# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2017

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: 001-37725

# ViewRay, Inc. (Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization) 2 Thermo Fisher Way **Oakwood Village, OH** (Address of principal executive offices)

42-1777485 (I.R.S. Employer Identification No.)

> 44146 (Zip Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🗵 No 🗆

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 🗵 No 🗆

Registrant's telephone number, including area code: (440) 703-3210

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	$\Box$ (Do not check if a smaller reporting company)	Smaller reporting company	X
Emerging growth company	$\boxtimes$		

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 July 28, 2017, the registrant had 59,007,383 shares of common stock, \$0.01 par value per share, outstanding,

# VIEWRAY, INC. FORM 10-Q

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# CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Report, contains forward-looking statements, including, without limitation, in the sections captioned "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere. Any and all statements contained in this Report that are not statements of historical fact may be deemed forward-looking statements. Terms such as "may," "might," "would," "should," "could," "project," "estimate," "pro-forma," "predict," "potential," "strategy," "anticipate," "attempt," "develop," "plan," "help," "believe," "continue," "intend," "expect," "future" and terms of similar import (including the negative of any of the foregoing) may be intended to identify forward-looking statements. However, not all forward-looking statements may contain one or more of these identifying terms. Forward-looking statements regarding (i) the plans and objectives of management for future operations, including plans or objectives relating to the development of commercially viable products, (ii) a projection of income (including any such statement contained in a discussion and analysis of financial condition by management or in the results of operations included pursuant to the rules and regulations of the Securities and Exchanges Commission, or SEC and (iv) the assumptions underlying or relating to any statement described in points (i), (ii) or (iii) above.

The forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances and may not be realized because they are based upon our current projections, plans, objectives, beliefs, expectations, estimates and assumptions and are subject to a number of risks and uncertainties and other influences, many of which we have no control over. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation:

- market acceptance of MRI-guided radiation therapy;
- the benefits of MRI-guided radiation therapy;
- our ability to successfully sell and market MRIdian in our existing and expanded geographies;
- the performance of MRIdian in clinical settings;
- competition from existing technologies or products or new technologies and products that may emerge;
- the pricing and reimbursement of MRI-guided radiation therapy;
- the implementation of our business model and strategic plans for our business and MRIdian;
- the scope of protection we are able to establish and maintain for intellectual property rights covering MRIdian;
- our ability to obtain regulatory approval in targeted markets for MRIdian;
- estimates of our future revenue, expenses, capital requirements and our need for additional financing;
- our financial performance;
- our expectations related to the MRIdian linear accelerator technology, or MRIdian Linac;
- developments relating to our competitors and the healthcare industry; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, titled "Risk Factors" and discussed elsewhere in this Report. Given these uncertainties, you are cautioned not to place undue reliance on these forward-looking statements. We disclaim any obligation to update the forward-looking statements contained in this Report to reflect any new information or future events or circumstances or otherwise, except as required by law.

This Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain devices, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.



# Item 1. Unaudited Condensed Consolidated Financial Statements

# VIEWRAY, INC. Condensed Consolidated Balance Sheets (In thousands, except share and per share data) (Unaudited)

		June 30, 2017	December 31, 2016		
ASSETS					
Current assets:					
Cash and cash equivalents	\$	53,927	\$	14,198	
Accounts receivable		1,820		4,200	
Inventory		15,358		8,082	
Deposits on purchased inventory		5,516		2,522	
Deferred cost of revenue		11,163		3,909	
Prepaid expenses and other current assets		5,117		3,023	
Total current assets		92,901		35,934	
Property and equipment, net		11,388		11,560	
Restricted cash		1,143		1,143	
Intangible assets, net		87		97	
Other assets		32		30	
TOTAL ASSETS	\$	105,551	\$	48,764	
LIABILITIES AND STOCKHOLDERS' DEFICIT					
Current liabilities:					
Accounts payable	\$	6,486	\$	4,980	
Accrued liabilities		7,486		6,334	
Customer deposits		25,900		19,400	
Deferred revenue, current portion		13,787		6,515	
Total current liabilities		53,659		37,229	
Deferred revenue, net of current portion		3,582		3,918	
Long-term debt		44,412		44,290	
Warrant liabilities		15,128		2,723	
Other long-term liabilities		5,757		4,257	
TOTAL LIABILITIES		122,538		92,417	
Commitments and contingencies (Note 6)					
Stockholders' deficit:					
Preferred stock, par value of \$0.01 per share; 10,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued and					
outstanding at June 30, 2017 and December 31, 2016 Common stock, par value of \$0.01 per share; 300,000,000 shares authorized at		_		_	
June 30, 2017 and December 31, 2016; 58,915,205 and 43,581,184 shares					
issued and outstanding at June 30, 2017 and December 31, 2016		579		426	
Additional paid-in capital		266,425		203,598	
Accumulated deficit		(283,991)		(247,677)	
TOTAL STOCKHOLDERS' DEFICIT		(16,987)		(43,653)	
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	\$	105,551	\$	48,764	
IOTAL LIADILITIES AND STOCKHOLDERS DEFICIT	Ф	105,551	Э	40,/04	

The accompanying notes are an integral part of these condensed consolidated financial statements.

# VIEWRAY, INC. Condensed Consolidated Statements of Operations (In thousands, except share and per share data) (Unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,			ıne 30,
	 2017	017 2016		2017		2016	
Revenue:							
Product	\$ 	\$	_	\$	—	\$	5,240
Service	579		299		1,687		515
Distribution rights	 119				238		
Total revenue	698		299		1,925		5,755
Cost of revenue:							
Product	328		139		594		6,066
Service	498		724		1,274		1,325
Total cost of revenue	 826		863		1,868		7,391
Gross margin	(128)		(564)		57		(1,636)
Operating expenses:							
Research and development	3,251		2,964		6,165		6,363
Selling and marketing	1,871		1,402		2,943		2,681
General and administrative	7,463		5,788		14,614		12,108
Total operating expenses	12,585		10,154		23,722		21,152
Loss from operations	(12,713)		(10,718)		(23,665)		(22,788)
Interest income	1		—		2		1
Interest expense	(1,792)		(1,377)		(3,529)		(2,459)
Other income (expense), net	6,151		(20)		(9,122)		(237)
Loss before provision for income taxes	\$ (8,353)	\$	(12,115)	\$	(36,314)	\$	(25,483)
Provision for income taxes	_		_		—		
Net loss	\$ (8,353)	\$	(12,115)	\$	(36,314)	\$	(25,483)
Net loss per share, basic and diluted	\$ (0.15)	\$	(0.32)	\$	(0.67)	\$	(0.67)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	 57,230,403		38,234,703	_	54,540,854		38,223,071

The accompanying notes are an integral part of these condensed consolidated financial statements.

# VIEWRAY, INC. Condensed Consolidated Statements of Cash Flows (In thousands) (Unaudited)

		Six Months Ended June 30,			
		2017		2016	
CASH FLOWS FROM OPERATING ACTIVITIES:					
Net loss	\$	(36,314)	\$	(25,483)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		1,004		856	
Stock-based compensation		1,782		1,245	
Accretion on asset retirement obligation		19		17	
Change in fair value of warrant liabilities		9,032		—	
Loss on disposal of property and equipment		9		2	
Inventory lower of cost or market adjustment		—		235	
Amortization of debt discount and interest accrual		1,605		1,059	
Changes in operating assets and liabilities:					
Accounts receivable		2,380		(880)	
Inventory		(7,276)		(3,472)	
Deposits on purchased inventory		(2,994)		1,059	
Deferred cost of revenue		(7,254)		1,237	
Prepaid expenses and other assets		(2,096)		(394)	
Accounts payable		1,808		1,091	
Accrued expenses and other long-term liabilities		976		686	
Customer deposits and deferred revenue		13,436		2,172	
Net cash used in operating activities		(23,883)		(20,570)	
CASH FLOWS FROM INVESTING ACTIVITIES:					
Purchase of property and equipment		(776)		(5,748)	
Purchase of intangible assets and other assets		_		(12)	
Net cash used in investing activities		(776)		(5,760)	
CASH FLOWS FROM FINANCING ACTIVITIES:					
Proceeds from common stock private placement, gross		26,100		_	
Payment of offering costs related to common stock private placement		(300)		_	
Proceeds from at-the-market offering of common stock, gross		39,524		_	
Payment of offering costs related to at-the-market offering of common stock		(1,129)			
Proceeds from draw down of long-term debt, net		_		14,982	
Proceeds from the exercise of stock options		193		110	
Net cash provided by financing activities		64,388		15,092	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		39,729		(11,238)	
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD		14,198		20,667	
CASH AND CASH EQUIVALENTS — END OF PERIOD	\$	53,927	\$	9,429	
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:	ф	00,027	Ψ	5,125	
Cash paid for interest	\$	1,924	\$	1,398	
*				1,390	
Cash paid for taxes	\$	1	\$		
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:					
Purchase of property and equipment in accounts payable and accrued expenses	\$	248	\$	969	
Transfer of property and equipment from inventory	\$	_	\$	117	
Offering cost in accounts payable and accrued expenses	\$	6	\$		

The accompanying notes are an integral part of these condensed consolidated financial statements.

