

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

Or

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

For the transition period from _____ to _____

Commission file number: 001-34822

MRI Interventions, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction
of Incorporation or Organization)

58-2394628

(IRS Employer
Identification Number)

5 Musick

Irvine, California
(Address of Principal Executive Offices)

92618

(Zip Code)

(949) 900-6833

(Registrant's Telephone Number, Including Area Code)

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

Yes No

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

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

Emerging Growth Company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 12, 2018, there were 11,022,372 shares of common stock outstanding.

MRI INTERVENTIONS, INC.

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Trademarks, Trade Names and Service Marks

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- estimates regarding the sufficiency of our cash resources and our ability to obtain additional financing, to the extent necessary or advisable;
- 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, 2017, which we filed with the SEC on March 21, 2018, 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>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,710,947	\$ 9,289,831
Accounts receivable, net	1,055,327	949,415
Inventory, net	2,498,109	2,314,184
Prepaid expenses and other current assets	261,856	192,727
Total current assets	7,526,239	12,746,157
Property and equipment, net	321,858	267,667
Software license inventory	819,400	871,900
Other assets	10,640	11,641
Total assets	\$ 8,678,137	\$ 13,897,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 700,485	\$ 759,445
Accrued compensation	643,734	806,445
Other accrued liabilities	252,820	480,159
Derivative liabilities	-	95,786
Deferred revenue	421,432	256,178
Senior secured note payable	-	2,000,000
Total current liabilities	2,018,471	4,398,013
Accrued interest	839,625	752,500
2014 junior secured notes payable, net	1,934,828	1,874,570
2010 junior secured notes payable, net	1,392,571	1,043,542
Total liabilities	6,185,495	8,068,625
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 25,000,000 shares authorized; none issued and outstanding at September 30, 2018 and December 31, 2017	-	-
Common stock, \$0.01 par value; 200,000,000 shares authorized; 11,022,372 shares issued and outstanding at September 30, 2018; and 10,693,851 issued and outstanding at December 31, 2017	110,223	106,937
Additional paid-in capital	108,364,065	106,757,920
Accumulated deficit	(105,981,646)	(101,036,117)
Total stockholders' equity	2,492,642	5,828,740
Total liabilities and stockholders' equity	\$ 8,678,137	\$ 13,897,365

See accompanying notes to Condensed Consolidated Financial Statements.

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

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

See accompanying notes to Condensed Consolidated Financial Statements.

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

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

See accompanying notes to Condensed Consolidated Financial Statements.

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

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

SUPPLEMENTAL CASH FLOW INFORMATION

Cash paid for:		
Income taxes	\$ -	\$ -
Interest	\$ 92,222	\$ 146,611

See accompanying notes to Condensed Consolidated Financial Statements.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements

1. Description of the Business and Liquidity

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

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

Liquidity

The Company has incurred net losses since its inception which has resulted in a cumulative deficit at September 30, 2018 of \$106 million. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. As discussed in Note 6, in May 2017, the Company completed a private offering of equity units (the “2017 PIPE”) through which the Company received aggregate gross proceeds of approximately \$13.25 million, before deducting placement agents’ fees and offering expenses aggregating approximately \$1.3 million. As a result of the foregoing, the Company’s cash and cash equivalent balances at September 30, 2018 aggregated approximately \$3.7 million.

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 that growth in operating expenses will be modest in comparison to the anticipated growth in revenues, thus resulting in decreases in the Company’s operating loss and cash used in operating activities. 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 sources of funds from the sale of equity or debt securities, which likely would result in dilution to the Company’s current stockholders, or from 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 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. An inability to obtain a sufficient amount of additional funding would create substantial doubt as to the Company’s ability to continue as a going concern.

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, 2017 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, 2017, which was filed with the SEC on March 21, 2018 (the “2017 Form 10-K”). The accompanying unaudited condensed consolidated balance sheet as of December 31, 2017 has been derived from the audited consolidated financial statements at that date but does not include all information and footnotes required by GAAP for a complete set of financial statements. The results of operations for the three and nine months ended September 30, 2018 may not be indicative of the results to be expected for the entire year or any future periods.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

Derivative Liabilities

As described in Note 7, at December 31, 2017, derivative liabilities represented the fair value of a conversion feature of a note payable and of certain warrants to purchase common stock. These derivative liabilities were calculated utilizing the Monte Carlo simulation valuation method. Changes in the fair values of these warrants were recognized as other income or expense in the related condensed consolidated statements of operations. Also as described in Note 7, neither the conversion feature nor the warrants were existed at September 30, 2018. Accordingly, the Company had no derivative liabilities as of that date.

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, or inputs other than quoted prices that are observable for the asset or liability. The lowest priority, referred to as Level 3, is given to unobservable inputs. There were no amounts in the Company's condensed consolidated balance sheet at September 30, 2018, that were derived from fair value calculations. The table below reflects the level of the inputs used in the Company's fair value calculations at December 31, 2017:

	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
<u>December 31, 2017</u>				
Derivative liabilities - warrants	\$ -	\$ -	\$ 79,286	\$ 79,286
Derivative liabilities – debt conversion feature	\$ -	\$ -	\$ 16,500	\$ 16,500

Inputs used in the Company's Level 3 calculation of fair value include the assumed dividend rate on the Company's common stock, risk-free interest rates, stock price volatility and the likelihood of a future equity financing transaction, 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.

Inventory

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

Revenue Recognition / Recently Adopted Accounting Pronouncement

Effective January 1, 2018, the Company adopted the provisions of Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers," which, with subsequent amendments thereto, created a new Topic 606 within the Accounting Standards Codification ("ASC"). Topic 606 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. Prior to adoption, the Company assessed the impact of Topic 606 and determined that adoption would not have a material effect on its consolidated financial statements. The Company adopted Topic 606 in conformity with its provisions on January 1, 2018 under the modified retrospective method.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

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

Lines of Business; Timing of Revenue Recognition

- *Functional neurology product, and biologics and drug delivery systems product sales*: Revenues from the sale of functional neurology products (consisting of disposable products sold commercially and related to cases utilizing the Company's ClearPoint system), and biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing the ClearPoint system), are generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are recognized at the point in time of delivery to the customer, which is the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.
- *Capital equipment sales*
 - *Capital equipment sales preceded by evaluation periods*: The predominance of capital equipment sales (consisting of integrated computer hardware and software that are integral components of the Company's ClearPoint system) are preceded by customer evaluation periods of generally 90 days. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, revenue from capital equipment sales following such evaluation periods is recognized at the point in time the Company is in receipt of an executed purchase agreement or purchase order.
 - *Capital equipment sales not preceded by evaluation periods*: Revenue from sales of capital equipment not having been preceded by an evaluation period is recognized at the point in time that the equipment has been delivered to the customer.

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

- *Capital equipment-related services*
 - *Rental and equipment service*: Revenue from rental of ClearPoint capital equipment is recognized ratably on a monthly basis over the term of the rental agreement, which is less than one year. Revenue from service of ClearPoint capital equipment previously sold to customers is based on agreements with terms ranging from one to three years and revenue is recognized ratably on a monthly basis over the term of the service agreement. A time-elapsed output method is used for rental and service revenues because the Company transfers control evenly by providing a stand-ready service.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

- *Installation, training and shipping:* Consistent with the Company's recognition of revenue for capital equipment sales as described above, fees for installation, training and shipping fees in connection with sales of capital equipment that have been preceded by customer evaluation periods are recognized as revenue at the point in time the Company is in receipt of an executed purchase order for the equipment. Installation, training and shipping fees related to capital equipment sales not having been preceded by an evaluation period are recognized as revenue at the point in time that the related services are performed.
- *Biologics and drug delivery services:*
 - *Outsourced recruitment and/or designation of a clinical services liaison between Company and its customer:* The Company recognizes revenue at the point in time that the liaison is either recruited or designated, which is the point at which the customer is able to direct, and obtain benefit from, use of the liaison. The Company made this determination based on the decision made by the customer to outsource this function to the Company, rather than to incur its own recruiting costs. Upon such recruitment or designation, the liaison becomes the customer's outsourced clinical support services coordinator.
 - *Outsourced technical clinical support of cases performed pursuant to customer-sponsored clinical trials:* The Company recognizes revenue at the point in time a clinical trial case is performed based on the allocated per-case transaction price.
 - *Other related services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.

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

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

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

Other Judgments and Estimates – Transaction price

Substantially all the Company's contracts with customers are based on customer-issued purchase orders for distinct products or services. For these contracts, the transaction price is determined upon establishment of the contract that contains the final terms of the sale.

One of the Company's contracts bundles performance obligations that include biologics and drug delivery system products, capital equipment products and clinical support services, for which the Company estimates the transaction price by allocating among the performance obligations reductions to revenue for discounts given on certain elements with the bundle.

See Note 3 for additional information regarding revenue recognition.

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.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At September 30, 2018, the Company had \$219,372 in bank balances that were in excess of the insured limits.

No customers accounted for sales equal to or greater than 10% of total sales in either the three-month or nine-month periods ended September 30, 2018. One customer accounted for 11% of total sales in the three-month period ended September 30, 2017, and no customers accounted for sales equal to or greater than 10% of total sales in the nine-month period ended September 30, 2017.

One customer accounted for 14% of total accounts receivable at September 30, 2018, and one customer accounted for 10% of total accounts receivable at December 31, 2017.

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at September 30, 2018 and December 31, 2017 was \$33,000 and \$29,000, respectively.

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

Recent Accounting Pronouncements

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. The Company currently has two leases for manufacturing and office space that would be subject to the provisions of ASU 2016-02. The Company believes that adoption of ASC Topic 842 (as amended by ASC 2017-13), will result in the establishment on the Company's consolidated balance sheet of an asset and liability for each such lease, but that neither such assets and liabilities nor the resulting lease expense recognition will have a material effect on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception," which, among other items, changes the classification of certain equity-linked financial instruments (or embedded features) with down round features. The standard is effective for the Company beginning in 2019, and early adoption is permitted. Because the derivative liabilities in existence at December 31, 2017 expired during the three months ended September 30, 2018 as described in Note 7, the Company has concluded that adoption of the standard on its effective date will not have a material effect on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718)," which expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The standard is effective for the Company beginning in 2019, and early adoption is permitted. The Company believes that adoption of the standard will not have a material effect on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820) – Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement," which modify the disclosure requirements for fair value measurements. The standard is effective for the Company beginning in 2020, at which time certain modifications are to be applied prospectively and others are to be applied retrospectively, and early adoption is permitted. The Company believes that adoption of the standard will not have a material effect on the Company's consolidated financial statements.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

3. Revenue Recognition

Revenue by Service Line

	Three Months Ended September 30,	
	2018	2017
Products:		
Disposable products:		
Functional neurology	\$ 1,448,850	\$ 1,284,029
Biologics and drug delivery	190,993	136,833
Capital equipment	99,961	207,573
Total product revenue	<u>1,739,804</u>	<u>1,628,435</u>
Services:		
Capital equipment and other	62,238	88,635
Biologics and drug delivery	5,000	-
Total service revenue	<u>67,238</u>	<u>88,635</u>
Total revenue	<u>\$ 1,807,042</u>	<u>\$ 1,717,070</u>

	Nine Months Ended September 30,	
	2018	2017
Products:		
Disposable products:		
Functional neurology	\$ 3,787,712	\$ 4,229,192
Biologics and drug delivery	483,251	291,023
Capital equipment	420,039	923,072
Total product revenue	<u>4,691,002</u>	<u>5,443,287</u>
Services:		
Capital equipment and other	218,742	256,860
Biologics and drug delivery	167,000	-
Total service revenue	<u>385,742</u>	<u>256,860</u>
Total revenue	<u>\$ 5,076,744</u>	<u>\$ 5,700,147</u>

Contract Balances

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

During the three and nine months ended September 30, 2018, the Company recognized capital equipment-related service revenue of \$41,391 and \$128,725, respectively, which was previously included in deferred revenue in the accompanying condensed consolidated balance sheet at December 31, 2017.

In connection with one customer contract, the Company bills the customer for certain product the customer ordered and is committed to purchase, but which is shipped at a future date. At September 30, 2018, such billings amounted to \$129,000, which amount is included in each of accounts receivable and deferred revenue in the accompanying condensed consolidated balance sheet.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

Remaining Performance Obligations

The Company's contracts with customers are predominantly of terms less than one year. Accordingly, the transaction price of remaining performance obligations related to such contracts at September 30, 2018 are not material.

Revenue with respect to remaining performance obligations related to capital equipment-related service agreements with original terms in excess of one year amounted to \$273,561 at September 30, 2018. The Company expects to recognize this revenue within the next three years.

One contract with a customer has a stated term of three years. However, the customer has the right to terminate the contract for convenience upon a 30-day notice, in which event the customer would be obligated to compensate the Company for up to three months of previously forecast purchases. Based on the foregoing, the Company uses the practical expedient available under Topic 606 pursuant to which such contracts are considered to have a term of less than one year and for which disclosure of the transaction price for the remaining performance obligations as of the end of each reporting period or when the Company expects to recognize this revenue is not required. Accordingly, the Company has not included such disclosure for this contract.

4. Inventory

Inventory consists of the following as of:

	September 30, 2018	December 31, 2017
Raw materials and work in process	\$ 1,383,772	\$ 1,167,142
Software licenses	35,000	52,500
Finished goods	1,079,337	1,094,542
Inventory, net, included in current assets	2,498,109	2,314,184
Software licenses – non-current	819,400	871,900
Total	<u>\$ 3,317,509</u>	<u>\$ 3,186,084</u>

5. Notes Payable

Senior Secured Note Payable

The indebtedness outstanding under the senior secured note payable to Brainlab, originally issued to Brainlab on April 5, 2011, and subsequently amended and restated on March 6, 2013 and April 4, 2016 (the "Brainlab Note"), at December 31, 2017, was \$2.0 million and had a maturity date of December 31, 2018. Interest, at an annual rate of 5.5%, was payable quarterly in arrears. On September 25, 2018, the Company repaid in full all the outstanding debt, together with interest. In connection with the repayment, the security agreement under which the Brainlab Note had been collateralized by all the assets of the Company was terminated.

2014 Junior Secured Notes Payable

The indebtedness outstanding under the 2014 Junior Secured Notes Payable (the "2014 Secured Notes") at each of September 30, 2018 and December 31, 2017 was \$1.975 million. On September 25, 2018, the Company entered into an amendment (the "Third Omnibus Amendment") with the holder of the 2014 Secured Notes representing a majority of the aggregate principal balance of such notes (the "Majority Note Holder") who, under the terms of the 2014 Secured Notes, has the ability to amend any term of the 2014 Secured Notes. Pursuant to the Third Omnibus Amendment, the Majority Note Holder and the Company agreed to extend the maturity date of all the 2014 Secured Notes by eighteen months from their original maturity date in March 2019 to September 2020. No other terms of the 2014 Secured Notes were modified. The 2014 Secured Notes bear interest at an annual rate of 12%, payable semi-annually in arrears, and are collateralized by a first-priority security interest in all the Company's assets.

