2016, 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: August 15, 2016

/s/ Francis P. Grillo

Francis P. Grillo
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 June 30, 2016, 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: August 15, 2016

/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, Francis P. Grillo 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 June 30, 2016, 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: August 15, 2016

/s/ Francis P. Grillo

Francis P. Grillo
Chief Executive Officer

/s/ Harold A. Hurwitz

Harold A. Hurwitz
Chief Financial Officer