#### VIEWRAY, INC. Notes to Condensed Consolidated Financial Statements (Unaudited)

# 1. Background and Organization

ViewRay, Inc., or ViewRay or the Company, and its wholly-owned subsidiary ViewRay Technologies, Inc., designs, manufactures and markets MRIdian, an MRI-guided radiation therapy system to image and treat cancer patients simultaneously.

Since inception, ViewRay Technologies, Inc. has devoted substantially all of its efforts towards research and development, initial selling and marketing activities, raising capital and the manufacturing and shipment of MRIdian systems. In May 2012, ViewRay Technologies, Inc. was granted clearance from the U.S. Food and Drug Administration, or FDA, to sell MRIdian with cobalt. In November 2013, ViewRay Technologies, Inc. received its first clinical acceptance of a MRIdian with cobalt at a customer site, and the first patient was treated with that system in January 2014. ViewRay Technologies, Inc. has had the right to affix the CE mark to MRIdian with cobalt in the European Economic Area since November 2016, the Company received the rights to affix the CE mark to MRIdian Linac, and in February 2017, the Company received 510(k) clearance from the FDA to market MRIdian Linac.

The Company's condensed consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for a reasonable period of time. The Company's principal sources of liquidity are cash flows from investment capital and available borrowings under its term loan agreement. These have historically been sufficient to meet working capital needs, capital expenditures, and debt service obligations. During the six months ended June 30, 2017, the Company incurred a net loss of \$36.3 million, and used cash in operations of \$23.9 million. The Company believes that its existing cash balance of \$53.9 million as of June 30, 2017, which is largely made up of the aggregate \$65.6 million of gross proceeds from the January 2017 private placement and equity issuances from at-the-market offerings during the first six months of 2017, is sufficient to provide liquidity to fund its operations for at least the next 12 months.

# 2. Summary of Significant Accounting Policies

# **Basis of Presentation**

The condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP, and pursuant to the rules and regulation of the Securities and Exchanges Commission, or SEC. The condensed consolidated financial statements include the accounts of ViewRay, Inc. and its wholly-owned subsidiary, ViewRay Technologies, Inc. All inter-company accounts and transactions have been eliminated in consolidation.

In the opinion of management, all adjustments, including normal recurring adjustments, considered necessary for a fair presentation of the Company's unaudited condensed consolidated financial statements have been included. The results of operations for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 or any future period. These unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2016.

The significant accounting policies used in preparation of these condensed consolidated financial statements are disclosed in the notes to consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 17, 2017, and have not changed significantly since such filing.

# **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which supersedes the revenue recognition requirements in Accounting Standards Codification 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict the transfer of 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. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenues and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU No. 2015-14 to defer the effective date by one year with early adoption permitted as of the original effective date. ASU No. 2014-09 will be effective for the Company's fiscal year beginning after December 15, 2017, and the interim periods thereafter. In addition, the FASB issued ASU No. 2016-08, 2016-10, 2016-12 and 2016-20 in March 2016, April 2016, May 2016 and December 2016, respectively, to help provide interpretive clarification on the new guidance in ASC Topic 606. ASU No. 2016-08, 2016-10 and 2016-12 are all effective during the same period as ASU No. 2014-09. The Company will adopt the standard on January 1, 2018.

In December 2016, the Company initiated its evaluation of ASU No. 2014-09, including the expected impact on its business processes, systems and controls, and potential differences in the timing and/or method of revenue recognition for its sales contracts. Based on the initial assessment, the Company does not believe the adoption of ASU No. 2014-09 will have a material impact on the amount or timing of its revenue recognition. Due to the nature of the Company's sales arrangements, product revenue, service revenue and distribution rights revenue are expected to remain substantially unchanged. The Company expects to adopt the standard using the full retrospective method, and the effect of initially applying the guidance will be adjusted retrospectively to each prior reporting period presented. The Company is still in the process of completing its analysis of the impact this standard will have on the disclosure of its consolidated financial statements, and expects the related disclosures to be updated upon adoption of the new standard. The Company will continue its evaluation of ASU No. 2014-09 through the date of adoption.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which supersedes the Accounting Standards Codification 840, Leases. This ASU requires lessees to recognize all leases, with exception of short-term leases, as a lease liability on the balance sheet. Under this ASU, a lease is defined as a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and a right-of-use asset which is an asset that represents the lessee's right to use, or control the use of, a specified asset during the lease term. The ASU also requires additional disclosure about the amount, timing and uncertainty of cash flow from leases. The new standard is effective for fiscal years beginning after December 15, 2018, and interim periods therein. Early adoption is permitted. For the Company, the impact of ASU No. 2016-02 will primarily relate to its accounting and reporting of leases as a lease. As disclosed in Note 6, future minimum payments under noncancelable operating leases are approximately \$2.8 million. This new standard will require the present value of these leases to be recorded in the consolidated balance sheets as a right of use asset and lease liability. The Company is continuing to evaluate the impact of this guidance on its condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which eliminates the diversity in practice related to the classification of certain cash receipts and payments for debt prepayment or extinguishment costs, the maturing of a zero coupon bond, the settlement of contingent liabilities arising from a business combination, proceeds from insurance settlements, distributions from certain equity method investees and beneficial interests obtained in a financial asset securitization. ASU No. 2016-15 designates the appropriate cash flow classification, including requirements to allocate certain components of these cash receipts and payments among operating, investing and financing activities. In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU No. 2016-15 and ASU No. 2016-18 should be applied using the retrospective transition method, requiring adjustment to all comparative periods presented, unless it is impracticable for some of the amendments, in which case those amendments would be made prospectively as of the earliest date practicable. The amendments in ASU No. 2016-15 and ASU No. 2016-18 are effective for fiscal years beginning after December 15, 2017, and interim periods therein. Early adoption is permitted, including adoption in an interim period. The Company had restricted cash of \$1.1 million at both June 30, 2017 and December 31, 2016. The adoption of ASU No. 2016-18 will not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, which provides clarified guidance on applying modification accounting to changes in the terms or conditions of a share-based payment award. Changes that do not impact the award's fair value, vesting conditions, or classification as an equity or liability instrument will not to be subject to modification accounting. ASU No. 2017-09 is effective prospectively for annual periods beginning after December 15, 2017 and interim periods therein. The Company is evaluating the impact of this update on its condensed consolidated financial statements and related disclosures, and does not believe the adoption of ASU No. 2017-09 will have a material impact.

# **Recently Adopted Accounting Pronouncements**

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory*, which requires entities to measure most inventory at the lower of cost and net realizable value, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. ASU No. 2015-11 is effective prospectively for annual periods beginning after December 15, 2016 and interim periods therein. Early application is permitted. The Company adopted ASU No. 2015-11 as required in the first quarter of fiscal year 2017. The adoption of the new guidance did not have a material impact on its condensed consolidated financial reporting statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): *Improvements to Employee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, application of award forfeitures to expense, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU No. 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods therein. Early adoption is permitted. The Company adopted ASU No. 2016-09 as required in the first quarter of fiscal

year 2017, and there was no material impact on the financial statements given the full valuation allowance position of its deferred tax assets.