Under the terms of a securities purchase agreement, the 2014 Secured Notes were issued in a private placement that included warrants (the "investor warrants") to purchase 0.01 shares of the Company's common stock for each dollar in principal amount. Under GAAP, the Company allocated the private placement proceeds proportionately between the 2014 Secured Notes and the investor warrants based on their relative fair values, with the amount allocated to the fair value of the investor warrants recorded as equity and as a discount to the carrying amount at the date of issuance. This discount is being amortized to interest expense over the contractual life, as amended as described above, of the 2014 Secured Notes using the effective interest method. The unamortized discount at September 30, 2018 and December 31, 2017 was \$27,108 and \$67,770, respectively. The carrying amount of the 2014 Secured Notes in the accompanying condensed consolidated balance sheets is also presented net of unamortized issuance costs, as discussed further below.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

The Company's placement agents earned cash commissions of \$145,500 as well as warrants (the "placement agent warrants") to purchase 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 fair value of the placement agent warrants, and other offering expenses 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 \$13,064 and \$32,660 at September 30, 2018 and December 31, 2017, respectively, are being amortized to interest expense over the contractual life, as amended as described above, of the 2014 Secured Notes using the effective interest method.

2010 Junior Secured Notes Payable

The indebtedness outstanding under the 2010 Junior Secured Notes Payable (the "2010 Secured Notes") at each of September 30, 2018 and December 31, 2017 was \$3.0 million. The 2010 Secured Notes accrue interest at an annual rate of 3.5% and are collateralized by a security interest in all the Company's assets, which security interest is junior and subordinate to the security interest that collateralizes 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 in November 2020.

Under the terms of a securities purchase agreement, the 2010 Secured Notes were issued in a private placement of units that included the 2010 Secured Notes and one share of the Company's common stock. Under GAAP, the Company allocated the \$3.0 million 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. The amount allocated to the value of the shares of common stock was recorded as equity and as a discount to the carrying value of the 2010 Secured Notes at their date of issuance. The unamortized discount at September 30, 2018 and December 31, 2017 was \$1,607,429 and \$1,956,458, respectively. This discount is being amortized to interest expense over the 10-year term of the notes using the effective interest method.

At each of September 30, 2018 and December 31, 2017, the Company's Chairman and one of the Company's officers held 2010 Secured Notes they purchased at the date of original issuance having an aggregate principal balance of \$197,000.

Scheduled Notes Payable Maturities

Scheduled principal payments as of September 30, 2018 with respect to notes payable are summarized as follows:

<u>Years ending December 31,</u>	
2018	-
2019	-
2020	<u>\$ 4,975,000</u>
Total scheduled principal payments	4,975,000
Less: Unamortized discounts and deferred financing costs	<u>(1,647,601)</u>
Total	<u>\$ 3,327,399</u>

6. Stockholders' Equity

2017 Private Placement

On May 26, 2017, the Company completed the 2017 PIPE pursuant to a Securities Purchase Agreement dated May 25, 2017 (the "2017 PIPE Purchase Agreement") with certain accredited investors (collectively, the "2017 PIPE Investors") for the private placement of 6,625,000 units (the "2017 PIPE Units") at a purchase price of \$2.00 per unit, with each unit consisting of: (i) one share of the Company's common stock; and (ii) a warrant to purchase one share of the Company's common stock (each, a "2017 PIPE Warrant" and collectively, the "2017 PIPE Warrants").

In connection with the sale of the 2017 PIPE Units, the Company received aggregate gross proceeds of approximately \$13.25 million, before deducting placement agents' fees and offering expenses aggregating approximately \$1.3 million. In addition, the placement agents for the 2017 PIPE received, in the aggregate, warrants ("2017 PIPE Placement Agent Warrants") to purchase up to 509,200 shares of common stock.

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

Purchase Agreement

The 2017 PIPE Purchase Agreement contains representations and warranties by the Company and the 2017 PIPE Investors and covenants of the Company and the 2017 PIPE Investors (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.

Warrants

The 2017 PIPE Warrants are exercisable, in full or in part, at any time prior to the fifth anniversary of their issuance, at an exercise price of \$2.20 per share, subject to provisions for: (a) adjustments in the case of certain corporate transactions; (b) consideration to be received in lieu of shares of the Company's common stock in the case of certain fundamental transactions; and (c) a "cashless exercise" feature. The 2017 PIPE Placement Agent Warrants have the same terms and conditions as the 2017 PIPE Warrants.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Director fees, whether paid in cash or in shares of common stock, are payable quarterly on the last day of each fiscal quarter. The number of shares of common stock issued to directors is determined by dividing the product of: (i)(a) the fees otherwise payable to each director in cash, times (b) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the three and nine months ended September 30, 2018, 15,933 and 38,341 shares, respectively were issued to directors as payment for director fees in lieu of cash. No shares were issued to directors as payment for director fees during the three or nine months ended September 30, 2017.

Stock Incentive Plans

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

Since June 2015, the Company has granted share-based awards under the MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan (the "2013 Plan"). Under the 2013 Plan, a total of 1,956,250 shares of the Company's common stock are reserved for issuance. Of this amount, stock grants of 162,393 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 895,645 shares were outstanding as of September 30, 2018. Accordingly, 898,212 shares remained available for grants under the 2013 Plan as of that date.

Stock option activity under all of the Company's Plans during the nine months ended September 30, 2018 is summarized below:

	<u>Shares</u>	<u>Weighted - Average Exercise Price</u>
Outstanding at December 31, 2017	1,238,199	\$ 12.47
Granted	147,500	1.81
Forfeited	(13,162)	15.02
Outstanding at September 30, 2018	<u>1,372,537</u>	<u>\$ 11.30</u>

MRI INTERVENTIONS, INC.
Notes to Condensed Consolidated Financial Statements, continued

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the three and nine months ended September 30, 2018 and 2017, share-based compensation expense related to options was:

Three Months Ended September 30,			
2018		2017	
\$	208,207	\$	186,982
Nine Months Ended September 30,			
2018		2017	
\$	968,488	\$	616,007

As of September 30, 2018, there was unrecognized compensation expense of \$616,879 related to outstanding stock options, which is expected to be recognized over a weighted average period of 1.64 years.

Warrants

Warrants have generally been issued for terms of up to five years. Common stock warrant activity for the nine months ended September 30, 2018 was as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at December 31, 2017	8,949,078	\$ 4.12
Issued	-	-
Exercised	(221,773)	2.20
Expired / Terminated	(49,749)	2.00
Outstanding at September 30, 2018	8,677,556	\$ 4.18

7. Derivative Liabilities

Derivative liabilities at December 31, 2017 arose from an amendment the Company entered into with Brainlab, with respect to the Brainlab Note and related warrants (the “Brainlab warrants”), the provisions of which created: (a) a conversion feature allowing for \$500,000 the principal balance of the Brainlab Note to be converted in a Qualified Public Offering, as defined in the amendment, at a public offering price that may be less than market value per share of the Company’s common stock; (b) down round strike price protection with respect to Brainlab warrants; and (c) warrants, issued in 2013, that contained net-cash settlement and down-round provisions (the “2013 warrants”). The conversion feature and the Brainlab warrants described herein terminated unexercised pursuant to the Company’s September 2018 repayment of the Brainlab Note as discussed in Note 5. The 2013 warrants expired in January 2018.

The fair values and the changes in fair values of derivative liabilities during the nine months ended September 30, 2018 and 2017 are as follows:

	Nine Months Ended September 30,	
	2018	2017
Balance, beginning of period	\$ 95,786	\$ 131,173
Reduction from warrant exercise	(31,468)	(10,659)
Gain on change in fair value for the period	(64,318)	(48,064)
Balance, end of period	\$ -	\$ 72,450

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, 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 our product revenues for the three and nine months ended September 30, 2018 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 September 30, 2018, we had accumulated losses of approximately \$106 million. We may continue to incur operating losses as we drive commercialization efforts related to our ClearPoint system products, potentially reinstate development of our ClearTrace system, 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 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 \$1.7 million and \$4.7 million for the three and nine months ended September 30, 2018, 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 included elsewhere in 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. Such costs include salaries, travel, and benefits for research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; consultant costs; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development costs may increase as we: (i) continue to develop enhancements to our ClearPoint system; (ii) resume our ClearTrace system product development efforts; and (iii) seek to expand the application of our technological platforms. From our inception through September 30, 2018, we have incurred approximately \$53 million in research and development expenses.

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

Sales and Marketing, and General and Administrative Expenses

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

Critical Accounting Policies

As described in Note 2 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, effective January 1, 2018, we adopted the provisions of ASC Topic 606, "Revenue from Contracts with Customers."

There have been no other significant changes in our critical accounting policies during the three or nine months ended September 30, 2018 as compared to the critical accounting policies described in our 2017 Form 10-K.

Results of Operations

Three Months Ended September 30, 2018 Compared to the Three Months Ended September 30, 2017

	Three Months Ended September 30,		
	2018	2017	Percentage Change
Product revenues	\$ 1,739,804	\$ 1,628,435	7%
Service and other revenues	67,238	88,635	(24)%
Total revenues	1,807,042	1,717,070	5%
Cost of revenues	553,221	688,847	(20)%
Research and development costs	617,241	589,716	5%
Sales and marketing expenses	764,599	899,103	(15)%
General and administrative expenses	1,078,171	866,727	20%
Other income (expense):			
Gain from change in fair value of derivative liabilities	22,295	109,803	(80)%
Other income, net	2,643	3,363	(21)%
Interest expense, net	(246,824)	(211,362)	17%
Net loss	\$ (1,428,076)	\$ (1,425,519)	-%

Revenue. Total revenues were \$1.8 million for the three months ended September 30, 2018, and \$1.7 million for the three months ended September 30, 2017, an increase of \$90,000, or 5%.

Functional neurology revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 13% to \$1.4 million for the three months ended September 30, 2018, from \$1.3 million for the same period in 2017. The increase was due primarily to a 9% increase in ClearPoint cases performed during the quarter ended September 30, 2018, relative to the same period in 2017. Of this increase, we experienced a favorable mix of ClearPoint cases during the quarter ended September 30, 2018, relative to the same period in 2017, as deep brain stimulation cases, the majority of which consume two ClearPoint kits, increased 11%, and laser ablation cases, the majority of which consume one ClearPoint kit, decreased 9%. We believe the decrease in laser ablation cases was influenced by FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space. While one of the third-party providers regained FDA clearance of its system in October 2018, and we believe the other third-party provider will eventually resolve matters with FDA, there can be no assurance as to when, or if at all, such resolution will occur, or whether such resolutions will result in an increase of laser ablation cases utilizing ClearPoint. There were no increases in functional neurology product prices during the period between the three months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 40% to \$191,000 for the three months ended September 30, 2018, from \$137,000 for the same period in 2017. This increase was due primarily to an increase in biologic and drug delivery product revenues resulting from their use in a greater number of cases during the quarter ended September 30, 2018, relative to the same period in 2017. There were no increases in biologics and drug delivery product prices during the period between the three months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, decreased 52% to \$100,000 for the three months ended September 30, 2018, from \$208,000 for the same period in 2017. Revenues from this product line historically have varied from quarter to quarter. This decrease was due primarily to a decrease from the third quarter of 2017 to the same period in 2018 in the number of ClearPoint systems sold. There were no increases in capital equipment product prices during the period between the three months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, decreased 30% to \$62,000 for the three months ended September 30, 2018, from \$89,000 for the same period in 2017. The decrease was due primarily to decreases in fees from installation, training and shipping services, consistent with the decrease in capital equipment sales revenue.

Cost of Revenues. Cost of revenues was \$553,000 for the three months ended September 30, 2018, representing gross margin of 69%, compared to \$689,000 for the same period in 2017, representing gross margin of 60%. The increase in gross margin was due primarily to decreases in overhead and indirect costs as a percentage of revenues during the three months ended September 30, 2018, relative to the same period in 2017, and to a favorable mix of product sales, with capital equipment sales, which have a lower margin relative to other revenue lines, representing a lower percentage of sales during the three months ended September 30, 2018, relative to the same period in 2017.

Research and Development Costs. Research and development costs were \$617,000 for three months ended September 30, 2018, compared to \$590,000 for the same period in 2017, an increase of \$27,000, or 5%. The increase was due primarily to increases in regulatory legal fees, licensing fees and compensation costs. These increases were partially offset by: (a) a reduction in payments related to certain license and product co-development agreements made during the quarter ended September 30, that did not recur during the same period in 2018; and (b) costs related to intellectual property.

Sales and Marketing Expenses. Sales and marketing expenses were \$765,000 for the three months ended September 30, 2018, compared to \$899,000 for the same period in 2017, a decrease of \$134,000, or 15%. This decrease was primarily due to a decrease in incentive compensation earned by our sales and clinical personnel.

General and Administrative Expenses. General and administrative expenses were \$1.1 million for the three months ended September 30, 2018, compared to \$867,000 for the same period in 2017, an increase of \$211,000, or 20%. This increase was due primarily to: (a) increases in stock-based compensation, legal fees and directors' compensation; and (b) a decrease in the activity-based cost allocation to other departments. These fluctuations were partially offset by a decrease in hiring and relocation costs.

Other Income (Expense). During the three months ended September 30, 2018 and 2017, we recorded gains of \$22,000 and \$110,000, respectively, resulting from changes in the fair value of our derivative liabilities. Derivative liabilities at September 30, 2017 arose from: (a) warrants, issued in 2013, that contained net-cash settlement and down-round provisions; and (b) an amendment the Company entered into with Brainlab, with respect to the Brainlab Note and related warrants, the provisions of which created a conversion feature allowing for \$500,000 the principal balance of the Brainlab Note to be converted in a Qualified Public Offering, as defined in the amendment, at a public offering price that may be less than market value per share of the Company's common stock, and down round strike price protection with respect to Brainlab warrants (the "Brainlab warrants"). The warrants discussed in (a) above expired in January 2018, and the derivatives related to the Brainlab Note discussed in (b) above were terminated upon our repayment in full of the Brainlab Note as discussed in Note 5 to the Condensed Consolidated Financial statements included elsewhere in this Quarterly Report. Accordingly, there were no remaining derivative liabilities at September 30, 2018.

Net interest expense for the three months ended September 30, 2018 was \$247,000, compared with \$211,000 for the same period in 2017. The increase was due to increased amortization of the discount and deferred issuance costs associated with the 2014 Secured Notes and the 2010 Secured Notes, both as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Nine Months Ended September 30, 2018 Compared to the Nine Months Ended September 30, 2017

	Nine Months Ended September 30,		
	2018	2017	Percentage Change
Product revenues	\$ 4,691,002	\$ 5,443,287	(14)%
Service and other revenues	385,742	256,860	50%
Total revenues	5,076,744	5,700,147	(11)%
Cost of revenues	1,743,981	2,239,808	(22)%
Research and development costs	1,828,846	2,231,616	(18)%
Sales and marketing expenses	2,653,044	2,945,263	(10)%
General and administrative expenses	3,119,617	2,786,698	12%
Other income (expense):			
Gain from change in fair value of derivative liabilities	64,318	48,064	34%
Other income, net	1,284	6,774	(81)%
Interest expense, net	(742,387)	(637,270)	16%
Net loss	<u>\$ (4,945,529)</u>	<u>\$ (5,085,670)</u>	<u>(3)%</u>

Revenue. Total revenues were \$5.1 million for the nine months September 30, 2018, and \$5.7 million for the nine months ended September 30, 2017, a decrease of \$623,000, or 11%.