# 3. Balance Sheet Components

# **Property and Equipment**

Property and equipment consisted of the following (in thousands):

	June 30, 2017	De	cember 31, 2016
Prototype	\$ 11,929	\$	6,405
Machinery and equipment	6,739		6,057
Leasehold improvements	4,371		4,371
Software	1,050		1,028
Furniture and fixtures	450		368
Construction in progress			5,498
Property and equipment, gross	 24,539		23,727
Less: accumulated depreciation and amortization	(13,151)		(12,167)
Property and equipment, net	\$ 11,388	\$	11,560

Depreciation and amortization expense related to property and equipment were \$532 thousand and \$438 thousand during the three months ended June 30, 2017 and 2016, respectively, and \$994 thousand and \$764 thousand during the six months ended June 30, 2017 and 2016, respectively.

# **Intangible Assets**

Intangible assets consisted of the following (in thousands):

	June 30, 2017	December 31, 2016		
License cost	\$ 512	\$ 512		
Patents	104	104		
Intangible assets, gross	616	616		
Accumulated amortization	(529)	(519)		
Intangible assets, net	\$ 87	\$ 97		

Intangible assets amortization expense were \$5 thousand and \$46 thousand during the three months ended June 30, 2017 and 2016, respectively, and \$10 thousand and \$92 thousand during the six months ended June 30, 2017 and 2016, respectively. Amortization of intangible assets was recorded in general and administrative expenses in the condensed consolidated statements of operations.

At June 30, 2017, the estimated future amortization expense of intangible assets was as follows (in thousands):

Year Ending December 31,	Estimated Amortiz Expe	ation
The remainder of 2017	\$	10
2018		19
2019		19
2020		19
2021		10
2022		3
Thereafter		7
Total amortization expense	\$	87

# Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2017			December 31, 2016		
Accrued payroll and related benefits	\$	3,387	\$	4,274		
Accrued accounts payable		2,860		1,202		
Accrued legal, accounting and governance fees		483		509		
Sales tax payable		53		13		
Other		703		336		
Total accrued liabilities	\$	7,486	\$	6,334		

# **Deferred Revenue**

Deferred revenue consisted of the following (in thousands):

	June 30, 2017	December 31, 2016
Deferred revenue:	 	
Product	\$ 11,950	\$ 5,050
Services	1,834	1,561
Distribution rights	3,585	3,822
Total deferred revenue	 17,369	 10,433
Less: current portion of deferred revenue	(13,787)	(6,515)
Noncurrent portion of deferred revenue	\$ 3,582	\$ 3,918

# 4. Fair Value of Financial Instruments

The Company's financial instruments that are carried at fair value mainly consist of Level 1 assets and Level 3 liabilities. Level 1 assets include highly liquid bank deposits and money market funds, which were not material at June 30, 2017 and December 31, 2016. Level 3 liabilities that are measured on a recurring basis consist of the 2017 and 2016 Placement Warrants, as described in Note 8. Placement warrant liabilities are valued using the Black-Scholes option-pricing model. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value of the warrants (see Note 9).

The gains and losses from re-measurement of Level 3 financial liabilities are recorded as part of other income (expense), net in the condensed consolidated statements of operations. During the three and six months ended June 30, 2017, the Company recorded a gain of \$6.2 million and a loss of \$9.0 million, respectively, related to the change in fair value of the 2017 and 2016 Placement Warrants. There have been no transfers between Level 1, Level 2 and Level 3 in any periods presented.

The following table sets forth the fair value of the Company's financial liabilities by level within the fair value hierarchy (in thousands):

	At June 30, 2017							
	Le	vel 1	L	evel 2	]	Level 3	_	Total
2017 Placement Warrants Liability	\$		\$	_	\$	8,384	\$	8,384
2016 Placement Warrants Liability		—		_		6,744		6,744
Total	\$		\$	_	\$	15,128	\$	15,128
				At Decemb	er 31,	2016		
	Le	vel 1	I	evel 2	1	Level 3		Total
2016 Placement Warrants Liability	\$	_	\$		\$	2,723	\$	2,723

The following table sets forth a summary of the changes in fair value of the Company's Level 3 financial liabilities (in thousands):

	Six Months En 30, 201	
Fair value, beginning of period	\$	2,723
Issuance of 2017 Placement Warrants		3,373
Change in fair value of Level 3 financial liabilities		9,032
Fair value, end of period	\$	15,128

# 5. Debt

# CRG Term Loan

In June 2015, ViewRay Technologies, Inc. entered into a Term Loan Agreement, or the CRG Term Loan, with Capital Royalty Partners II L.P., Capital Royalty Partners II – Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P. or together with their successors by assignment, CRG, for up to \$50.0 million of which \$30.0 million was made available to the Company upon closing with the remaining \$20.0 million available on or before June 26, 2016 at its option upon the occurrence of either (i) an initial public offering of its common stock on a nationally recognized securities exchange that raises a minimum of \$40.0 million in net cash proceeds with a minimum of \$120.0 million post-money valuation, or Qualifying IPO, or (ii) achievement of a minimum of \$25.0 million gross revenue from the sales of the MRIdian system during any consecutive 12 months before March 31, 2016. The Company drew down the first \$30.0 million on the closing date. The CRG Term Loan has a maturity date of June 26, 2020 and bears cash interest at a rate of 12.5% per annum to be paid quarterly during the interest-payment-only period of 3 years. The interest-payment-only period can be extended for another year until June 26, 2019 if the Company completes an underwritten public offering on or before June 26, 2018. During the interest-payment-only period, the Company has the option to elect to pay only 8% of the 12.5% per annum interest in cash, and the remaining 4.5% of the 12.5% per annum interest, or deferred payment in-kind interest, added to the aggregate principal amount of the CRG Term Loan. Principal payment and any deferred payment in-kind interest will be paid quarterly in equal installments following the end of the interest-payment-only period through maturity date.

The CRG Term Loan is subject to a prepayment penalty of 3% on the outstanding balance during the first 12 months following the funding of the Term Loan, 2% on the outstanding balance after year 2 but on or before year 3, and 0% on the outstanding loan if prepaid after year 3 thereafter until maturity. The Term Loan is also subject to a facility fee of 7% based on the sum of the amount drawn and any outstanding payment in-kind interest payable on maturity date or the date such loan becomes due. All direct financing costs were accounted for as a discount on the CRG Term Loan and will be amortized to interest expense during the life of the loan using the effective interest method. The CRG Term Loan is subject to financial covenants and is collateralized by essentially all assets of the Company and limits its ability with respect to additional indebtedness, investments or dividends, among other things, subject to customary exceptions.

In March 2016, the Company and CRG executed an amendment to the original terms of the CRG Term Loan such that, with regard to the conditions for borrowing the remaining \$20.0 million available under the CRG Term Loan, the Company may, at its election, draw down (i) an amount of either \$10.0 million or \$15.0 million in up to two advances upon achievement of a minimum of \$15.0 million of aggregate product and service revenue during any consecutive 12 month period ending on or before March 31, 2016 and (ii) an additional \$5.0 million (or \$10.0 million, if the previous draw made was only in an amount of \$10.0 million) upon achievement of a minimum of \$25.0 million of aggregate product and service revenue during any consecution of the first sales contract of the Company's second generation product. The Company achieved the minimum of \$15.0 million gross revenue requirement in March 2016 which made the first \$15.0 million of the remaining \$20.0 million credit facility immediately available for draw down. In May 2016, the Company drew down the additional \$15.0 million available amount.

In April 2017, the Company and CRG executed an amendment to the terms of its CRG Term Loan, as amended in March 2016. Amendments to the CRG Term Loan include availability of the existing \$5.0 million tranche at ViewRay's option through June 30, 2017, the addition of a \$15.0 million tranche of borrowing capacity available at ViewRay's option through September 30, 2017, extension of the interest-only and payment in-kind period, a decrease to the combined 2016 and 2017 revenue covenant and a 1.75% increase to the facility fee. At June 30, 2017, the Company had not drawn down on the additional \$5.0 million tranche.

At June 30, 2017, the Company had \$45.0 million in outstanding debt to CRG, and was in compliance with all financial covenants under the CRG Term Loan.

#### 6. Commitments and Contingencies

# **Operating Leases**

The Company leases office space in Oakwood Village, Ohio and Mountain View, California under non-cancellable operating leases. At June 30, 2017, the future minimum payments for the operating leases are as follows (in thousands):

Year Ending December 31,	e Minimum yments
The remainder of 2017	\$ 578
2018	1,188
2019	1,079
Total future minimum payments	\$ 2,845

### Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company records a provision for a liability when it believes that it is both probable that a liability has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount.