Functional neurology revenue, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system, decreased 10% to \$3.8 million for the nine months ended September 30, 2018, from \$4.2 million for the same period in 2017. The decrease was due primarily to a decrease in the number of ClearPoint kits sold during the nine months ended September 30, 2018, relative to the same period in 2017. We believe the decrease in sales was influenced by two factors: (a) FDA actions taken in early 2018 that adversely affected third-party providers in the laser ablation space; and (b) the introduction of a new deep brain stimulation system that did not have approval for use in the MRI suite for most of 2018. While the FDA actions was resolved by one of the affected third-parties in October 2018, and the new deep brain stimulation system received FDA clearance during the quarter ended September 30, 2018, no assurance can be given that such resolutions will result in a resumption of cases utilizing ClearPoint to previously experienced levels. There were no increases in functional neurology product prices during the period between the nine months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing the ClearPoint system, increased 66% to \$483,000 for the nine months ended September 30, 2018, from \$291,000 for the same period in 2017. This increase was due primarily to the commencement of such services during the nine months ended September 30, 2018, consisting primarily of fees earned for the designation of clinical services liaisons for a customer's use in a clinical trial of its drug. There were no service revenues related to this product line in the same period of 2017. There were no increases in biologics and drug delivery product prices during the period between the nine months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, decreased 54% to \$420,000 for the nine months ended September 30, 2018, from \$923,000 for the same period in 2017. Revenues from this product line historically have varied from period to period. This decrease was due primarily to a decrease in the number of ClearPoint systems sold. There were no increases in capital equipment product prices during the period between the nine months ended September 30, 2017 and the same period in 2018 that would be reasonably expected to affect a typical customer order.

Capital equipment-related services, consisting of fees for capital equipment rental, service, installation, training and shipping, decreased 15% to \$219,000 for the nine months ended September 30, 2018, from \$257,000 for the same period in 2017. The decrease was due primarily to decreases in fees from installation, training and shipping services, consistent with the decrease in capital equipment sales revenue.

Cost of Revenues. Cost of revenues was \$1.7 million for the nine months September 30, 2018, representing gross margin of 66%, compared to \$2.2 million for the same period in 2017, representing gross margin of 61%. The increase in gross margin was due primarily to a favorable sales mix, with capital equipment sales, which have a lower margin relative to other revenue lines, representing a lower percentage of sales during the nine months ended September 30, 2018, relative to the same period in 2017.

Research and Development Costs. Research and development costs were \$1.8 million for nine months ended September 30, 2018, compared to \$2.2 million for the same period in 2017, a decrease of \$403,000, or 18%. The decrease was due primarily to upfront payments, aggregating \$610,000, the majority of which was paid in shares of our common stock, required under certain license and product co-development agreements entered into in April 2017. No such payments were made during the nine months ended September 30, 2018. Adding to the decrease were decreases in software development costs. These decreases were partially offset by increases in each of regulatory legal costs, compensation and outside engineering services.

Sales and Marketing Expenses. Sales and marketing expenses were \$2.7 million for the nine months ended September 30, 2018, compared to \$2.9 million for the same period in 2017, a decrease of \$292,000, or 10%. This decrease was primarily due to a decrease in compensation, both base and incentive, which was partially offset by an increase in marketing costs.

General and Administrative Expenses. General and administrative expenses were \$3.1 million for the nine months ended September 30, 2018, compared to \$2.8 million for the same period in 2017, an increase of \$333,000, or 12%. This increase was due primarily to increases in stock-based compensation, Board compensation and insurance, and a decrease in costs allocated to other departments, which were partially offset by decreases in investor relations.

Other Income (Expense). During the nine months ended September 30, 2018 and 2017, we recorded gains of \$64,000 and \$48,000, respectively, resulting from changes in the fair value of our derivative liabilities. Derivative liabilities at September 30, 2017 arose from: (a) warrants, issued in 2013, that contained net-cash settlement and down-round provisions; and (b) an amendment the Company entered into with Brainlab, with respect to the Brainlab Note and related warrants, the provisions of which created a conversion feature allowing for \$500,000 the principal balance of the Brainlab Note to be converted in a Qualified Public Offering, as defined in the amendment, at a public offering price that may be less than market value per share of the Company's common stock, and down round strike price protection with respect to Brainlab warrants (the "Brainlab warrants"). The warrants discussed in (a) above expired in January 2018, and the derivatives related to the Brainlab Note discussed in (b) above were terminated upon our repayment in full of the Brainlab Note as discussed in Note 5 to the Condensed Consolidated Financial statements included elsewhere in this Quarterly Report. Accordingly, there were no remaining derivative liabilities at September 30, 2018.

Net interest expense for the nine months ended September 30, 2018 was \$742,000, compared with \$637,000 for the same period in 2017. The increase was due to increased amortization of the discount and deferred issuance costs associated with the 2014 Secured Notes and the 2010 Secured Notes, both as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report.

Liquidity and Capital Resources

At September 30, 2018, we had cash and cash equivalent balances aggregating \$3.7 million, resulting primarily from completion of the 2017 PIPE discussed in Note 6 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report. Net cash used in operating activities was \$4.0 million for the nine months ended September 30, 2018.

Our plans for the next twelve months reflect our 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. We also anticipate that growth in operating expenses will be modest in comparison to the anticipated growth in revenues, thus resulting in decreases in our operating loss and cash used in operating activities. 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 sources of funds from the sale of equity or debt securities, which likely would result in dilution to our current stockholders, or from the establishment of a credit facility or the entry into an agreement with a strategic partner or some 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. An inability to obtain a sufficient amount of additional funding would create substantial doubt as to our ability to continue as a going concern.

Cash Flows

Cash activity for the nine months ended September 30, 2018 and 2017 is summarized as follows:

	Nine Months Ended September 30,	
	2018	2017
Cash used in operating activities	\$ (4,048,210)	\$ (4,246,781)
Cash used in investing activities	(62,651)	(24,515)
Cash provided (used) by financing activities	(1,468,023)	11,984,495
Net change in cash and cash equivalents	<u>\$ (5,578,884)</u>	<u>\$ 7,713,199</u>

Net Cash Flows from Operating Activities. We used \$4.0 million and \$4.2 million of cash for operating activities during the nine months ended September 30, 2018 and 2017, respectively.

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

During the nine months ended September 30, 2017, uses of cash in operating activities primarily consisted of: (i) our \$5.1 million net loss; (ii) increases in inventory of \$312,000, and in prepaid expenses and other current assets of \$104,000; and (iii) a decrease in accounts payable and accrued expenses of \$271,000. These uses were partially offset by: (a) non-cash expenses included in our net loss aggregating \$1.5 million and consisting primarily of depreciation and amortization, share-based compensation, expenses paid through the issuance of common stock, and amortization of debt issuance costs and original issue discounts; and (b) an increase in deferred revenue of \$59,000.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities for the nine months ended September 30, 2018 and 2017 were \$63,000 and \$25,000, respectively, and consisted of equipment acquisitions.

Net Cash Flows from Financing Activities. Net cash flows from financing activities for the nine months ended September 30, 2018 consisted of the \$2 million repayment of the Brainlab Note as described in Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report, net of cash proceeds received from warrant exercises of \$532,000.

Net cash flows from financing activities for the nine months ended September 30, 2017 consisted of net cash proceeds of \$12.0 million received from the 2017 PIPE.

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, resume the currently suspended development of our ClearTrace system, and pursue additional applications for our technology platforms. Our cash balances are primarily held in non-interest-bearing demand accounts. 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, complete the development of our ClearTrace system and pursue additional applications for our technology platforms. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our product and services sales, marketing and distribution capabilities, and other corporate infrastructure;

- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the scope, rate of progress and cost of our research and development activities relating to our ClearTrace system (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 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 (the "Exchange Act"). Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2018 to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2018.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2018, 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 2017 Form 10-K. Additional information regarding some of those risks and uncertainties is contained in the notes to the Condensed Consolidated Financial Statements appearing in Part I, Item 1 of this Quarterly Report, and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing in Part I, Item 2 of this Quarterly Report. The risks and uncertainties disclosed in our 2017 Form 10-K, our quarterly reports on Form 10-Q and other reports filed with the SEC are not necessarily all the risks and uncertainties that may affect our business, financial condition and results of operations in the future.

There have been no material changes to the risk factors as disclosed in our 2017 Form 10-K.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

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

Exhibit Number	Exhibit Description
<u>10.1</u>	<u>Form of Third Omnibus Amendment dated September 25, 2018 by and among MRI Interventions, Inc., and the holders of the Company's 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019 (incorporated by reference to Exhibit 10.1 to MRI Interventions, Inc.'s Current Report on Form 8-K (File No. 001-34822) filed with the SEC on September 25, 2018)</u>
<u>10.2†*</u>	<u>License and Collaboration Agreement, dated as of October 16, 2018, by and between MRI Interventions, Inc. and Clinical Laserthermia Systems AB</u>
<u>10.3†*</u>	<u>Distribution Agreement, dated as of October 16, 2018, by and between MRI Interventions, Inc. and Clinical Laserthermia Systems AB</u>
<u>31.1*</u>	<u>Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u>
<u>31.2*</u>	<u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934</u>
<u>32+</u>	<u>Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code</u>
101.INS*	XBRL Instance
101.SCH*	XBRL Taxonomy Extension Schema
101.CAL*	XBRL Taxonomy Extension Calculation
101.DEF*	XBRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Labels
101.PRE*	XBRL Taxonomy Extension Presentation

* Filed herewith.

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

† Confidential treatment requested under Rule 24b-2 under the Securities Exchange Act of 1934. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the confidential treatment request.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 13, 2018

MRI INTERVENTIONS, INC.

By: /s/ Joseph M. Burnett

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

By: /s/ Harold A. Hurwitz

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

*** Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this “Agreement”) is entered into and made effective October 16, 2018 (“Effective Date”), by and between MRI Interventions, Inc., a Delaware corporation (“MRI”), and Clinical Laserthermia Systems AB, a Swedish corporation (“CLS”). MRI and CLS may be referred to individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, MRI designs, develops, offers, and sells systems, devices and technology related to performing minimally invasive surgical procedures under direct, intra-procedural magnetic resonance imaging guidance (collectively, the “MRI Products”);

WHEREAS, CLS designs and develops minimally invasive methods for tissue thermal therapy and ablation and has developed laser treatment solutions based on immune stimulating interstitial laser thermotherapy (imILT®) methods, including laser applicators (“Applicators”) and the TRANBERG® Thermal Therapy System (the “CLS System”) (collectively, the “CLS Products”); and

WHEREAS, the Parties desire to develop a strategic business relationship whereby each Party shall collaborate and share certain information and technology with one another in a manner intended to benefit the Parties’ current businesses and to develop, evaluate, and commercialize certain New Products (as defined herein) on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, in consideration of the representations, warranties, covenants, and agreements contained herein, and for other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties mutually agree as follows:

1. DEFINITIONS. As used in this Agreement, the following terms shall have the meanings ascribed to them below, whether used in the singular or plural. Other terms may be defined elsewhere in this Agreement and shall have the meanings indicated throughout this Agreement.

(a) “Affiliate” means, with respect to any Party, any other legal entity that, directly or indirectly, controls, is controlled by, or is under common control with, such Party; provided, however, that in each case any such other entity shall be considered to be an Affiliate only during the time period during which such control exists. For purposes of this definition, “control” (and derivatives thereof including “controlled by” and “under common control with”), as used with respect to any entity, means the possession, directly or indirectly, of more than fifty percent (50%) of the voting equity or ownership interest in or of such entity.

(b) “Applicable Law” means all applicable provisions of all international, federal, state, and local statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders,

decisions, injunctions, award judgments, permits, and licenses of or from governmental authorities, including without limitation those relating to or governing the use or regulation of the subject item and the listing standards or agreements of any national or international securities exchange.

(c) “CLS IP” means any and all Intellectual Property Developed by or for CLS, or acquired by or licensed to CLS, prior to the Effective Date of this Agreement, or during the term of this Agreement to the extent related solely to the CLS Products, including all versions and stages thereof, and all derivative works, improvements, or enhancements to any of the foregoing. Without limiting the foregoing, the CLS IP shall include the CLS Patents and all specifications, manufacturing and development methodologies, software, firmware and electronics, test and user data, and other Know-How relating to the CLS Products and proprietary to CLS.

(d) “CLS Patent(s)” shall mean (i) the United States and foreign patent applications and patents owned by CLS as of the Effective Date set forth in Exhibit A hereto, and any continuations, continuations in part, divisions, extensions, reissues, reexaminations, applications or substitutions with respect thereto and all foreign equivalents; and (ii) any and all other patents or patent applications owned by CLS prior to or during the term of this Agreement with claims covering any aspect of the CLS Products.

(e) “Commercialize” means to promote, license, market, distribute, offer for sale, sell or provide product support for the products with respect to which this term is used herein, and “Commercializing” and “Commercialization” shall be interpreted accordingly.

(f) “Confidential Information” means any and all forms and types of financial, business, marketing, operations, scientific, technical, economic and engineering information, whether tangible or intangible, including without limitation, patterns, plans, compilations, program devices, formulas, designs, prototypes, samples, methods, techniques, processes, procedures, programs, Intellectual Property, Know-How, source code, object code, databases, data, proposed product names or marks, marketing materials or programs, plans, specifications, information relating to past, present and prospective customers, users, partners, vendors and suppliers, manufacturing information, business plans, price lists, costing information, employee and consulting relationship information, accounting and financial data, profit margin, marketing and sales data, strategic plans, and all other proprietary information (including all originals, copies, digests and summaries in any form) provided by or on behalf of one Party (“Discloser”) to the other Party (“Recipient”) hereunder, including any and all non-public information regarding, related to, arising from or associated with this Agreement, and the terms and conditions of this Agreement. Notwithstanding the foregoing to the contrary, Confidential Information shall exclude any information that a Recipient can establish by documentary evidence, bearing the burden of proof: (i) was known to such Recipient before receipt thereof from or on behalf of Discloser; (ii) was disclosed to Recipient by a third person who had a right to make such disclosure without any obligation of confidentiality to Discloser; (iii) is available in the public domain without violation of this Agreement by Recipient or other obligation of confidentiality; or (iv) is independently developed by Recipient or Recipient’s Personnel without use of or reference to Discloser’s Confidential Information.

(g) “Develop” means, with respect to any Intellectual Property or New Products, to create, design, invent, reduce to practice, author, discover, develop or conceive.

(h) “Field” means the field of medical procedures, processes and therapies related to neuro applications, including intracranial and spine surgery.

(i) “Gross Margin” means total sales revenue less the cost of goods sold, divided by total sales revenue, expressed as a percentage.

(j) “Intellectual Property” means United States and foreign (a) patents, patent applications, patent disclosures and all related continuations, continuations-in-part, divisionals, reissues, reexaminations, utility models, certificates of invention and design patents, patent applications, registrations and applications for registrations; (b) trademarks and service marks, and trade dress, Internet domain names, logos, trade names and corporate names, and registrations and applications for registration thereof; (c) works of authorship and any copyright registrations or applications for registration thereof; (d) mask works and registrations and applications for registration thereof; (e) computer software, data and documentation; (f) trade secrets, including without limitation ideas, specifications, inventions, designs, Know-How, methods, discoveries, developments and any other proprietary information, whether patentable or non-patentable and whether or not reduced to practice; (g) Confidential Information; and (h) all copies and tangible embodiments of the foregoing.

(k) “Know-How” means research and design details, technical requirements, specifications, and documentation, including without limitation, engineering information, CAD drawings and files, 510(k) or PMA (as each defined herein) files and any subsequent letters to file, and verification, validation and testing protocols.

(l) “MRI IP” means any and all Intellectual Property Developed by or for MRI, or acquired by or licensed to MRI, prior to the Effective Date of this Agreement, or during the term of this Agreement to the extent related solely to the MRI Products, including all versions and stages thereof, and all derivative works, improvements, or enhancements to any of the foregoing. Without limiting the foregoing, the MRI IP shall include the MRI Patents and all specifications, manufacturing and development methodologies, software, firmware and electronics, test and user data, and other Know-How relating to the MRI Products and proprietary to MRI.

(m) “MRI Patent(s)” shall mean (i) the United States and foreign patent applications and patents owned by MRI as of the Effective Date set forth in Exhibit B hereto, and any continuations, continuations in part, divisions, extensions, reissues, reexaminations, applications or substitutions with respect thereto and all foreign equivalents; and (ii) any and all other patents or patent applications owned by MRI prior to or during the term of this Agreement with claims covering any aspect of the MRI Products.

(n) “Newly Developed IP” means all Intellectual Property that is Developed by the Parties in connection with the New Products, including Know-How, and any feedback, improvements, modifications, enhancements to, or derivative works that are based on any feedback, recommendations, or suggestions provided by or on behalf of either Party regarding the

Newly Developed IP. For the avoidance of doubt, Newly Developed IP shall not include any CLS IP or MRI IP.

(o) “New Products” means any and all new products, systems, or technology developed by the Parties in connection with this Agreement and identified in a Statement of Work, including without limitation products, devices, designs, applications, and technology integrating, combining, or incorporating the CLS Products with MRI Products.

(p) “Open Source Software” means any software, source code, or other material that is distributed as “free software,” “open source software,” or under a similar licensing or distribution model, including, without limitation, the GNU General Public License, GNU Lesser General Public License, Mozilla Public License, BSD License, the Artistic License, the Netscape Public License, the Sun Community Source License, the Sun Industry Standards License, and the Apache License.

(q) “Personnel” of a referenced Party (i.e. CLS Personnel or MRI Personnel, respectively) means any employee, independent contractor or other individual person who is a provider of services (regardless of how such individual is classified for the purposes of applicable employment and tax laws) of (i) such Party or its Affiliate(s) and/or (ii) any subcontractor of such Party providing any services in connection with or relating to this Agreement.

2. COLLABORATION.

(a) Purpose. The Parties acknowledge and agree that the purpose of the Agreement is to establish a framework between the Parties pursuant to which (i) CLS grants to MRI certain exclusive rights to sell the CLS Products in the Field as further set forth in Section 2(b) below; and (ii) the Parties collaborate to Develop New Products for use and Commercialization in the Field.

(b) CLS Products. CLS hereby grants MRI the exclusive right to Commercialize the CLS Products and New Products in the Field. MRI intends to exercise its rights under this Section in good faith to Commercialize the CLS Products in the clinical setting for the mutual benefit of the Parties. MRI shall purchase from CLS and CLS agrees to sell to MRI the CLS Products for the fees set forth in Section 7(a) and in the amounts and quantities and pursuant to terms specified in written purchase orders mutually agreed upon by the Parties (each a “Purchase Order”). In exchange for the above exclusive right granted to MRI and subject to Section 2(c)(ii), the Parties agree that during the term of this Agreement, CLS will be MRI’s exclusive supplier of laser treatment equipment within the Field. The Parties are also parties to that certain Distribution Agreement of even date herewith whereby CLS appoints MRI as its exclusive distributor of certain CLS Products.

(c) New Product Development.

(i) Statement of Work. On or after the Effective Date, the Parties may enter into one or more written statement(s) of work mutually agreed upon by the Parties (each, a “SOW”) to describe specific projects, the obligations of each Party, and the costs and budget with respect to the Development described in such SOW. All SOWs must be approved in writing by the Parties prior to the commencement thereof. The Joint Steering Committee (as defined below) is responsible for drafting each SOW. Each SOW shall

describe the respective obligations of and services to be provided by each Party and, once executed by each Party, shall be incorporated herein by reference as though fully set forth herein. If there is a conflict between the provisions of this Agreement and any SOW, the provisions of this Agreement shall control unless the SOW expressly and specifically provides otherwise by reference to this Section 2(c)(i) with intent to modify.

(ii) Initial SOW. Promptly following the Effective Date, the Parties shall cooperate in good faith to agree upon the initial SOW, which shall include without limitation terms governing the Development of thermometry software for the CLS Products for use in the Field, including the scope of the Development to be performed and the milestones and schedule for such Development (the "Initial SOW"). The Parties agree and acknowledge that the Initial SOW shall be executed by the Parties by or before December 31, 2018. In the event the Parties are unable to agree upon the Initial SOW by December 31, 2018, each Party may, in its sole discretion, terminate this Agreement in whole or in part (including by terminating the exclusive supplier obligation set forth in Section 2(b)). In the foregoing event, nothing shall prevent either Party from seeking and entering into an arrangement with an alternate third party provider or developer of thermometry software.

(iii) Change Order. Changes to any SOW shall become effective only upon the execution of a written change order ("Change Order") by the authorized representatives of each of the Parties. Each Change Order shall describe the impact of the change on the respective obligations of each Party, and once executed by each Party, shall be incorporated herein by reference as though fully set forth herein. For each Change Order, the Parties will evaluate in good faith any change that increases or decreases the scope or magnitude of performance of the Collaboration, corresponding commercially reasonable increases or decreases in compensation to a Party, appropriate and commercially reasonable revisions to the services and deliverable schedule, and the availability of the required resources and prior commitments to other customers.

(iv) Transfer of Know-How. The Parties shall, to the extent commercially reasonable or necessary to Commercialize or Develop the New Products, provide each other with all Know-How related to the CLS Products and MRI Products, respectively, to facilitate the Development and Commercialization of New Products promptly following the Effective Date in the form and format mutually agreed by the Parties.

(v) Development. Notwithstanding anything herein to the contrary, the Parties agree that the Development of the New Products shall be conducted in close consultation and co-operation between the Parties. Each Party shall keep the other Party fully and regularly informed of the progress of the Development of New Products for which the Party is responsible and shall answer any question raised by the other Party during performance and after completion of Development of New Products.

(vi) Costs. CLS and MRI shall, as a main rule and unless otherwise agreed in a SOW, be jointly responsible for all costs associated with the Development of New Products in the Field, including but not limited to costs associated with *** for new indications in the Field. Each project and budget must be approved by both Parties prior

to initiation. Notwithstanding anything to the contrary herein, should a specific project turn out to improve a CLS Product or a MRI Product in a way not originally anticipated in the SOW, the Parties agree to negotiate in good faith an appropriate allocation of costs for such Development.

(vii) Commercialization.

- (1) MRI shall use commercially reasonable efforts to Commercialize the CLS Products and New Products Developed in connection with this Agreement in the Field. MRI may not Commercialize the CLS Products or New Products under MRI's brand name unless mutually agreed by the Parties. Prior to MRI Commercializing New Products, the Parties will agree on what brand name and trademark to use for such New Products in the Commercialization.
- (2) Correspondingly, to the extent applicable, as determined by CLS in its own discretion, but subject to Section 4(d), CLS shall have the right to Commercialize the New Products outside of the Field. In case of such Commercialization by CLS, the Parties shall jointly negotiate in advance in good faith the commercial terms for any MRI Products included in such commercial offerings by CLS and the Parties shall agree on the commercial terms to apply for the New Products.
- (3) The Parties further agree to discuss in good faith the potential grant by MRI to CLS of distribution rights outside of the US and Canadian markets to the joint offering of MRI Products, CLS Products and New Products, on such markets where MRI is not active and where CLS has or wishes to establish market presence, either on its own or through distribution partners. Such good faith discussions shall be based on each of the Parties' strategies for establishing sales channels outside of the US and Canada, with the mutual aim of maximizing the geographical reach and sales of the joint offering of products.

(viii) Open Source. The New Products may, unless explicitly excluded in the relevant SOW, include Open Source Software; provided, that each Party shall maintain an accurate and complete list of any Open Source Software incorporated into New Products by or on behalf of such Party and, upon the other Party's written request, provide such list to the other Party. However, the Parties agree that copyleft or other licenses with similar restrictions may not be included in the New Products. Neither Party may subject any proprietary portion of a New Product to any Open Source license obligation. Nothing in this Agreement limits any rights under, or grants rights that supersede, the terms of any applicable Open Source license. Confidential Information may not be incorporated in any Open Source Software or derivative thereof.

(d) Regulatory. MRI shall be responsible for any costs associated with clinical or regulatory filings, reports, or submissions required by Applicable Law for MRI to Commercialize New Products or any derivative products Developed based on the Newly Developed IP in the Field, including any Premarket Notifications ("510(k)s") or Premarket Approval ("PMAs") to the Food

and Drug Administration (the “FDA”) for any New Products. MRI shall also be responsible for responding to and handling any consumer complaints arising from the Commercialization of the New Products in the Field. Subject to Section (e)(ii) below, MRI shall own all rights, title, and interests in any 510(k)s submitted by or on behalf of MRI for any New Products. Each Party agrees, upon the reasonable request of the other Party, during or after the term of this Agreement, to take such further acts as may be reasonably necessary or desirable for clinical or regulatory filings, reports, or submissions required by Applicable Law.

(e) Right to Manufacture and Escrow.

(i) In the event that either Party (1) experiences a Bankruptcy Event (as defined in Section 12(o)); or (2) ceases to do business, that Party (the “Nonperforming Party”) shall immediately notify the other Party hereof in writing.

(ii) In order for the other Party to continue to Develop, and/or Commercialize the CLS/MRI Products and/or New Products in any of the situations detailed in Section 2(e)(i), the Nonperforming Party shall take all actions reasonably necessary to allow the other Party to take possession of, manufacture, or have manufactured such Products until such time as the other Party determines in good faith that the Nonperforming Party is able to meet its obligations under this Agreement and any applicable SOW (the “Step-In Term”). Without limiting the foregoing, the Nonperforming Party will allow the other Party to take possession of necessary related materials, including but not limited to Know How, source code, encryption keys, administrative passwords, configurations, software, interfaces, documentation, manufacturing specifications, and supplier lists (collectively, “Materials”). The Nonperforming Party will use commercially reasonable efforts to assign, transfer, or subcontract to the other Party or its designee, at the other Party’s option, any third-party agreements that are needed to take possession of, manufacture or have manufactured, Develop, and/or Commercialize the CLS/MRI Products and/or New Products. In the event CLS is the Nonperforming Party, CLS shall grant to MRI any rights necessary for MRI to use any applicable 510(k) necessary for MRI to continue the Commercialization of the CLS Products and/or New Products in the Field.

(iii) At any time prior to the initiation of Commercialization of a fully developed New Product, the Parties shall enter into a three-party escrow agreement for the escrow of the Materials (“Escrow Agreement”) in an SOW or other written agreement. The Parties shall negotiate the terms and conditions of such an Escrow Agreement in good faith with an escrow agent mutually selected by the Parties (“Escrow Agent”); provided, that the Parties agree that access to the Materials shall be permitted by the Escrow Agent to either Party upon written certification by such Party to the Escrow Agent that any of the events described in Sections 2(e)(i)(1)-(2) has occurred in relation to the Nonperforming Party (each, a “Release Event”). Upon the Escrow Agent’s receipt of such a notice that a Release Event is at hand, the Escrow Agent shall inform the Nonperforming Party thereof and allow the Nonperforming Party a five (5) business days period to evidence that no Release Event exists. If, after such period, a Release Event is at hand, the Materials shall be released by the Escrow Agent and the Party to which the Materials are released shall have a worldwide, royalty-free, non-exclusive license to use and maintain the Materials for its business purposes and in accordance with the licenses

granted hereunder for the duration of the Step-In Term. In case of a Release Event, the Party receiving the Materials shall compensate the Nonperforming Party for its use of the Materials in accordance with the commercial terms set out in this Agreement (subject to deduction for the Party's reasonable manufacturing costs) or as otherwise applied between the Parties according to agreed SOWs.

(iv) Without limiting the foregoing, the Parties may agree in writing that MRI shall be entitled to manufacture the CLS Products and New Products through a third party subcontractor or at a facility owned or operated by MRI; provided, that in no event shall MRI manufacture CLS Products or New Products without the prior written consent of CLS and the prior agreement between the Parties on the commercial terms and conditions to apply for such manufacturing (including but not limited to the license fee or other compensation due to CLS for CLS Products and New Products manufactured by MRI). In connection with such a consent from CLS to manufacture under this Section 2(e) (iv), CLS shall grant MRI such rights as may be reasonably necessary for MRI to manufacture and Commercialize the CLS Products and/or New Products in the Field. CLS shall in such event also give MRI access to relevant parts of the Materials, as needed for such manufacture.

(f) Support. In addition to the warranties set forth in this Agreement, CLS agrees to (i) provide all reasonable support requested by MRI for the CLS Products; (ii) provide, at no additional charge, when and if generally available to CLS's customers, any updates, improvements, or enhancements to the CLS Products; (iii) without undue delay respond to any reasonable support requests from MRI, and (iv) without undue delay correct or provide a work around acceptable to CLS for any errors in the CLS Products. For the avoidance of doubt, MRI shall be solely responsible for the handling of all first line service and support communications in relation to customers acquiring CLS Products or New Products for use in the Field from MRI hereunder.

3. GOVERNANCE.

(a) Joint Steering Committee. The Parties will form a joint steering committee, which will be responsible for the oversight of the development and implementation of Development of New Products in accordance with the terms of this Agreement ("Joint Steering Committee" or "JSC"). The Joint Steering Committee shall, among other things, (i) assist in the management of the development, implementation, optimization and coordination of the New Products; (ii) review, and provide comment on SOWs; (iii) provide single-point communication for seeking consensus within both Parties' organizations regarding the Development, testing and Commercialization of the New Products and any other significant activities relating to this Agreement; and (iv) address business disputes between the Parties, and (v) monitor the progress of and facilitate changes to the Development of New Products as industry requirements and the Parties' interests evolve over time. The Parties acknowledge and agree that the Joint Steering Committee shall not have the power to amend any of the terms or conditions of this Agreement or to bind either Party with respect to any obligations not expressly provided in this Agreement or in any SOW. This Agreement shall not be amended except pursuant to Section 12(f). The JSC shall be composed of four (4) members — two (2) CLS executives or Personnel appointed by CLS, and two (2) MRI executives or Personnel appointed by MRI (collectively, the "JSC Members"); provided, however, that in the event a

member appointed by a Party shall not be in attendance at any meeting, the other member appointed by that same Party shall have full authority to vote for both such members. The initial JSC Members are as set forth on Exhibit C to this Agreement. The removal of any JSC Member may be effected only by the Party entitled to appoint such JSC Member. Any vacancy on the Joint Steering Committee may be filled only by the Party entitled to appoint such JSC Member.