In the normal course of business, the Company may become involved in legal proceedings. The Company will accrue a liability for such matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. When only a range of possible loss can be established, the most probable amount in the range is accrued. If no amount within this range is a better estimate than any other amount within the range, the minimum amount in the range is accrued. The accrual for a litigation loss contingency might include, for example, estimates of potential damages, outside legal fees and other directly related costs expected to be incurred. At June 30, 2017 and December 31, 2016, the Company was not involved in any material legal proceedings.

#### **Purchase Commitments**

At June 30, 2017 and December 31, 2016, the Company had no outstanding firm purchase commitments.

### 7. Distribution Agreement

In December 2014, the Company entered into a distribution agreement with Itochu Corporation, or Itochu, a Japanese entity, pursuant to which the Company appointed Itochu as its exclusive distributor for the sale and delivery of the Company's MRIdian products within Japan. The exclusive distribution agreement has an initial term of 10 years from December 2014 and contains features customary in such distribution agreements. Under this distribution agreement, the Company will supply its products and services to Itochu based upon the Company's then-current pricing. In consideration of the exclusive distribution rights granted, Itochu agreed to pay a distribution fee of \$4.0 million in three installments: (i) the first installment of \$1.0 million was due upon execution of the distribution agreement; (ii) the second installment of \$1.0 million was due within 10 business days following submission of the application for regulatory approval of the Company's product to the Japan regulatory authority; and (iii) the final installment of \$2.0 million was due within 10 business days following receipt of approval for the Company's product from the Japanese Ministry of Health, Labor and Welfare. The distribution in aggregate were received in December 2014 and December 2015, respectively. In August 2016, the Company received the third and final \$2.0 million installment upon the receipt of regulatory approval to market MRIdian in Japan. The entire \$4.0 million distribution fee received was reclassified to deferred revenue as it was no longer refundable. In August 2016, the Company started recognizing distribution agreement on a straight-line basis over the remaining term of the exclusive distribution agreement of approximately 8.5 years. The distribution rights revenue on a straight-line basis over the remaining term of the exclusive distribution agreement of approximately 8.5 years. The distribution rights revenue was \$119 thousand and \$238 thousand for the three and six months ended June 30, 2017.

#### 8. Equity Financing

#### **Private Placements**

In September 2016, the Company completed the final closing of a private placement offering, or the 2016 Private Placement, through which it sold an aggregate of 4,602,506 shares of its common stock at a purchase price of \$2.95 per share and warrants that provide the warrant holders the right to purchase 1,380,745 shares of common stock, or the 2016 Placement Warrants, and raised total gross proceeds of \$1.38 million. The 2016 Placement Warrants have a per share exercise price of \$2.95 per share, are exercisable at any time at the option of the holder and expire seven years from the date of issuance.

In January 2017, the Company completed the final closing of a private placement offering, or the 2017 Private Placement, through which it sold (i) 8,602,589 shares of its common stock and (ii) warrants that provide the warrant holders the right to purchase an aggregate of 1,720,512 shares of common stock, or the 2017 Placement Warrants, and raised total gross proceeds of \$26.1 million. The 2017 Placement Warrants have a per share exercise price of \$3.17 per share, became exercisable after six months and expire seven years from the date of issuance.

### **At-The-Market Offering of Common Stock**

In January 2017, the Company filed a shelf registration statement on Form S-3 with the SEC, which included a base prospectus covering the offering, issuance and sale of up to a maximum aggregate offering of \$75.0 million of the Company's common stock, preferred stock, debt securities, warrants, purchase contracts and/or units; and the Company entered into a sales agreement with FBR Capital Markets & Co., or FBR, under which it may sell up to \$25.0 million of its common shares pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act. FBR acted as sales agent on a best efforts basis and used commercially reasonable efforts to sell on behalf of the Company all of the shares of common stock requested to be sold by the Company, consistent with its normal trading and sales practices, on mutually agreed terms between FBR and the Company. There is no arrangement for funds to be received in any escrow, trust or similar arrangement. In April 2017, the Company agreed to sell up to an additional \$25.0 million of the Company's common stock in accordance with the terms of a sales agreement with FBR and pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act.

FBR is entitled to compensation of up to 3.0% of the gross sales price per share sold. In connection with the sale of the Company's common stock on the Company's behalf, FBR is deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of FBR is deemed to be underwriting commissions or discounts. The Company has also agreed to provide indemnification and contribution to FBR with respect to certain liabilities, including liabilities under the Securities Act.

As of June 30, 2017, the Company sold an aggregate of 6,482,682 shares of its common stock at an average market price of \$6.10 per share, resulting in aggregate gross proceeds of approximately \$39.5 million.

In April 2017, the Company filed another shelf registration statement on Form S-3, which included a base prospectus covering the offering, issuance and sale of up to a maximum aggregate offering of \$100.0 million of the Company's common stock, preferred stock, debt securities, warrants, purchase contracts and/or units. As of June, 30, 2017, no securities had been sold pursuant to this registration statement.

# 9. Warrants

#### **Equity Classified Common Stock Warrants**

In connection with a debt financing in December 2013, the Company issued warrants to purchase 128,231 shares of its common stock with an exercise price of \$5.84 per share. These warrants are exercisable any time at the option of the holder until December 16, 2023.

In connection with the merger of the Company and ViewRay Technologies, Inc. in July 2015, or the Merger, in July and August 2015, the Company conducted a private placement offering during which the Company issued warrants, or 2015 Placement Warrants, that provide the warrant holder the right to purchase 198,760 shares of common stock at an exercise price of \$5.00 per share. These 2015 Placement Warrants are exercisable at any time at the option of the holder until the five year anniversary of its date of issuance.

All of these warrants remain outstanding at June 30, 2017 and December 31, 2016, and were accounted for as equity awards.

# Liability Classified Common Stock Warrants

In connection with the 2016 Private Placement, in August and September 2016, the Company issued warrants, the 2016 Placement Warrants, that provide the warrant holder the right to purchase 1,380,745 shares of common stock at an exercise price of \$2.95 per share. These 2016 Placement Warrants are exercisable at any time at the option of the holder until the seven year anniversary of its date of issuance. The 2016 Placement Warrants also contain protection whereby warrants will expire immediately prior to the consummation of a Change of Control and holders have the right to receive cash in the amount equal to the Black-Scholes value of warrants. A Change of Control is defined as (i) a merger or consolidation of the Company with another corporation, (ii) the sale, transfer or other disposal of substantially all of the assets or a majority of the Company's outstanding shares of capital stock, (iii) a purchase or exchange offer accepted by the holders of a majority of the outstanding voting shares of the Company's capital stock, or (iv) a "person" or "group," as defined by Section 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended, is or will become the beneficial owner, directly or indirectly, of at least a majority of the voting power of the Company's capital stock. The 2016 Placement Warrants were accounted for as a liability at the date of issuance and are adjusted to fair value at each balance sheet

date, with the change in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations.

As separate classes of securities were issued in a bundled transaction, the gross proceeds from the 2016 Private Placement of \$13.8 million was allocated first to the 2016 Placement Warrants based on its fair value upon issuance, and the residual was allocated to the common stock. The fair value upon issuance of \$2.7 million for the 2016 Placement Warrants was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions: expected term of seven years, expected volatility of 61.6%, risk-free interest rate of 1.4% and expected dividend yield of 0%.

During the three and six months ended June 30, 2017, the Company recorded a gain of \$2.8 million and a loss of \$4.0 million, respectively, related to the change in fair value of the 2016 Placement Warrants. The fair value of the 2016 Placement Warrants of \$6.7 million and \$2.7 million at June 30, 2017 and December 31, 2016, respectively, was estimated using the Black-Scholes option pricing model and the following weighted-average assumptions:

	June 30, 2017	December 31, 2016
2016 Placement Warrant:		
Expected term (in years)	6.2	6.7
Expected volatility	65.8%	63.6%
Risk-free interest rate	2.0%	2.3%
Expected dividend yield	0.0%	0.0%

At June 30, 2017, the 2016 Placement Warrants had not been exercised and were still outstanding.