(b) Meetings. The Joint Steering Committee shall hold meetings regularly during the performance of work or Development under this Agreement or any other SOW at times, dates, and locations to be mutually agreed upon by the JSC Members. Notwithstanding the foregoing, during the pendency of any New Product Development, the Parties shall hold meetings no less than bi-weekly unless otherwise mutually agreed upon by the Parties. In addition, meetings of the Joint Steering Committee may be called by any two of the JSC members, at any time upon written notice delivered to the other JSC members at least fourteen (14) days prior to the proposed meeting date. Joint Steering Committee meetings may be held, and individual JSC Members may attend, in person, by audio or video teleconference or similar communications equipment by means of which all persons participating in the meeting can hear each other. Each Party shall be responsible for all of its own expenses in participating in any Joint Steering Committee meetings.

4. INTELLECTUAL PROPERTY.

(a) License to MRI to CLS IP. CLS hereby grants to MRI and its Affiliate(s), a limited, fully-paid up, exclusive, perpetual, worldwide, irrevocable (unless this Agreement is terminated for breach), non-transferable (except as permitted in this Agreement) right and license to access, modify, create derivative works of, enhance, improve, and otherwise use the CLS IP solely in connection with the (i) Commercialization of existing CLS Products in the Field in accordance with Section 2; and (ii) the Development and Commercialization by MRI of any New Products in the Field; provided, however, that MRI shall not sublicense its rights hereunder without CLS' prior written consent, except for non-exclusive sublicenses granted to MRI's customers in the ordinary course of business, and any permitted sublicense under this Section 4(a) shall be on terms no less protective of the CLS IP than those set forth herein. Except for the rights granted in this Section 4, no other right in the CLS IP is conveyed, transferred, assigned or licensed to MRI or any other person or entity, including by way of any implied license and CLS retains all right, title and interest therein.

(b) CLS Patents. With respect to any and all CLS Patents included in the CLS IP, the licensed rights set forth above in Section 4(a), solely with respect to any subject matter or claims expressly covered by the CLS Patents, shall terminate on the date on which the last of any CLS Patents (or valid claims thereunder) expires or is held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having been expired. For the avoidance of doubt, to the extent any right in any CLS Patent expires or terminates in accordance with the terms set forth in this Section 4(b), the license to any related Know-How proprietary to CLS shall survive such termination or expiration.

(c) Newly Developed IP. Unless otherwise agreed in the related SOW, the Parties will jointly own all right, title, and interest in and to all Newly Developed IP, without any obligation to make any payments of any kind to the other Party with respect to the Newly Developed IP,

including, without limitation, revenue splits, royalties and commissions, or other accounting; provided, that (i) MRI shall have the exclusive right in accordance with Section 2(b) to use, exploit, or Commercialize any Newly Developed IP in the Field and, (ii) CLS shall have the exclusive right during the term of this Agreement, to use, exploit, or Commercialize any Newly Developed IP outside of the Field. The SOW for each New Product shall set forth the rights and restrictions of each Party as it relates to the jointly-owned Newly Developed IP. Each Party agrees, upon the reasonable request of the other Party, during or after the term of this Agreement, to take such further acts as may be reasonably necessary or desirable to reflect and establish the joint ownership of and other rights with respect to any Newly Developed IP, including but not limited to entering into applicable cross license.

(d) Exclusivity. The Parties agree that the licenses set forth above in Section 4(a) and Section 4(b) shall be exclusive to MRI as between (i) MRI and any third party, and (ii) MRI and CLS, in the Field. For avoidance of doubt, except as necessary to perform its activities under this Agreement, CLS shall have no right to use, license, sell, offer for sale, Commercialize or exploit the CLS IP within the Field or grant any third party the foregoing rights in the Field without the prior written consent of MRI. For the avoidance of doubt, the foregoing will not prevent CLS from marketing and selling CLS Products or New Products to customers outside the Field, or to customers using the CLS Products or New Products for general applications, including customers who use CLS Products or New Products for multiple applications (such as general sales to radiology departments); provided, that in no event shall CLS Commercialize any software or Applicators specifically designed for or intended to facilitate the use of the CLS Products or New Products in the Field.

(e) License to CLS to MRI IP. MRI hereby grants to CLS and its Affiliates a limited, fully-paid up, non-exclusive, perpetual, worldwide, non-transferable (except as permitted in this Agreement), irrevocable (unless the Agreement is terminated for breach) right and license to access, modify, create derivative works of, enhance, improve, and otherwise use the MRI IP solely in connection with the Development by CLS of any New Products; provided, however, that CLS shall not sublicense its rights hereunder without MRI's prior written consent and any permitted sublicense granted by CLS under this Section (e) shall be on terms no less protective of the MRI IP than those set forth herein. Except for the rights granted in this Section 4(e), no other right in the MRI IP is conveyed, transferred, assigned or licensed to CLS or any other person or entity, including by way of any implied license and MRI retains all right, title and interest therein.

(f) MRI Patents. With respect to any and all MRI Patents included in the MRI IP, the licensed rights set forth above in Section 4(e), solely with respect to any subject matter or claims expressly covered by the MRI Patents, shall terminate on the date on which the last of any MRI Patents (or valid claims thereunder) expires or is held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having been expired. For the avoidance of doubt, to the extent any right in any MRI Patent expires or terminates in accordance with the terms set forth in this Section 4(f), the license to any related Know-How proprietary to MRI shall survive such termination or expiration.

(g) Trade Secrets. Pursuant to the Defend Trade Secrets Act of 2016, the Parties acknowledge and understand, and shall cause any Personnel to acknowledge and understand, that:

(i) an individual may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding.

(ii) Further, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secrets to the attorney and use the trade secret information in the court proceeding if the individual: (a) files any document containing the trade secret under seal; and (b) does not disclose the trade secret, except pursuant to court order.

(h) Intellectual Property Prosecution and Enforcement. Each Party is responsible for all costs associated with the Intellectual Property it solely owns. With respect to Intellectual Property solely owned by a Party, such Party shall have sole discretion to decide whether to file for protection, the countries in which it will file for protection, the content of such filings, the conduct of the prosecution of such filings, and whether to enforce or maintain such protection. With respect to jointly owned Newly Developed IP, except as set forth in an SOW, the Parties jointly will prepare, file, prosecute and maintain any applications or registrations for Intellectual Property associated therewith, provided, that each Party shall provide the other Party with all reasonable assistance and cooperation, including the preparation and filing of any assignments, terminal disclaimers and other documents, required to procure, preserve and the protections for all Newly Developed IP under the U.S. Patent Act and the patent laws of any other country or jurisdiction, as applicable. The Parties will share the costs for such measures. The Parties shall promptly notify the other in writing of any alleged or threatened infringement of any Intellectual Property of the other Party or Newly Developed IP of which they become aware. The Parties shall reasonably cooperate in bringing any enforcement action against any third-party infringer of the New Products and any Newly Developed IP and as set forth in the SOW. Should the Parties not agree on what legal measures to be taken with respect to such enforcement actions, MRI shall have the sole power of decision and bear its costs with respect to enforcement actions in the Field and CLS shall have the sole power of decision and bear its costs with respect to enforcement actions outside the Field. The other Party shall then cooperate, at its own expense, in such enforcement action(s), including without limitation, by executing such documents and providing such assistance as reasonably deemed necessary by the defending Party in connection with any action(s) taken against such infringement.

5. CONFIDENTIALITY.

(a) Obligations. Each Recipient shall: (i) maintain Discloser's Confidential Information in confidence during the term of this Agreement and for a period of five (5) years thereafter, provided that any Confidential Information that comprises a trade secret shall be maintained in confidence in perpetuity until such trade secret ceases to constitute a trade secret within the meaning of any Applicable Law related to such trade secret, so long the reason such trade secret no longer so constitutes is not due the breach of confidentiality by Recipient or its Personnel (or any person or entity to which such Party may have provided access to such trade secret), or due to any violation of law (e.g. hacking of computer systems); (ii) limit dissemination

to those of its Personnel who reasonably require use or access to such Confidential Information in order to perform under this Agreement; (iii) not disclose such Confidential Information to any other person or entity (other than Affiliates); and (iv) use such Confidential Information only to the extent necessary to perform this Agreement. The Parties may establish by written agreement additional procedures and requirements with respect to the treatment of Confidential Information, including the establishment of different clearance levels for Personnel having access to Confidential Information, classification and marking of Confidential Information based on level of sensitivity (e.g. Confidential, Highly Confidential, etc.), and the storage and transfer of Confidential Information by and between the Parties and their Personnel. If Recipient is compelled to disclose any Confidential Information of Discloser by order of a court of competent jurisdiction, any such disclosure will not be a breach of this Agreement; provided, that Recipient first gives Discloser prompt written notice of such required disclosure in order to permit Discloser to seek all applicable governmental or judicial protection available. Notwithstanding the foregoing to the contrary, each Party shall also have the right to share copies of this Agreement (as it may be redacted to protect any commercially sensitive information) as part of any due diligence data room established by such Party.

(b) Publicity. Except as expressly provided in this Agreement or as required under applicable stock exchange regulations for any of the Parties, any proposed publication, communication or presentation of information related to this Agreement, by a Party, shall be subject to prior written approval by the other Party, which may, in its sole discretion, provide approval in writing. In the absence of such written notice of approval, authorization is not considered to be given.

6. TERM AND TERMINATION.

(a) Term. This Agreement shall commence on the Effective Date and shall continue unless terminated pursuant to Section 2(c)(ii), Section 6(b) or Section 7(c).

(b) Termination.

(i) This Agreement may be terminated upon written notice by either Party if the other Party is in material breach of its obligations hereunder and has not cured such breach or shown such breach to be non-existent within thirty (30) days after notice requesting cure of the breach.

(ii) This Agreement may be terminated upon written notice immediately by either Party upon a Bankruptcy Event of the other Party; provided that, notwithstanding a termination pursuant to this Section 6(b)(ii), Sections 2(e) and 12(o) shall survive and the terminating Party may exercise its rights under Sections 2(e) and 12(o).

(c) Effect of Termination; Survival. Within thirty (30) days after termination or expiration of this Agreement, each Party shall return or destroy all Confidential Information of the other Party then in its possession, and each Party shall certify in writing that all such Confidential Information has been returned or destroyed. To the extent that any such Confidential Information cannot be returned or destroyed using commercially reasonable efforts, or if any such Confidential Information is required to be retained following the expiration or termination of this Agreement

(such as pursuant to any “litigation hold” letter), any such Confidential Information shall maintained in confidence in accordance with Section 5 until it has ceased to constitute Confidential Information. Notwithstanding the foregoing or anything contained herein, neither Party shall be required to destroy or alter any computer or network archival and backup tapes, or archival and backup files (collectively, “Archives”), provided that such Archives shall be kept confidential in accordance with the terms of this Agreement. Upon expiration or termination of this Agreement for any reason, including any termination for breach by the other Party, all provisions of this Agreement that, by their nature should survive such termination or expiration to retain their meaning and significance, shall survive. Without limiting the foregoing and unless terminated pursuant to Section 2(c)(ii), Section 6(b) or Section 7(c), the following Sections of this Agreement shall survive and remain binding on the Parties following any expiration or termination of this Agreement: Section 1 (Definitions); Section 2(e) (Right to Manufacture and Escrow); Section 4(a), (b), (c), (d), (e) (f)-(h)(Intellectual Property); Section 5 (Confidentiality); this Section 6(c) (Effect of Termination; Survival); Section 8 (Representations and Warranties); Section 9 (Indemnification); Section 10 (Limitation of Liability); and Section 12 (Miscellaneous).

7. COMPENSATION, MINIMUM VOLUMES AND MARKETING SAMPLES.

(a) Subject to the terms and conditions of this Agreement, in consideration of the rights and licenses granted herein, MRI shall pay to CLS the following payments:

(i) For each Applicator purchased by MRI, MRI shall pay the prices set forth herein; provided, that in the event changes in market conditions substantially impact the pricing or availability of Applicators in the Field, the Parties agree to renegotiate in good faith to reduce the prices set forth in this Section 7(a)(i):

- (1) from the Effective Date until December 31, 2021, \$*** per unit;
- (2) from January 1, 2022 to December 31, 2025, \$*** per unit; and
- (3) after January 1, 2026, \$*** per unit.

(ii) For each CLS System or a subsequent hardware/software system indicated for use in the Field and manufactured by or on behalf of CLS for MRI, MRI shall pay \$*** per unit.

(b) MRI shall provide CLS with a non-binding twelve month rolling forecast plan, updated monthly, outlining MRI’s volume forecasts for Applicators and New Products covered by this Agreement (the “Forecast”). The Forecast is an estimate only and is not a firm commitment on the part of MRI to purchase the quantities stated therein or any quantity, provided, however, that CLS may plan production and invoice MRI for the rolling next three (3) month’s estimate in the Forecast (the “Three Month Binding Forecast”).

(c) Provided that MRI does not experience any interruption to product usage in the market (i.e. due to backorder in supply from CLS or CLS’s act or omission, regulatory recall or intellectual property claim), MRI commits to purchasing from CLS for sale within the Field the

following minimum number of Applicators (the “Minimum Volumes”) after market launch date of the first commercially viable Applicators hereunder (such market launch date to be agreed between the Parties) and, if such Minimum Volumes are not met by MRI, CLS shall be entitled to notify MRI in writing of breach of contract at which point MRI has thirty (30) days to cure and, failing such cure, CLS shall be entitled to terminate this Agreement by providing written notice to MRI within ten (10) days after the expiration of the thirty (30) day cure period.

The following Minimum Volumes shall apply;

- *** Applicators during the 12 month period from 0 to 12 from market launch date
- *** Applicators during the 12 month period from 13 to 24 from market launch date
- *** Applicators during the 12 month period from 25 to 36 from market launch date
- *** Applicators during the 12 month period from 37 to 48 from market launch date
- *** Applicators during the 12 month period from 48 to 60 from market launch date

In no event less than six months prior to 60 months from the market launch date, the Parties shall negotiate in good faith the Minimum Volumes and prices for the Applicators to apply for each 12-month period from such 60 months and onwards during the coming 60-month period; provided, that in no event will the re-negotiated Minimum Volumes exceed ***% of the reasonably estimated market volume for procedures in the Field and in no event will the re-negotiated prices have as effect that CLS’s gross margin for the sale of Applicators to MRI will exceed ***% or fall below ***%. If, despite such good faith negotiations, the Parties are unable to agree on such continued Minimum Volumes or prices for Applicators for the coming 60-month period, either Party shall be entitled to terminate this Agreement in writing with not less than twelve (12) months’ written notice. This procedure shall further be repeated for any future 60-month period following thereafter.

It is expressly agreed by the Parties that commercially viable Applicators ready for market launch will include at a minimum, (i) FDA cleared Neuro Applicators and CLS System, (ii) mutually agreed upon lure fittings to ensure compatibility between CLS and MRI SmartFrame disposable components, (iii) thermometry software including essential neuro specific features as outlined in first SOW due by December 31st, 2018 and (iv) peel-away sheath component as detailed by second SOW due by December 31st 2018.

(d) Notwithstanding the foregoing, CLS shall provide up to *** units of the Applicators to MRI per calendar year at CLS’s actual cost to be used solely for demonstration and marketing purposes. CLS shall also provide *** (***) CLS Systems to MRI at CLS’s actual cost for the following purposes:

- (i) *** (***) as demonstration units for MRI’s territory managers;
- (ii) *** (***) for MRI’s marketing department for tradeshow and training courses; and
- (iii) *** (***) for placement, at sites agreed between the Parties, into key opinion leader accounts or show sites for clinical work and feedback.

(e) CLS further agrees that, from market launch date according to the above, to keep a minimum of three (3) months of consignment inventory of Applicators on site at MRI facility in Irvine (or another US location of MRI's choice) to ensure any disruption to supply can be mitigated with that extra three months of time. The Parties will base the level of consignment inventory on MRI's Three Month Binding Forecast.

(f) MRI shall pay CLS the undisputed fees set forth herein in full and complete consideration for the rights granted hereunder. All fees shall be payable within thirty (30) days from the date specified herein or any applicable SOW after receipt of invoice therefor from CLS.

8. REPRESENTATIONS AND WARRANTIES.

- (a) Mutual Representations and Warranties. Each Party represents and warrants to the other Party that:
- (i) it has the full right, power, and authority to enter into this Agreement and to perform its obligations hereunder;
 - (ii) it has all necessary regulatory approvals, permits, or licenses necessary for the purposes contemplated under this Agreement, including having a valid 510(k) for the Commercialization by MRI of CLS Products and New Products prior to any Commercial launch;
 - (iii) this Agreement has been duly executed by it and is legally binding upon it, is enforceable in accordance with its terms, and does not conflict with any agreement, instrument, or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any material law or regulation of any court, governmental body, or administrative or other agency having jurisdiction over it;
 - (iv) it shall perform its obligations described in this Agreement in a timely and professional manner; and
 - (v) it shall comply with all Applicable Laws related to this Agreement and the New Products, including the submission of any regulatory filings required by Applicable Law.
 - (vi) it has valid legal and/or beneficial title under the CLS/MRI IP and CLS/MRI Products for the purposes contemplated under this Agreement and to grant the licenses or assignment of rights (as the case may be) contained in this Agreement;
 - (vii) it has not received any material written communications alleging that the CLS/MRI IP, the CLS/MRI Products, or the conduct of the Parties as currently proposed under this Agreement would violate any of the Intellectual Property rights of a third party;
 - (viii) during the term of this Agreement, it will not to diminish, alter or impair its rights under the CLS/MRI IP or the CLS/MRI Products;

- (ix) such Party has not intentionally withheld any prior art or unreasonably withheld noncumulative information material to the patentability of the CLS/MRI Patents from the U.S. Patent and Trademark Office; and
- (x) any warranties offered with respect to the CLS/MRI Products as of the Effective Date shall apply with equal force to any CLS/MRI Products to the extent incorporated into, integrated with, or combined with any New Products.

(b) Disclaimer. Except as expressly set forth in this Section 8 of this Agreement, neither Party makes any warranties, express or implied, either in fact or by operation of law, by statute, or otherwise, with respect to the New Products or the licenses or rights granted under this Agreement. Each Party further acknowledges that any Intellectual Property as provided by the other Party (including any data included therein), respectively, is provided or made available “as is” and without any warranty as to completeness or accuracy, and that any samples, parts, prototypes, work in process, or other products or materials provided by the other Party have not been tested and that each Party assumes all risk with respect to the use thereof by such Party’s Personnel, including any injury to person or damage to property that may result therefrom.

9. INDEMNIFICATION.

(a) Indemnification by MRI. MRI agrees to indemnify, defend, and hold harmless CLS, its Affiliates, and their respective officers, directors, Personnel, and agents (collectively, the “CLS Indemnitees”) from and against any and all third-party claims, suits, actions, demands, damages, and liabilities, including reasonable legal costs and fees to which any CLS Indemnitee may become subject to as a result of any claim, demand, action, or other proceeding by any third party (each, a “Claim”) to the extent such Claim arises out of (i) any allegation that the MRI IP infringes, misappropriates, or otherwise violates the Intellectual Property, proprietary, or other rights of any third party; (ii) the use of the MRI Products; or (iii) MRI’s gross negligence, fraud, or willful misconduct, or violation of Applicable law.

(b) Indemnification by CLS. CLS agrees to indemnify, defend, and hold harmless MRI, its Affiliates, and their respective officers, directors, Personnel, and agents (collectively, the “MRI Indemnitees”) from and against any and all third-party claims, suits, actions, demands, damages, and liabilities, including reasonable legal costs and fees to which any MRI Indemnitee may become subject to as a result of any Claim to the extent such Claim arises out of: (i) any allegation that the CLS IP infringes, misappropriates, or otherwise violates the Intellectual Property, proprietary, or other rights of any third party; (ii) the use of the CLS Products; or (iii) CLS’s gross negligence, fraud, or willful misconduct, or violation of Applicable law.

(c) Indemnification Process. The Party seeking indemnification (the “Indemnified Party”) shall provide prompt written notice of any Claim to the indemnifying Party (the “Indemnifying Party”); provided, however, that failure to give prompt notice shall not affect the Indemnifying Party’s obligations under this Section 9 unless and to the extent that the failure materially prejudices the defense of the matter. The Indemnified Party shall cooperate with the Indemnifying Party in all reasonable respects, and at the Indemnifying Party’s expense, in connection with the investigation and defense of any such Claim. The Indemnifying Party shall have sole control of the defense of any action on any such Claim and all negotiations for its

settlement or compromise; provided, that the Indemnified Party, at its sole cost and expense, shall have the right to engage its own legal counsel, and if such settlement or compromise would (i) impose any costs, obligations, or limitations on the Indemnified Party, or (ii) admit fault by the Indemnified Party, then the Indemnifying Party shall not settle or compromise the Claim without the Indemnified Party's prior written consent.

10. LIMITATION OF LIABILITY.

(a) Limitations. Except to the extent arising out of (i) a Party's indemnification obligations under Section 9, (ii) a Party's breach of its confidentiality obligations under Section 5, (iii) a Party's gross negligence, fraud, or willful misconduct, or (iv) a Party's breach of any exclusivity provisions in the Agreement, including the obligations and rights granted in Sections 2(b), 4(a), and 4(d), neither Party nor its Affiliates will be liable under any contract, negligence, strict liability, product liability or other legal or equitable theory for any indirect, incidental, consequential, multiple, special or punitive damages or loss of profits or revenues, whether arising out of breach of contract, tort (including negligence) or otherwise (including the entry into, performance, or breach of this Agreement), regardless of whether such loss or damage was foreseeable or the Party against whom such liability is claimed has been advised of the possibility of such loss or damage, and notwithstanding the failure of any agreed or other remedy of its essential purpose.

(b) Liability cap. With the exception of the cases stated in Section 10(a)(i)-(iv), each Party's total cumulative liability to the other Party will not exceed the greater of: (a) an amount equal to 100% of the total amounts payable by MRI to CLS under this Agreement; and (b) 1,000,000 USD (one million US dollars).

11. DISCUSSIONS REGARDING A CLOSER COMMERCIAL COLLABORATION.

The Parties agree to discuss and evaluate the possibilities of additional collaboration opportunities. The Parties agree to use good faith efforts to conclude any such discussions by December 31, 2018, unless otherwise agreed by the Parties.

12. MISCELLANEOUS PROVISIONS.

(a) Assignment. Neither Party may assign or otherwise transfer this Agreement, directly or indirectly, including by operation of law, or otherwise, or any of its rights or obligations, without the prior written consent of the other Party; provided, that a Party may assign or transfer this Agreement without consent pursuant to a change of control or in connection with a merger or the sale of all or substantially all of its business or assets, however structured. Any assignment or transfer in violation of this Agreement will be null and void. This Agreement shall be binding upon and inure to the benefit of the Parties' successors and permitted assigns.

(b) Entire Agreement. This Agreement and any exhibits hereto constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all prior discussions, understandings, negotiations, representations, or commitments, whether written or oral.

(c) Governing Law; WAIVER OF JURY TRIAL. This Agreement is governed in accordance with the laws of the State of New York, without giving effect to any choice of law rules that may direct the application of the laws of any other jurisdiction. The Parties agree to bring any claims, controversies, or disputes arising from or related to this Agreement exclusively in the state and federal courts sitting in New York, New York, and the Parties hereby expressly agree to submit to the exclusive venue and jurisdiction of such courts. The Parties agree and acknowledge that the United Nations Convention on Contracts for the International Sale of Goods (CISG) shall not apply. EACH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY FOR ANY COURT PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY FOR WHICH A PARTY MAY BRING SUCH A COURT PROCEEDING.

(d) Equitable Relief. In any claim for equitable relief, each Party acknowledges that a breach by the other Party of this Agreement, including Section 2 or 5, may cause the non-breaching Party irreparable harm, for which an award of damages would not be adequate compensation and, in the event of such a breach or threatened breach, the non-breaching Party shall be entitled to seek equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance, and any other relief that may be available from any court, and the Parties hereby waive any requirement for the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

(e) Waiver; Discharge. The failure of any Party to enforce at any time any of the provisions of this Agreement shall not, absent an express written waiver signed by the authorized representative of the Party making such waiver specifying the provision being waived, be construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any part thereof or the right of the Party thereafter to enforce each and every such provision. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

(f) Amendment. This Agreement may not be amended, by course of conduct or otherwise, except pursuant to a written amendment that expressly refers to this Agreement and this Section 12(f) and signed by the authorized representatives of each of the Parties.

(g) Notices. All notices or other communications to a Party required or permitted hereunder shall be in writing and shall be delivered personally or shall be sent by a reputable express delivery service or by certified mail, postage prepaid with return receipt requested, addressed as follows:

To MRI:
Chief Executive Officer
MRI Interventions, Inc.
5 Musick
Irvine, CA 92618

To CLS:
Chief Executive Officer
Clinical Laserthermia Systems AB
Medicon Village | Scheelevägen 2
SE-223 81 Lund, Sweden

(h) Expenses. Except as expressly provided herein, each Party shall pay its own expenses incident to this Agreement and the preparation for, and consummation of, the transactions provided for in this Agreement.

(i) Titles and Headings: Construction. The titles and headings to Sections of this Agreement are inserted for the convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. This Agreement shall be construed without regard to any presumption or other rule requiring construction hereof against the Party causing this Agreement to be drafted.

(j) Severability. If any provision of this Agreement is held invalid, illegal, or unenforceable, such provision shall be enforced to the maximum extent permissible, and the remaining provisions shall nonetheless be enforceable according to their terms.

(k) Relationship. This Agreement does not make either Party the employee, agent, or legal representative of the other for any purpose whatsoever. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party. In fulfilling its obligations pursuant to this Agreement, each Party shall be acting as an independent contractor, and no partnership, joint venture or other similar relationship, or any fiduciary duty or other similar duty relating to any such relationship, shall be implied as to apply between the Parties or their respect Personnel.

(l) Benefit. Nothing in this Agreement, expressed or implied, is intended to confer on any person other than the Parties to this Agreement or their respective successors or permitted assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement.

(m) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed as original and all of which together shall constitute one instrument. A signed copy of this Agreement delivered by facsimile, e-mail, or other means of electronic transmission (to which a PDF copy is attached) shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

(n) Execution of Further Documents. Each Party agrees to execute and deliver without further consideration any further applications, licenses, assignments, or other documents, and to perform such other lawful acts as the other Party may reasonably request to fully secure or evidence the rights or interests herein.

(o) Bankruptcy. The Parties acknowledge and agree that the Intellectual Property licensed hereunder is “intellectual property” as defined in Section 101(35A) of the Bankruptcy Code, which have been licensed hereunder in a contemporaneous exchange for value. The Parties further acknowledge and agree that if a Party or any of its permitted successors or assigns: (i) becomes insolvent or generally fails to pay, or admits in writing its inability to pay, its debts as

they become due; (ii) applies for, or consents to, the appointment of a trustee, receiver or other custodian for it, or makes a general assignment for the benefit of its creditors; (iii) commences, or has commenced against it, any bankruptcy, reorganization, debt arrangement, or other case or proceeding under any bankruptcy or insolvency law, or any dissolution or liquidation proceedings; or (iv) elects to reject, or a trustee on behalf of it elects to reject, this Agreement or any agreement supplementary hereto, pursuant to Section 365 of the Bankruptcy Code, or if this Agreement or any agreement supplementary hereto is deemed to be rejected pursuant to Section 365 of the Bankruptcy Code for any reason (each a "Bankruptcy Event"), then this Agreement, and any agreement supplementary hereto, shall be governed by Section 365(n) of the Bankruptcy Code and the licensee Party will retain and may elect to fully exercise its rights under this Agreement in accordance with Section 365(n) of the Bankruptcy Code.

[Remainder of page intentionally left blank; signature page(s) follow]

IN WITNESS WHEREOF, each of the Parties has caused this LICENSE AND COLLABORATION AGREEMENT to be executed by their duly authorized representatives as of the Effective Date.

MRI INTERVENTIONS, INC.

By: /s/ Joseph Burnett

Name: Joseph Burnett

Title: President & CEO

CLINICAL LASERTHERMIA SYSTEMS AB

By: /s/ Lars-Erik T. Eriksson

Name: Lars-Erik T. Eriksson

Title: CEO

ATTACHMENTS:

EXHIBIT A: CLS PATENTS AND PATENT APPLICATIONS

EXHIBIT B: MRI PATENTS AND PATENT APPLICATIONS

EXHIBIT C: JSC Members

EXHIBIT A
CLS PATENTS AND PATENT APPLICATIONS

EXHIBIT B
MRI PATENTS AND PATENT APPLICATIONS

EXHIBIT C
JSC MEMBERS

Members appointed by MRI:

Joe Burnett – President And CEO
Pete Piferi – Chief Operating Officer

Members appointed by CLS:

Lars-Erik Eriksson, CEO
Dan Mogren, Chief Commercial Officer

*** Indicates portions of this exhibit that have been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

CLINICAL LASERTHERMIA SYSTEMS AB

AND

MRI INTERVENTIONS INC

DISTRIBUTION AGREEMENT

[10-16-2018]

DISTRIBUTION AGREEMENT

This agreement (this “**Agreement**”) is effective as of October 16, 2018 (the “Effective Date”) and is made

BETWEEN:

- (1) **Clinical Laserthermia Systems AB**, Reg. No. 556705-8903, a company duly incorporated and organized under the laws of Sweden, having its registered address at Medicon Village, Scheelevagen 2, SE-223 81 Lund, Sweden (“**CLS**”); and
- (2) **MRI Interventions Inc**, File No. 2870717, a company duly incorporated and organised under the laws of Delaware, having its registered address at 5 Musick Irvine, CA 92618 (the “**Distributor**” or “**MRI**”).