In connection with the 2017 Private Placement, in January 2017, the Company issued warrants, the 2017 Placement Warrants, that provide the warrant holder the right to purchase 1,720,512 shares of common stock at an exercise price of \$3.17 per share. These 2017 Placement Warrants became exercisable after six months and expire seven years from the date of issuance. The 2017 Placement Warrants also contain protection whereby warrants will expire immediately prior to the consummation of a Change of Control and holders have the right to receive cash in the amount equal to the Black-Scholes value of warrants. A Change of Control in the 2017 Placement Warrants is defined the same way as for the 2016 Placement Warrants described above. The 2017 Placement Warrants were accounted for as a liability at the date of issuance and are adjusted to fair value at each balance sheet date, with the change in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations.

As separate classes of securities were issued in a bundled transaction, the gross proceeds from the 2017 Private Placement of \$26.1 million was allocated first to the 2017 Placement Warrants based on its fair value upon issuance, and the residual was allocated to the common stock. The fair value upon issuance of \$3.4 million for the 2017 Placement Warrants was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions: expected term of seven years, expected volatility of 62.9%, risk-free interest rate of 2.2% and expected dividend yield of 0%.

During the three and six months ended June 30, 2017, the Company recorded a gain of \$3.4 million and a loss of \$5.0 million, respectively, related to the change in fair value of the 2017 Placement Warrants. The fair value of the 2017 Placement Warrants of \$8.4 million was estimated using the Black-Scholes option pricing model and the following weighted-average assumptions:

		2017
2	017 Placement Warrant:	
	Expected term (in years)	6.6
	Expected volatility	65.9%
	Risk-free interest rate	2.0%
	Expected dividend yield	0.0%

At June 30, 2017, the 2017 Placement Warrants had not been exercised and were still outstanding.

# 10. Stock-Based Compensation

A summary of the Company's stock option activity and related information is as follows:

		Options Outstanding						
	Shares Available for Grant	Number of Stock Options Outstanding	Weighted- Average Exercise Price		Weighted- Average Remaining Contractual Life (Years)		Aggregate Intrinsic Value (In thousands)	
Balance at December 31, 2016	2,168,391	6,127,291	\$	2.60	7.3	\$	7,800	
Additional options authorized	1,743,247	—						
Options granted	(2,112,487)	2,112,487		5.10				
Options exercised	—	(230,733)		0.84				
Options cancelled	34,921	(34,921)		2.71				
Balance at June 30, 2017	1,834,072	7,974,124	\$	3.31	7.7	\$	25,264	
Vested and exercisable at June 30, 2017		4,216,526	\$	2.11	6.5	\$	18,401	
Vested and expected to vest at June 30, 2017		7,657,935	\$	3.26	7.6	\$	24,669	

The weighted-average grant date fair value of options granted to employees was \$3.13 and \$2.88 per share during the six months ended June 30, 2017 and 2016, respectively. The grant date fair value of options vested was \$1.9 million and \$1.4 million during the six months ended June 30, 2017 and 2016, respectively.

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options. The aggregate intrinsic value of options exercised was \$1.5 million and \$0.5 million during the six months ended June 30, 2017 and 2016, respectively.

At June 30, 2017, total unrecognized compensation cost related to stock-based awards granted to employees, net of estimated forfeitures, was \$9.7 million which is expected to be recognized over a weighted-average period of 3.0 years.

# **Determination of Fair Value**

The determination of the fair value of stock options on the date of grant using an option-pricing model is affected by the estimated fair value of the Company's common stock, as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock options using the Black-Scholes option-pricing model include actual and projected employee stock option exercise behaviors, expected price volatility of the Company's common stock, the risk-free interest rate and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine.

# Fair Value of Common Stock

Prior to the Merger, the fair value of the common stock underlying the stock-based awards was determined by ViewRay Technologies, Inc.'s board of directors, with input from management and third-party valuations. Post-Merger and up through March 30, 2016, the Company's common stock shares were listed on the OTC Bulletin Board. Beginning March 31, 2016, the Company's common stock shares were listed on The NASDAQ Global Market, or NASDAQ. Fair value of the common stock is the adjusted closing price of the Company's common stock on the trading date on these stock exchanges.

# Expected Term

The expected term represents the period that the Company's option awards are expected to be outstanding. The Company considers several factors in estimating the expected term of options granted, including the expected lives used by a peer group of companies within the Company's industry that the Company considers to be comparable to its business and the historical option exercise behavior of its employees, which the Company believes is representative of future behavior.

### Expected Volatility

As the Company has a limited trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated by taking a combination of the average historic price volatility of the Company's common stock and industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the Company's industry which were the same as the comparable companies used in the common stock valuation analysis. The Company intends to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of its own share price becomes available, or unless circumstances change such that the identified companies are no longer similar to the Company, in which case, more suitable companies whose share prices are publicly available would be used in the calculation.

### Risk-Free Interest Rate

The risk-free interest rate is based on the zero coupon U.S. Treasury notes, with maturities similar to the expected term of the options.

# **Expected Dividend Yield**

The Company does not anticipate paying any dividends in the foreseeable future and, therefore, uses an expected dividend yield of zero in the Black-Scholes option-valuation model.

In addition to the Black-Scholes assumptions discussed immediately above, the estimated forfeiture rate also has a significant impact on the related stock-based compensation. The forfeiture rate of stock options is estimated at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest.

The fair value of employee stock option was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Six Months June 3	
	2017	2016
Expected term (in years)	6.0	6.0
Expected volatility%	67.1%	69.7%
Risk-free interest rate%	2.1%	1.3%
Expected dividend yield%	0.0%	0.0%

### **Restricted Stock Units**

In September 2016, the Company granted 112,578 shares of restricted stock units, or RSUs, to its board of directors for their past services. These RSUs had a grant date fair value of \$3.58 per share, and were fully vested upon issuance and will be released and settled upon termination of the board services or the occurrence of a change in control event.

In December 2016, the Company granted 18,017 and 20,645 shares of RSUs to certain executive officers for bonus compensation and one consultant for their service, respectively. These RSUs were fully vested upon issuance and the 18,017 shares of RSUs granted to certain executive officers were released in the first quarter of fiscal 2017.

For the six months ended June 30, 2017, no additional RSUs were issued and no stock-based compensation expense related to RSUs was recorded in the accompanying condensed consolidated statements of operations.



# Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the Company's condensed consolidated statements of operations is classified as follows (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,				
		2017		2016		2017		2016
Research and development	\$	216	\$	235	\$	381	\$	356
Selling and marketing		72		14		123		38
General and administrative		725		440		1,278		851
Total stock-based compensation expense	\$	1,013	\$	689	\$	1,782	\$	1,245

During the three and six months ended June 30, 2017 and 2016, there were no stock-based compensation expenses capitalized as a component of inventory or recognized in cost of revenue. Stock-based compensation relating to stock-based awards granted to consultants were insignificant during the three and six months ended June 30, 2017 and 2016.

# 11. Income Tax

Due to the current operating losses, the Company recorded zero income tax expense during the three and six months ended June 30, 2017 and 2016, respectively. During these periods, the Company's activities were limited to U.S. federal and state tax jurisdictions, as it does not have any foreign operations. The federal and state effective tax rate is approximately 35%.

Due to the Company's history of cumulative losses, management concluded that, after considering all the available objective evidence, it is not more likely than not that all of the Company's net deferred tax assets will be realized. Accordingly, the Company's deferred tax assets, which includes net operating loss, or NOL, carryforwards and tax credits related primarily to research and development continue to be subject to a valuation allowance as of June 30, 2017. The Company will continue to maintain a full valuation allowance until there is sufficient evidence to support recoverability of its deferred tax assets.

The Company had unrecognized tax benefits of \$1.3 million and \$940 thousand at June 30, 2017 and December 31, 2016, respectively. The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. Unrecognized tax benefits may change during the next 12 months for items that arise in the ordinary course of business.

Interest and/or penalties related to income tax matters are recognized as a component of income tax expense. During the six months ended June 30, 2017 and 2016, there were no accrued interest and penalties related to uncertain tax positions.