WHEREAS:

- (A) CLS is engaged in the research and development of minimally invasive methods for cancer treatment and manufactures the products listed in Exhibit B (the “**Products**”);
- (B) CLS desires to appoint the Distributor as the exclusive distributor for the Products in use applications within “Interventional MRI” exclusive of use indications within neuro (brain and spine) (the “**Non-Neuro Field**”) in the Territory (as defined below).

IT IS AGREED as follows:

1 Definitions

1.1 In this Agreement, the following definitions are used:

“**Agreement**” means this Agreement, including all the appendices and schedules attached to it;

“**Confidential Information**” as defined in Section 20.2;

“**Customers**” shall mean customers for the Products within the Territory;

“**Parties**” means CLS and the Distributor, collectively, and “**Party**” means CLS or the Distributor;

“**Products**” means CLS’s products listed in Exhibit B; and

“**Territory**” means United States of America and Canada.

2 Grant

2.1 CLS hereby grants to the Distributor the exclusive right to market and sell the Products in the Territory in accordance with and subject to the terms and conditions of this Agreement for use in the Non-Neuro Field.

2.2 Notwithstanding the foregoing, CLS reserves the right, without incurring any liability or obligation to the Distributor, to discontinue at any time the sale of certain Products, by amending Exhibit B; provided, that such amendments of Exhibit B shall, unless otherwise agreed by the parties, enter into force on the later of six (6) months from the Distributor having received the amended Exhibit or the fulfilment by Distributor of any orders for such Products entered into by Distributor prior to the receipt of the amended Exhibit B.

3 Legal Relationship

3.1 The Distributor shall buy the Products as an independent contractor and shall sell the Products in its own name, for its own account and on its own risk. Nothing in this Agreement will constitute or be deemed to constitute a partnership, an employment relationship or an agency.

3.2 For the avoidance of doubt, the Distributor shall be free to set its own prices for the Products in its sale of Products to Customers. CLS may from time to time supply the Distributor with a non-binding, indicative price list for the end-customer prices applied by CLS.

3.3 Neither Party shall have any authority to act on behalf of the other Party in any matter whatsoever, or to bind the other Party in any other way without the other Party's prior written consent. Neither Party will be liable or responsible for any acts or defaults of the other Party or the other Party's employees or contractors.

4 Activities Outside the Territory

4.1 The Distributor shall refrain from actively seeking customers for the Products, from establishing any branch active in the sale of the Products, and from maintaining any distribution depot for the Products, on markets outside the Territory.

4.2 The Distributor shall without delay forward all enquiries and orders from customers outside the Territory to CLS.

5 Non-competition

The Distributor or any of its subsidiaries, owners or managers shall during the term of this Agreement, neither directly nor indirectly without the prior written consent of CLS, market, sell or develop any products which are competing with any of the Products in the Non-Neuro Field in the Territory.

6 Information and Forecasts

6.1 The Distributor shall not later than 31 October each year, furnish CLS with a non-binding sales forecast containing the Distributor's estimated sales volumes during the subsequent calendar year. In addition hereto, the Distributor shall, one (1) month before the beginning of every calendar quarter, furnish CLS with a non-binding estimated sales forecast covering the relevant calendar quarter.

6.2 The Distributor shall keep CLS reasonably informed about planned direct marketing activities and shall on a quarterly basis provide CLS with a report concerning major developments in the market and upon written request provide CLS with mutually agreed upon statistical information and market data for the Territory. Unless prohibited by applicable law, the Distributor shall make commercially reasonable efforts to inform CLS about any material adverse changes that have occurred, in the Distributor's financial situation, ownership or management.

7 The Distributor's Marketing Activities

7.1 The Distributor shall use commercially reasonable efforts to carry out such direct marketing activities with respect to sales of the Products in the Territory. The costs related to direct promotion and sales activities shall be borne by the Distributor unless otherwise agreed by the Parties from time to time. For specification of commitments and fees for agreed services to CLS, see Exhibit A.

7.2 The Distributor shall maintain its own web site, on which the Products will be marketed in accordance with the reasonable, written instructions or marketing manuals provided from time to time from CLS to the Distributor.

7.3 CLS shall, to the extent requested by the Distributor in writing, provide the Distributor with reasonable quantities of brochures, catalogues and other sales promotion materials and marketing directives and services concerning the Products.

7.4 The Distributor shall discontinue any advertising or sales promotions to which CLS objects in writing based on objectively valid grounds that such promotions violate applicable law or otherwise is in conflict with CLS's own marketing of the Products.

7.5 The Distributor shall be solely responsible for determining that sales of the Products within the Territory are in conformity with applicable legislation and good marketing practises, and for obtaining all necessary related approvals, certifications and registrations. The Distributor accepts full responsibility for compliance with such regulations in relation to its third parties subcontractors, and shall indemnify, defend and hold harmless CLS from any claims, fines, penalties or damages that are raised against CLS by a third party due to any breach by the Distributor of applicable law, approvals, certifications or registrations.

8 The Distributor's Sales Efforts

8.1 The Distributor shall use commercially reasonable efforts to promote the sales of the Products within the Territory and shall establish and maintain a reasonably efficient and competent sales organisation in order to optimise the sales of the Products and to assure prompt handling of requests, orders and shipments. The Distributor shall further ensure that it employs a qualified demonstrator. For specification of commitments and fees for agreed services to CLS, see Exhibit A.

8.2 The Distributor shall use commercially reasonable efforts to maintain an up-to-date database of Customers and prospective Customers. A list of customers set forth in such database shall be provided to CLS upon CLS's written request, which request shall be made on no more frequent than once per calendar quarter. Any customer list provided

by Distributor is the trade secret and Confidential Information of Distributor. CLS may upon the prior written consent of Distributor contact a Customer or potential Customer in the event that negotiations between the Distributor and the Customer stall.

8.3 The Distributor shall purchase from CLS at least the following units of Products during the first two (2) years following the Effective Date (the "Minimum Purchase Target"):

Year 1: *** Applicators and *** Tranberg Mobile Laser Units

Year 2: *** Applicators and *** Tranberg Mobile Laser Units

The Minimum Purchase Target, and the Product prices, shall thereafter be negotiated annually. If the Parties are not able to agree on the quantities, the Minimum Purchase Target quantities for the relevant year shall correspond to either (i) the number of Products sold in the preceding year, or (ii) ***% of the Minimum Purchase Target for the preceding year, whichever is the highest.

8.4 Subject to Section 11.3, in the event that the Distributor does not reach its Minimum Purchase Target for either year set forth in Section 8.3, CLS may at its sole discretion, by giving ninety (90) days written notice, either terminate the Agreement or, convert forthwith the exclusive rights granted under this Agreement into non-exclusive rights.

9 Stock

9.1 The Distributor shall maintain a stock of the Products which is adequate to allow of prompt deliveries to Customers in the Territory.

9.2 The Distributor shall comply with and cause its contractors, transporters, storage contractors and all other persons involved in the storage or transportation of Products to comply with any and all reasonable instructions provided in advance in writing by CLS with respect to the conditions under which the Products are transported and/or stored and with respect to measures intended to prevent the deterioration and/or degeneration of Products.

10 Service

10.1 CLS agrees to (i) provide all reasonable support requested by MRI for the CLS Products; (ii) provide, when and if generally available to CLS's customers, any updates, improvements, or enhancements to the CLS Products; (iii) without undue delay respond to any reasonable support requests from MRI, and (iv) without undue delay correct or provide a workaround reasonably acceptable to Distributor for any errors in the CLS Products.

10.2 Without limiting the foregoing, MRI shall be responsible for initial handling of Product complaints. The Distributor shall promptly inform CLS of all complaints received concerning the Products. The Distributor shall use commercially reasonable efforts to follow up all complaints for the purpose of avoiding negative effects on the goodwill of CLS and the Products. The Parties shall cooperate in good faith with respect to any Product complaints. Where there is a requirement by law or regulations to inform or interact with the competent authorities, each Party is obliged to fulfil all such requirements applicable to such Party in relation to all services under this Agreement.

11 Orders and Supply

- 11.1 The Distributor shall order the Products in writing from CLS. No order is binding until CLS has confirmed an order. CLS will state the estimated delivery time in such confirmation. Notwithstanding the provisions in the Distributor's order, each contract of sale shall be subject to the terms and conditions contained in this Agreement.
- 11.2 The Distributor acknowledges that CLS's delivery capacity varies depending on, *inter alia*, the general market conditions, other orders received and CLS' suppliers' delivery capacity. As soon CLS has reason to assume that a delay in the agreed delivery could occur, CLS shall notify the Distributor thereof, and shall in such case be entitled to reasonable prolongation of the delivery date of up to three (3) months. Notwithstanding the foregoing, CLS shall however always endeavour to maintain a delivery capacity that enables CLS to deliver the Products in accordance with accepted orders.
- 11.3 To the extent that material delays in CLS's delivery capacity as set forth in Section 11.2 result in Distributor's inability to meet either of the Minimum Purchase Targets set forth in Section 8.3 for a specific year, CLS shall not have the right to either modify or terminate the Agreement as otherwise set forth in Section 8.4 for the year in question.

12 Prices and Payment

- 12.1 The Distributor shall purchase the Products at the prices set out in CLS's price list applicable at the time when CLS has received the order. CLS's price list as of the Effective Date appears on Exhibit B. CLS shall have the right to change the price list at no more than once per calendar year during the term of this Agreement by giving the Distributor ninety (90) days' prior written notice; provided, that, in no event shall any price increase specifically targeted towards the Territory exceed the greater of (a) five percent (5%); or (b) the change during the previous twelve (12) month period in the U.S. Consumer Price Index for all Urban Consumers. However, the above stated shall not affect CLS's right to undertake general price increases for the Products which are applied to CLS's customers in general. CLS shall further be entitled to adjust the prices due to fluctuations of more than five percent (5%) on the EUR/USD exchange rate.
- 12.2 Unless otherwise agreed in writing, the Distributor shall pay undisputed amounts for all Products under this Agreement net thirty (30) days from the date of CLS' invoice.
- 12.3 In the event that the Distributor at any time should fail to make payment in full on the due date CLS shall be entitled to claim interest on the sum overdue until payment is made at the rate of ten (10) per cent per annum. In such event of delayed payment, CLS shall further be entitled to withhold any deliveries of Products to the Distributor until payment has been made in full.

13 General Conditions of Delivery

- 13.1 Unless otherwise agreed in writing, the Products shall be delivered Ex Works from CLS's supplier (Incoterms 2010).

13.2 For each delivery from CLS, CLS's standard terms of sale, as applicable from time to time, shall apply. CLS shall inform the Distributor of such standard terms of sale in writing. CLS shall have the right to change the terms of sale at any time during the term of this Agreement by giving the Distributor thirty (30) days' written notice, provided that such changes are generally applied by CLS in relation to its customers. If the provisions of this Agreement should be in conflict with the terms of sale, the provisions of this Agreement shall prevail.

14 Acceptance

14.1 The Distributor shall immediately following each delivery of any Product inspect the Product in respect of any external damages and assure that the delivery is in accordance with the order. Defaults and defects which are detected at delivery shall immediately be reported in writing to CLS.

14.2 When a Product is unpacked and assembled by the Distributor, and in any event before the Product has been used or sold by the Distributor, the Distributor shall perform a full inspection of the Product if this was not possible on receipt of the Product. The obligation to report any defects to CLS as per Section 14.1 shall then apply.

14.3 At the request of CLS, the Distributor shall make defective goods available to CLS for inspection and control.

15 Liability for Defects

Without limiting any rights or obligations set forth in this Agreement, CLS's standard terms of sale may provide additional terms with respect to defects in the Products. In the event of any conflict between the terms of this Agreement and CLS's standard terms of sale, the terms of this Agreement shall control.

16 Trademarks and Other Intellectual Property Rights

16.1 All intellectual property rights and other rights, including without limitation patents, design rights, trademarks, copyright and know how, relating to the Products and any and all documentation related thereto shall at all times be the exclusive property of CLS.

16.2 Nothing in this Agreement shall constitute or be construed as a transfer of ownership of any of CLS's intellectual property rights or other rights or to otherwise give the Distributor any proprietary rights to CLS's intellectual property rights.

16.3 CLS hereby grants to the Distributor a royalty-free, exclusive (other than in relation to CLS), limited license to use CLS's trademarks within the Territory for marketing purposes for Products in the Non-Neuro Field only and in accordance with this Agreement. The Distributor is expressly forbidden to register any of CLS's trademarks or other intellectual property rights – either as the Distributor's trademark, firm or in any other respect – and all use of CLS's intellectual property rights shall inure to the benefit of CLS. The Distributor shall not use any other trademark in conjunction with CLS's trademarks, unless approved in writing by CLS. The Distributor has no right to use CLS's trademarks in its business name or for any other purpose than the marketing and sale of the Products.

- 16.4 Unless agreed to by the Parties in writing, the Distributor shall not remove or change any trademark, trade name, sign or other mark on any Products or its packaging or make any alterations in the construction or design of any Product.
- 16.5 The Distributor shall promptly notify CLS of any claim related to the actual, threatened or suspected infringement of CLS's patents, trademarks or other intellectual property rights or if it is alleged that the corresponding rights of others are being infringed due to the sale of the Products. CLS is not obliged to defend its intellectual property rights; provided, that to extent that any claim that CLS decides not to defend materially impacts or limits Distributor's rights under this Agreement, Distributor shall have the right to terminate this Agreement in whole or in part. If CLS chooses to defend its rights the Distributor undertakes to assist CLS as reasonably requested.
- 16.6 If a claim or suit in alleging infringement, misappropriation, or violation of a third party's intellectual property rights is brought or threatened against the Distributor due to its selling of the Products, CLS shall indemnify, defend and hold harmless the Distributor for the against any and all judgments, damages, and liabilities, including reasonable legal costs and fees to which Distributor may become subject to as a result of any such claim or; provided, that CLS has been notified immediately in writing of such claim, suit or proceeding and given reasonable information and assistance to settle the claim or control the defence or any suit or proceeding; further, provided, that any failure on the part of Distributor to notify CLS or provide information or assistance shall not relieve CLS of obligations hereunder unless such failure adversely and materially impacts CLS's defense of such claim.
- 16.7 In addition, in the event that any proceedings for infringement or challenge of CLS's intellectual property rights are instituted by a third party, CLS may, at its option, modify the Products to render them non-infringing; provided that any modification does not materially degrade the functionality of the Products, replace them with functionally equivalent non-infringing products or to obtain a suitable license from a third party.
- 17 Product Liability
- 17.1 CLS is not liable for any damages caused by the Products (i) to any movable or immovable property or the consequences of such damage, occurring while the Products are in the Distributor's possession, or (ii) to any other products manufactured or sold by the Distributor, in each case other than damage caused by CLS's gross negligence or wilful misconduct or Product defects, whether or not discovered or discoverable during Distributor's inspection upon receipt of such Product from CLS.
- 17.2 The Distributor shall indemnify and hold CLS harmless to the extent that CLS incurs liability towards any third party in respect of loss or damage for which CLS is not liable in relation to the Distributor pursuant to Section 17.1.
- 17.3 Subject to the limitations stated above, CLS shall indemnify, defend, and hold harmless Distributor for any third party claims arising from or related to damage to person and property caused by the Products or CLS's gross negligence, fraud, or wilful misconduct.