# 12. Net Loss per Share

Since the Company was in a loss position for all periods presented, diluted net loss per common share is the same as basic net loss per common share for all periods presented, because the inclusion of all potential common shares outstanding would have an anti-dilutive effect. The following weighted-average common stock equivalents were excluded from the calculation of diluted net loss per share for the periods presented, because including them would have an anti-dilutive effect:

	Three Month June 3		Six Month June		
	2017	2016	2017	2016	
Options to purchase common stock	8,006,323	6,113,707	7,561,888	6,087,898	
Common stock warrants	3,428,248	326,991	3,266,653	326,991	
Restricted stock units	110,494	_	111,530	_	
Total	11,545,065	6,440,698	10,940,071	6,414,889	

# 13. Related Party Transactions

In December 2004, the Company entered into a licensing agreement with the University of Florida Research Foundation, or UFRF, whereby UFRF granted the Company a worldwide exclusive license to certain of UFRF's patents in exchange for 33,652 shares of common stock and a 1% royalty, with a minimum \$50,000 royalty payment per quarter, from sales of products developed and sold by the Company utilizing the licensed patents.

In January 2017, the Company entered into a sales consulting agreement with Puissance Capital Management, or PCM, to assist with business development activities in a key market in Asia. PCM is the investment manager of Puissance Cross Board Opportunities LLP, a stockholder in the Company. Theodore T. Wang, Ph.D., a member of the Company's board of directors, is the managing member of the general partners of PCM. The sales consulting agreement has a term of one year with a total consideration of \$1.3 million.

# 14. Segment and Geographic Information

The Company has one business activity, which is radiation therapy technology combined with magnetic resonance imaging, and operates in one reportable segment. The Company's chief operating decision-maker, its chief executive officer, reviews its operating results on an aggregate basis for purposes of allocating resources and evaluating financial performance. Also, the Company does not have segment managers as the Company manages its operations as a single operating segment.

# 15. Subsequent Events

In July 2017, the Company approved grants of fully-vested RSUs to members of its board of directors for their past services as directors of the Company. These grants have a total grant date fair value of \$300 thousand, and will be released and settled upon termination of the board service or the occurrence of a change in control event.

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The interim financial statements included in this Quarterly Report on Form 10-Q and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Annual Report filed with the SEC on March 17, 2017. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements are subject to risks and uncertainties, including those under "Risk Factors" in this Quarterly Report that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements.

Unless otherwise indicated, references in this section to "ViewRay," "we," "us," "our" and "the Company" refer to ViewRay, Inc. and its consolidated subsidiary, ViewRay Technologies, Inc.

As a result of the merger of the Company and ViewRay Technologies, Inc. in July 2015, or the Merger, and the change in business and operations of the Company, a discussion of the past financial results of the Company is not pertinent, and under applicable accounting principles the historical financial results of ViewRay Technologies, Inc., the accounting acquirer, prior to the Merger are considered the historical financial results of the Company.

The following discussion highlights ViewRay's results of operations and the principal factors that have affected our financial condition as well as our liquidity and capital resources for the periods described, and provides information that management believes is relevant for an assessment and understanding of the statements of financial condition and results of operations presented herein. The following discussion and analysis are based on ViewRay's unaudited condensed consolidated financial statements contained in this Quarterly Report, which we have prepared in accordance with U.S. GAAP. You should read the discussion and analysis together with such condensed consolidated financial statements and the related notes thereto.

#### **Company Overview**

We design, manufacture and market MRIdian, an MRI-guided radiation therapy system to simultaneously image and treat cancer patients. MRI is a broadly used imaging tool that has the ability to differentiate between types of soft tissue clearly, unlike X-ray or computed tomography, or CT, which are the most commonly used imaging technologies in radiation therapy today. MRIdian integrates MRI technology, radiation delivery and our proprietary software to locate, target and track the location and shape of soft-tissue tumors while radiation is delivered. These capabilities allow MRIdian to accurately deliver radiation to the tumor while reducing the amount delivered to healthy tissue, as compared to other radiation therapy treatments today. We believe this leads to improved patient outcomes and reduced side effects from off-target radiation delivery.

We received initial 510(k) marketing clearance from the FDA for our treatment planning and delivery software in January 2011 and for MRIdian with cobalt in May 2012. We also received permission to affix the Conformité Européene, or CE, mark to MRIdian with cobalt in November 2014, allowing MRIdian with cobalt to be sold within the European Economic Area, or EEA. In August 2016, we received regulatory approval from the Japanese Ministry of Health, Labor and Welfare to market MRIdian with cobalt in Japan. In August 2016, we also received approval from the China Food and Drug Administration to market MRIdian with cobalt in China. In September 2016, we received CE mark approval of MRIdian Linac in the EEA. In February 2017, we received 510(k) clearance from the FDA to market MRIdian Linac. In June 2017, we received 510(k) clearance to market RayZR, our high resolution multi-leaf collimator, or MLC. In July 2017, the first cancer patients to be treated using MRIdian Linac were treated at Henry Ford Health System in Detroit.

MRIdian is a radiation therapy solution that enables treatment and real-time imaging of a patient's anatomy simultaneously. The high-quality images that it generates differentiate the targeted tumor, surrounding soft tissue and nearby critical organs. MRIdian also records the level of radiation dose that the treatment area has received, enabling physicians to adapt the prescription between treatments as needed. We believe this improved visualization and accurate dose recording will enable better treatment, improve patient outcomes and reduce side effects. Key benefits to users and patients include improved imaging and patient alignment, on-table adaptive treatment planning, motion management and an accurate recording of the delivered radiation dose. Physicians have already used MRIdian to treat a broad spectrum of radiation therapy patients with more than 45 different types of cancer, as well as patients for whom radiation therapy was previously not an option.

At June 30, 2017, we have installed MRIdian with cobalt systems at eight cancer centers located at Washington University in St. Louis; University of California, Los Angeles; University of Wisconsin—Madison; Sylvester Comprehensive Cancer Center at the University of Miami; Seoul National University in South Korea; VU University Medical Center in the Netherlands, Policlinico "A. Gemelli" Hospital in Italy, and National Cancer Center in Japan. One other MRIdian with cobalt system has been delivered and is expected to be installed in early 2018 at Edogawa Hospital in Japan.

We currently market MRIdian through a direct sales force in the United States and distributors in the rest of the world. We market MRIdian to a broad range of worldwide customers, including university research and teaching hospitals, community hospitals, private practices, government institutions and freestanding cancer centers. Our sales and revenue cycle varies based on the customer and can be lengthy, sometimes lasting up to 18 to 24 months or more from initial customer contact to sales contract execution. Following execution of a sales contract, it generally takes nine to 12 months for a customer to customize an existing facility or construct a new vault. After the customer completes its vault customization, it typically takes approximately ninety days for us to install MRIdian and perform on-site testing of the system, including the completion of acceptance test procedures.

We generated product, service and distribution rights revenue of \$0.7 million and \$0.3 million, and had net losses of \$8.4 million and \$12.1 million during the three months ended June 30, 2017 and 2016, respectively. We generated product, service and distribution rights revenue of \$1.9 million and \$5.8 million, and had net losses of \$36.3 million and \$25.5 million during the six months ended June 30, 2017 and 2016, respectively. At June 30, 2017, we had backlog with a total value of \$182.1 million.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- add personnel to support our product development and commercialization efforts;
- continue our research and development efforts;
- seek regulatory approval for MRIdian in certain foreign countries; and,
- operate as a public company.

Accordingly, we may seek to fund our operations through public or private equity, debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop enhancements to and integrate new technologies into MRI-guided radiation therapy systems.

# New Orders and Backlog

New orders are defined as the sum of gross product orders, representing MRIdian contract price, recorded during the period. We define backlog as the accumulation of all orders for which revenue has not been recognized and we consider valid. Backlog includes customer deposits or letters of credit, except when the product order is to a government entity or when the product order is from an existing customer with credit to cover the deposit. Deposits received are recorded as a liability on the balance sheet. Orders may be revised or cancelled according to their terms or upon mutual agreement between the parties. Therefore, it is difficult to predict with certainty the amount of backlog that will ultimately result in revenue. The determination of backlog includes objective and subjective judgment about the likelihood of an order contract becoming revenue. We perform a quarterly review of backlog to verify that outstanding orders in backlog memain valid, and based upon this review, orders that are no longer expected to result in revenue are removed from backlog. Among other criteria, to consider a transaction to be in backlog we must possess an outstanding and effective written agreement for the delivery of a MRIdian signed by a customer and receipt of a minimum customer deposit. For removal of an order from our backlog, the following criteria are considered: any changes in customer or distributor plans or financial conditions; the customer's or distributor's continued intent and ability to fulfill the order contract; changes to regulatory requirements; the status of regulatory approval required in the customer's jurisdiction, if any; and other reasons for potential cancellation of order contracts.

During the six months ended June 30, 2017, we received new orders for MRIdian systems, totaling \$49.6 million. At June 30, 2017, we had backlog with a total value of \$182.1 million.



#### **Components of Statements of Operations**

# Revenue

Product Revenue. Product revenue consists of sales of MRIdian systems, as well as optional components, such as additional planning workstations and body coils.

Following execution of a sales contract, it generally takes nine to 12 months for a customer to customize an existing facility or construct a new vault. Upon the commencement of installation at a customer's facility, it typically takes approximately ninety days to complete the installation and on-site testing of the system, including the completion of acceptance test procedures. On-site training takes approximately one week and can be conducted concurrently with installation and acceptance testing. Sales contracts generally include customer deposits upon execution of the agreement, and in certain cases, additional amounts due at shipment or commencement of installation, and final payment due generally upon customer acceptance.

Revenue recognition for MRIdian systems that we install generally occurs when the customer acknowledges that the system operates in accordance with standard product specifications, the customer accepts the installed unit and title and risk of loss are transferred to the customer. For sales of MRIdian systems that we are not responsible for installation, revenue is recognized when the entire system is delivered and title and risk of loss are transferred to the customer.

Service Revenue. We generally offer maintenance service at no cost to customers to cover parts, labor and maintenance for one to two years. In addition, we offer multi-year, postinstallation maintenance and support contracts that provide various levels of service support, which enables our customers to select the level of on-going support services, including parts and labor, which they require. These post-installation contracts are for a period of one to five years and provide services ranging from 24/7 on-site parts and labor, and preventative maintenance to labor only with a longer response time. We also offer technology upgrades to our MRIdian systems, when and if available, for an additional fee. Service revenue is recognized on a straight-line basis over the term during which the contracted services are provided.

*Distribution Rights Revenue.* In December 2014, we entered into a distribution agreement with Itochu Corporation pursuant to which we appointed Itochu as our exclusive distributor for the promotion, sale and delivery of MRIdian products within Japan. In consideration of the exclusive distribution rights granted, we received \$4.0 million, which was recorded as deferred revenue and starting in August 2016 was recognized as distribution rights revenue on a straight-line basis over the remaining term of the distribution agreement of approximately 8.5 years.

### Cost of Revenue

**Product Cost of Revenue.** Product cost of revenue primarily consists of the cost of materials, installation and services associated with the manufacturing and installation of MRIdian systems, as well as medical device excise tax (in the years to which this is applicable) and royalty payments to the University of Florida Research Foundation. Product cost of revenue also includes lower of cost or market inventory, or LCM, adjustments if the carrying value of the inventory is greater than its net realizable value. For strategic reasons, we initially sold our MRIdian systems prior to December 31, 2015 at prices lower than our projected costs to manufacture and install. As we accumulated materials, installation and other costs for these systems, we regularly assessed the carrying value of the related inventory value and recorded charges, or LCM, adjustments to reduce inventory to the lower of cost and net realizable value. The remaining realizable value of inventory was charged to product cost of revenue as those initial sites were completed and accepted. This resulted in a LCM charge of \$0.2 million for the six months ended June 30, 2016. There was no LCM charge for the six months ended June 30, 2017.

We expect our materials, installation and service costs to decrease as we continue to scale our operations, improve product designs and work with our third-party suppliers to lower costs. We expect to continue to lower costs and increase sales prices as we transition to MRIdian Linac.

Service Cost of Revenue. Service cost of revenue is comprised primarily of personnel costs, training and travel expenses to service and perform maintenance on installed MRIdian systems. Service cost of revenue also includes the costs of replacement parts under maintenance and support contracts.



# **Operating Expenses**

*Research and Development.* Research and development expenses consist primarily of compensation and related costs for personnel, including stock-based compensation, employee benefits and travel. Other significant research and development costs arise from third-party consulting services, laboratory supplies, research materials, medical equipment, computer equipment and licensed technology, and related depreciation and amortization. We expense research and development expenses as incurred. As we continue to invest in improving MRIdian and developing new technologies, we expect our research and development expenses to increase.

Selling and Marketing. Selling and marketing expenses consist primarily of compensation and related costs for our direct sales force, sales management, and marketing and customer support personnel, and include stock-based compensation, employee benefits and travel expenses. Selling and marketing expenses also include costs related to trade shows and marketing programs. We expense selling and marketing costs as incurred. We expect selling and marketing expenses to increase in future periods as we expand our sales force and our marketing and customer support organizations and increase our participation in trade shows and marketing programs.

*General and Administrative*. Our general and administrative expenses consist primarily of compensation and related costs for our operations, finance, human resources, regulatory, and other administrative personnel, and include stock-based compensation, employee benefits and travel expenses. In addition, general and administrative expenses include third-party consulting, legal, audit, accounting services, quality and regulatory functions and facilities costs, and gain or loss on the disposal of property and equipment. We expect our general and administrative expenses to increase as our business grows and as we invest in the development of MRIdian Linac.

#### Interest Income

Interest income consists primarily of interest income received on our cash and cash equivalents.

#### Interest Expense

Interest expense consists primarily of interest and amortization related to our long-term debt entered in 2015 from Capital Royalty II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P., or together with their successors by assignment, CRG, and such loan the CRG Term Loan.

# Other Income (Expense), Net

Other income (expense), net consists primarily of changes in the fair value of the 2017 and 2016 Placement Warrants and foreign currency exchange gains and losses.

The outstanding 2017 and 2016 Placement Warrants are re-measured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded as a component of other income (expense), net.



# **Results of Operations**

The following tables set forth our results of operations for the periods presented:

	Three Moi Jun	Six Mont	ths Ende e 30,		
	 2017	2016	2017	,	2016
		(in tho	usands)		
Revenue:					
Product	\$ _	\$ —	\$ —	\$	5,240
Service	579	299	1,687		515
Distribution rights	119	—	238		_
Total revenue	 698	299	1,925		5,755
Cost of revenue:					
Product	328	139	594		6,066
Service	498	724	1,274		1,325
Total cost of revenue	 826	863	1,868		7,39
Gross margin	 (128)	(564)	57		(1,63
Operating expenses:					
Research and development	3,251	2,964	6,165		6,36
Selling and marketing	1,871	1,402	2,943		2,68
General and administrative	7,463	5,788	14,614		12,10
Total operating expenses:	 12,585	10,154	23,722	_	21,15
Loss from operations	(12,713)	(10,718)	(23,665)		(22,78
Interest income	1	_	2		
Interest expense	(1,792)	(1,377)	(3,529)		(2,459
Other income (expense), net	6,151	(20)	(9,122)		(23)
Loss before provision for income taxes	 (8,353)	(12,115)	(36,314)		(25,48
Provision for income taxes	_	_	_		_
Net loss	\$ (8,353)	\$ (12,115)	\$ (36,314)	\$	(25,48

# Comparison of the Three Months Ended June 30, 2017 and 2016

Revenue

	 Three Mor Jun				
	 2017 2016		2016	016 C	
	 (in tho	usands)		_	
Product	\$ 	\$	—	\$	
Service	579		299		280
Distribution rights	119		_		119
Total revenue	\$ 698	\$	299	\$	399

Total revenue during the three months ended June 30, 2017 increased \$0.4 million compared to the three months ended June 30, 2016. The increase was primarily due to a \$0.3 million increase in service revenue and a \$0.1 million increase in distribution rights revenue during the three months ended June 30, 2017 compared to the three months ended June 30, 2016.

Product Revenue. There was no product revenue recognized during the three months ended June 30, 2017 and 2016.

*Service Revenue.* Service revenue increased \$0.3 million during the three months ended June 30, 2017 compared to the three months ended June 30, 2016 due to increased billings to existing customers, as well as the increased install base, which was eight MRIdian with cobalt systems worldwide during the three months ended June 30, 2017 compared to six MRIdian with cobalt systems worldwide during the three months ended June 30, 2017 compared to six MRIdian with cobalt systems worldwide during the three months ended June 30, 2017 compared to six MRIdian with cobalt systems worldwide during the three months ended June 30, 2016.