- 17.4 If a claim for damage as described in this Section is lodged by a third party against one of the Parties, the latter Party shall promptly inform the other Party thereof in writing.
- 17.5 Each Party shall notify the other in writing of such claim in accordance with Section 17.4 and shall give authority to settle the claim or control the defence of any suit and proceeding; provided, that any failure of a Party to comply with the foregoing shall not limit CLS's obligations under this Section 17 unless such failure materially and adversely impacts CLS's ability to defend a claim. In the event that a Product, or parts thereof, becomes subject to a recall reasonably decided by CLS, the Distributor shall participate and assist in such a process in accordance with CLS's reasonable instructions. The Distributor is entitled to compensation for its reasonable direct and documented costs occurred in relation to such given assistance.
- 17.6 Both Parties shall keep and maintain a product liability insurance in accordance with industry standards and applicable law.
- 18 Limitation of Liability
- 18.1 A Party's liability for any claim of any kind, including negligence, for any loss or damage arising out of, connected with, or resulting from this Agreement or from the design, manufacture, sale, delivery, resale or use of the Products or any part thereof, as the case may be, shall be limited to the amounts paid or payable by Distributor to CLS in the twelve months preceding the claim.
- 18.2 In no event shall either Party be liable towards the other Party for any loss of production or profit, loss of use, loss of data, loss of contracts or for any other consequential, economic or indirect loss whatsoever in respect of the sale, purchase, use or disposition of the Products.
- 18.3 The limitations of liability and exceptions in this Section 18 shall not apply to (a) Party's indemnity obligations hereunder, (b) a Party's breach of its confidentiality obligations hereunder, (c) third party claims relating to Product liability, or (d) a Party's gross negligence or wilful misconduct.
- 19 Force Majeure
- 19.1 The Parties shall be relieved from liability for a failure to perform any obligation under this Agreement during such period, and to the extent that the due performance thereof by either of the Parties is prevented by reason of any circumstance beyond the reasonable control of the Parties ("discharging circumstance"). War, warlike hostilities, mobilisation, or general military call-up, civil war, fire, flood, industrial disputes, shortage, or inability to obtain material, equipment, or transportation or other circumstances of similar importance, shall be considered as discharging circumstances.
- 19.2 If a Party wishes to invoke an event of force majeure, it shall give immediate notice to the other Party of the commencement and the cessation of such event of force majeure, failing which, the Party shall not be discharged from liability for any non-performance caused by such event of force majeure.

- 19.3 The time for performance of the relevant obligations of a Party shall be appropriately extended by the period, during which a situation of force majeure shall have continued, provided, however, that if performance of a contractual obligation is prevented by a force majeure event for a period of thirty (30) days or more, each Party shall be entitled to terminate this Agreement.
- 20 Confidentiality
- 20.1 The Parties hereby undertake, during the term of this Agreement and thereafter, to hold in confidence any and all Confidential Information (as defined below), disclosed by the other Party pursuant to this Agreement and not to disclose to third parties any Confidential Information thus received without the prior written consent of the disclosing Party. Furthermore, the Parties shall take reasonable steps to prevent an unauthorised disclosure or use of such Confidential Information by employees, subagents or other intermediaries.
- 20.2 For the purpose of this Agreement “Confidential Information” shall mean any and all information (whether in written or oral form), including but not limited to technical, practical and commercial information, excluding however (a) information which is known or which becomes known in full detail to the public otherwise than by breach of the obligations herein contained; (b) information which the disclosing Party can show was in its possession before receiving it from the other Party; (c) information which a Party has received or receives from a third party without restraints as to the disclosure thereof; and (d) information which a Party is legally obliged to disclose by compulsory law, court order or by order of another authority of competent jurisdiction.
- 20.3 This confidentiality undertaking shall survive any termination of this Agreement.
- 21 Term and termination
- 21.1 This Agreement enters into force on the date hereof and shall remain in effect for an initial period of two (2) years. Thereafter, the Agreement shall be automatically renewed for consecutive periods of one (1) year at the time, unless terminated by either Party through written notice to the other Party not less than sixty (60) days prior to the expiration of the initial period or any renewal periods.
- 21.2 Either Party may terminate this Agreement with immediate effect if
- (a) the other Party fails to fulfil its obligations under this Agreement, provided such failure is of material importance for the other Party and the failure has not been cured within 30 days of receiving written notification from the Party invoking this Paragraph. The notification shall be made without unreasonable delay, once the Party becomes aware of the relevant circumstances; or
 - (b) the other party has been subject to an application for bankruptcy proceedings or enters into composition, reorganisation or similar arrangements with its creditors or ceases to carry on business or is wound up or goes into liquidation or has a receiver appointed for all or any part of its assets.

- 21.3 Either Party may also terminate the Agreement as otherwise provided in this Agreement, including CLS's right to terminate in accordance with Section 8.4, subject, however, to Section 11.3.
- 21.4 Furthermore, CLS may immediately terminate this Agreement if there is a substantial change of control in the Distributor whether through a change of ownership, through a shareholders agreement or otherwise.
- 22 Consequences of Termination
- 22.1 At the expiration or termination of this Agreement by any reason whatsoever the each Party shall cease all use of and, at that request of the disclosing Party, promptly return to the disclosing Party or otherwise destroy, as the disclosing Party may instruct, all Confidential Information relating to the Products and the business of the disclosing Party which the Distributor may have in its possession or under its control. The Distributor shall also provide an up to date transcript of the Distributor's register of customers for the Products.
- 22.2 At the expiration of this Agreement CLS may at its option repurchase all or part of the stock of the Products, which the Distributor may have at such time at such prices equal to the net prices paid by the Distributor excluding taxes, import duties or other levies and insurance and transport costs.
- 22.3 Notwithstanding anything to the contrary herein, any order for delivery of Products placed by the Distributor with CLS and accepted by CLS before notice of termination was given shall be completed in accordance with the terms of the individual delivery contract, even if delivery is to take place after the expiration of this Agreement, and Distributor's rights under this Agreement shall survive termination or expiration of this Agreement until such time as Distributor sells off any remaining inventory not repurchased by CLS according to Section 22.2 above.
- 22.4 The Distributor shall have no further rights to use the trademarks or any of CLS's intellectual property rights. Upon termination of this Agreement, regardless of the reason therefore, the Distributor is also obliged to submit the Customer and potential Customer database, as well as records of dealings with Customers to CLS without delay and in no event later than thirty (30) days after termination of the Agreement.
- 22.5 Subject to the Distributor's termination of the Agreement due to CLS's breach according to Section 21.2, the Distributor shall not be entitled to any compensation whatsoever, including but not limited to, loss of present or future profits on sales or anticipated sales, or expenditures, investments or commitments made, in connection with the termination of this Agreement or as a result of the termination of this Agreement as permitted under this Agreement.
- 23 Assignments and Sub-Distributors
- 23.1 This Agreement shall be binding upon and inure to the benefit of the successors of the Parties but shall not be assignable by either of the Parties without the prior written consent of the other Party. Either Party may however assign or transfer its rights and obligations under this Agreement in whole without the consent of the other Party to any

company directly or indirectly controlling, controlled by or under common control of such Party, or, subject to CLS's right to terminate the Agreement under Section 21.4, pursuant to a change of control or in connection with a merger or the sale of all or substantially all of its business or assets, however structured.

- 23.2 The Distributor shall be entitled to designate sub-distributors or any other similar representatives for the sale of the Products in the Territory only if and to the extent CLS consents thereto in writing. If such a representative is appointed the Distributor shall cause the representative to act in every respect in conformity with the provisions of this Agreement. The Distributor is in such event responsible for any act or omission by the representative and any breach by such representative of the provisions of this Agreement shall always be considered as a breach by the Distributor of its obligations under this Agreement.
- 24 Miscellaneous
- 24.1 All notices and other communications required or permitted under this Agreement must be in writing in the English language and shall be deemed to have been received by a Party when (a) delivered by post, unless actually received earlier, on the third business day after posting, if posted within Sweden, or the fifth business day, if posted to or from a place outside Sweden; (b) delivered by hand, on the day of delivery; or (c) sent by e-mail which has been confirmed by the recipient, on the day of receipt.
- 24.2 The language of communication between CLS and the Distributor shall be English. Documents by CLS will be issued in English language. In the event that the Distributor requires translation, the Distributor shall secure such translation on its own behalf and at its own expense.
- 24.3 The parties hereto have agreed that the following persons are authorised to act on their behalf in dealings regarding this agreement:
- on behalf of CLS: Lars-Erik Eriksson; Dan J. Mogren
 - on behalf of the Distributor: Joseph Burnett
- 24.4 Each of the Parties to this Agreement confirms that this Agreement represents the entire understanding and constitutes the whole agreement between the Parties in relation to its subject matter and supersedes all prior agreements, covenants, arrangements, communications, representations or warranties, whether oral or written, by any officer, agent, employee or representative of either of the Parties. This Agreement may only be amended, changed or modified by an instrument in writing duly executed by the Parties. For the avoidance of doubt, nothing in this Agreement limits any rights or obligations of the Parties pursuant to that certain License and Collaboration Agreement between the Parties of even date herewith.
- 24.5 Unless otherwise explicitly stated herein, in no event shall any delay, failure or omission of a Party in enforcing, exercising or pursuing any right, claim or remedy under this Agreement be deemed as a waiver thereof, unless such right, claim or remedy has been expressly waived in writing.

24.6 This Agreement shall be governed by and construed in accordance with the laws of Sweden.

24.7 Any dispute, controversy or claim arising out of or in connection with this contract, or the breach, termination or invalidity thereof, shall be finally settled by arbitration administered by the Arbitration Institute of the Stockholm Chamber of Commerce (the “**SCC**”). The Rules for Expedited Arbitrations shall apply, unless the SCC in its discretion determines, taking into account the complexity of the case, the amount in dispute and other circumstances, that the Arbitration Rules shall apply. In the latter case, the SCC shall also decide whether the Arbitral Tribunal shall be composed of one or three arbitrators. The place of arbitration shall be Malmö, Sweden. The language to be used in the arbitral proceedings shall be English.

This Agreement has been duly executed in two original copies, of which each of the Parties has taken one copy.

Oct, the 16th 2018

CLINICAL LASERTHERMIA SYSTEMS AB

Oct, the 16th 2018

MRI Interventions Inc

/s/ Hans Von Celsing
Hans Von Celsing, Chairman

/s/ Joseph Burnett
Joseph Burnett, President & CEO

/s/ Lars-Erik T. Eriksson

Lars-Erik T. Eriksson

CEO

EXHIBIT A

Distributor (“MRIC”) Commitments:

- MRIC will immediately open requisitions and hire or designate additional clinical specialists – CLS to have input into job descriptions and ability to participate in interview process
- MRIC will train ALL clinical specialists on Tranberg system use by end of January 2019 (training provided by CLS)
- MRIC will train ALL sales representatives on product messaging by end of January 2019 (training provided by CLS)
- MRIC will open a requisition for additional quality / complaint specialist to support CLS products
- MRIC will handle first-line product / quality support for CLS and provide regular updates to CLS for product complaints, MDRs, product development and other sources
- MRIC sales representatives will create a contact list of non-neuro surgeons at existing hospitals and deliver to CLS by June 30 2019
- MRIC sales representatives will schedule minimum of 10 in-service presentations in existing MRIC accounts by end 2019 to be supported by CLS
- MRIC will tie *** % of variable compensation of their sales representatives to CLS Non-Neuro activities

CLS Fees for above:

- \$*** per quarter paid in first month of each quarter starting October 2018
- Pricing agreed to in Exhibit B of distribution agreement
- Additional funding and resourcing plans will be discussed at time of thermometry software launch or June 2019, whichever is first

EXHIBIT B

CLS PRODUCT & PRICE LIST 2018-2019

Kit # Name Price	Kit Content:	Part #	Unit Price [USD]	Min order [Kit/Unit]
TRANBERG® xxxx				
# 9101-01 Mobile Laser Unit Kit Price: *** USD	1 pc Mobile Laser Unit	1001-01	***	
	1 pc Mains Cable (US)	4001-03	***	
	1 pc IFU	TBD	-	***
	5 pcs Protective Goggles	4002-01	***	
	1 pc Laser Warning Sign	4003-01	***	
# 9413-11 MR LA_RADNC-I23 Kit Price: *** USD	Sterile disposable MR-compatible Applicator Kit:			
	1 pc Laser Applicator Radial non-cooled OD=1.75mm, L=1200cm	4012-05	***	***
	1 pc MR-cannula 14G IL=23cm; Mtrl: Nitinol	4013-05	***	
	1 pc MR-stylet for cannula; Mtrl: Nitinol	4013-06	***	
# 9413-12 MR LA_D15NC-I23 Kit Price: *** USD	Sterile disposable MR-compatible Applicator Kit:			
	1 pc Laser Applicator 15 mm Diffuser non-cooled OD=1.75mm, L=1200cm	4017-02	***	***
	1 pc MR-cannula 14G IL=23cm; Mtrl: Nitinol	4013-05	***	
	1 pc MR-stylet for cannula; Mtrl: Nitinol	4013-06		
# 9413-13 MR LA_D25NC-I23 Kit Price: *** USD	Sterile disposable MR-compatible Applicator Kit:			
	1 pc Laser Applicator 25 mm Diffuser non-cooled OD=1.75mm, L=1200cm;	4017-04	***	***
	1 pc MR-cannula 14G IL=23cm; Mtrl: Nitinol	4013-05	***	
	1 pc MR-stylet for cannula; Mtrl: Nitinol	4013-06		
LA = Laser Applicator; RAD = Radial; D = Diffuser; NC = Non-cooled; I = Introducer; OD=Outer diam; L= Length; IL= Insertion Length MR = Magnetic Resonance				

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

I, Joseph M. Burnett, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2018, of MRI Interventions, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer

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

I, Harold A. Hurwitz, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2018, of MRI Interventions, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2018

/s/ Harold A. Hurwitz

Harold A. Hurwitz
Chief Financial Officer

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

Each of the undersigned, Joseph M. Burnett and Harold A. Hurwitz, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this quarterly report on Form 10-Q for the quarter ended September 30, 2018, of MRI Interventions, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this quarterly report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 13, 2018

/s/ Joseph M. Burnett

Joseph M. Burnett
Chief Executive Officer

/s/ Harold A. Hurwitz

Harold A. Hurwitz
Chief Financial Officer