*Distribution Rights Revenue*. Distribution rights revenue increased \$0.1 million during the three months ended June 30, 2017 compared to the three months ended June 30, 2016. The increase was due to our receipt of Japanese regulatory approval in August 2016 after which we started recognizing the distribution rights revenue on a straight-line basis over the remaining term of the exclusive distribution agreement with Itochu.

# Cost of Revenue

	 Three Mo Jun				
	 2017		2016		Change
	 (in tho	usands)			
Product	\$ 328	\$	139	\$	189
Service	498		724		(226)
Total cost of revenue	\$ 826	\$	863	\$	(37)

**Product Cost of Revenue.** Product cost of revenue increased \$0.2 million during the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to a write-down of inventory for the three months ended June 30, 2017. Product cost of revenue of \$0.3 million during the three months ended June 30, 2017 was primarily attributable to \$0.2 million of inventory adjustments and \$0.1 million of warehousing costs.

*Service Cost of Revenue.* Service cost of revenue decreased by \$0.2 million during the three months ended June 30, 2017 compared to the three months ended June 30, 2016 primarily due to higher service activities at installed sites for the three months ended June 30, 2016.

#### **Operating Expenses**

	Three Months Ended June 30,					
	2017 2016			2016		Change
	(	_				
Research and development	\$3,	251	\$	2,964	\$	287
Selling and marketing	1,	871		1,402		469
General and administrative	7,	463		5,788		1,675
Total operating expenses	\$ 12,	585	\$	10,154	\$	2,431

**Research and Development.** Research and development expenses during the three months ended June 30, 2017 increased by \$0.3 million, compared to the three months ended June 30, 2016. The higher expense for the current quarter was primarily attributable to a \$0.3 million increase in consulting fees.

Selling and Marketing. Selling and marketing expenses during the three months ended June 30, 2017 increased \$0.5 million, compared to the three months ended June 30, 2016. This increase was primarily attributable to a \$0.4 million increase in trade show expense.

*General and Administrative*. General and administrative expenses during the three months ended June 30, 2017 increased \$1.7 million, compared to the three months ended June 30, 2016. This increase was primarily attributable to a \$0.8 million increase in personnel expense related to a headcount increase from 50 to 69 employees, as well as a \$0.6 million increase in consulting fees.

### Interest Expense



Interest expense increased \$0.4 million during the three months ended June 30, 2017 compared to the three months ended June 30, 2016, primarily due to a higher loan balance as a result of the additional \$15.0 million draw down in May 2016.

### Other Income (Expense), Net

	Three Months Ended June 30,				
	2017 2016				Change
	 (in thou	sands)		_	
Other income (expense), net	\$ 6,151	\$	(20)	\$	6,171

Other income (expense), net during the three months ended June 30, 2017 consisted primarily of a \$6.2 million change in fair value of warrant liability related to the 2017 and 2016 Placement Warrants.

# Comparison of the Six Months Ended June 30, 2017 and 2016

Revenue

		Six Months Ended June 30, 2017 2016				
					Change	
		(in thousands)				
Product	\$	_	\$	5,240	\$	(5,240)
Service		1,687		515		1,172
Distribution rights		238				238
Total revenue	\$	1,925	\$	5,755	\$	(3,830)

Total revenue during the six months ended June 30, 2017 decreased \$3.8 million compared to the six months ended June 30, 2016. The decrease was primarily due to a \$5.2 million decrease in product revenue, partially offset by a \$1.2 million increase in service revenue and a \$0.2 million increase in distribution rights revenue during the six months ended June 30, 2017 compared to the six months ended June 30, 2016.

**Product Revenue.** Product revenue during the six months ended June 30, 2017 decreased \$5.2 million compared to the six months ended June 30, 2016. The decrease was due to no product revenue recognized during the six months ended June 30, 2017 as compared to \$5.2 million of product revenue recognized during the six months ended June 30, 2016 related to the installation of a MRidian with cobalt system at one customer in Amsterdam.

Service Revenue. Service revenue increased \$1.2 million during the six months ended June 30, 2017 compared to the six months ended June 30, 2016 due to increased billings to existing customers, as well as the increased install base, which was eight MRIdian with cobalt systems worldwide during the six months ended June 30, 2017 compared to six MRIdian with cobalt systems worldwide during the six months ended June 30, 2017 compared to six

*Distribution Rights Revenue*. Distribution rights revenue increased \$0.2 million during the six months ended June 30, 2017 compared to the six months ended June 30, 2016. The increase was due to our receipt of Japanese regulatory approval in August 2016 after which we started recognizing the distribution rights revenue on a straight-line basis over the remaining term of the exclusive distribution agreement with Itochu.

# Cost of Revenue

		Six Months Ended June 30, 2017 2016				
					Change	
		(in thousands)				
Product	\$	594	\$	6,066	\$	(5,472)
Service		1,274		1,325		(51)
Total cost of revenue	\$	1,868	\$	7,391	\$	(5,523)

**Product Cost of Revenue.** Product cost of revenue decreased \$5.5 million during the six months ended June 30, 2017 compared to the six months ended June 30, 2016 as no MRIdian systems were delivered and installed during the first six months of fiscal 2017, compared to the delivery and installation of one MRIdian with cobalt system at one customer in Amsterdam during the first six

months of fiscal 2016. Product cost of revenue of \$0.6 million during the six months ended June 30, 2017 was primarily attributable to \$0.3 million of warehousing and shipping costs and \$0.3 million write-down of inventory.

Service Cost of Revenue. Service cost of revenue was flat during the six months ended June 30, 2017, as compared to the six months ended June 30, 2016.

#### **Operating Expenses**

	Six Months Ended June 30,				
	 2017		2016		Change
	 (in thousands)				
Research and development	\$ 6,165	\$	6,363	\$	(198)
Selling and marketing	2,943		2,681		262
General and administrative	14,614		12,108		2,506
Total operating expenses	\$ 23,722	\$	21,152	\$	2,570

**Research and Development.** Research and development expenses during the six months ended June 30, 2017 decreased \$0.2 million, compared to the six months ended June 30, 2016. This decrease was primarily attributable to a \$0.4 million decrease in personnel expenses related to lower average headcount during the six months ended June 30, 2017, and a \$0.1 million decrease in travel expenses, partially offset by a \$0.4 million increase in consulting fees.

Selling and Marketing. Selling and marketing expenses during the six months ended June 30, 2017 increased \$0.3 million, compared to the six months ended June 30, 2016. This increase was primarily attributable to a \$0.4 million increase in trade show expense.

*General and Administrative*. General and administrative expenses during the six months ended June 30, 2017 increased \$2.5 million compared to the six months ended June 30, 2016. This increase was primarily attributable to a \$1.4 million increase in personnel expense related to a headcount increase from 50 to 69 employees, a \$1.1 million increase in consulting fees and a \$0.3 million increase in accounting expense, partially offset by a decrease of \$0.5 million related to legal expense.

# Interest Expense

	Six Months Ended June 30,			
	 2017 2016		Change	
	 (in thousands)			
Interest expense	\$ (3,529) \$	(2,459)	\$	(1,070)

Interest expense increased \$1.1 million during the six months ended June 30, 2017 compared to the six months ended June 30, 2016, primarily due to the higher loan balance as a result of the additional \$15.0 million draw down in May 2016.

# Other Income (Expense), Net

	Six Months Ended June 30,			
	 2017 2016			Change
	(in thousar			
income (expense), net	\$ (9,122) \$	(237)	\$	(8,885)

Other income (expense), net during the six months ended June 30, 2017 consisted primarily of a \$9.0 million change in fair value of warrant liability related to the 2017 and 2016 Placement Warrants.

### Liquidity and Capital Resources

Since our inception in 2004, we have incurred significant net losses and negative cash flows from operations. During the six months ended June 30, 2017 and 2016, we had net losses of \$36.3 million and \$25.5 million, respectively. At June 30, 2017, and December 31, 2016, we had an accumulated deficit of \$284.0 million and \$247.7 million, respectively.



At June 30, 2017 and December 31, 2016, we had cash and cash equivalents of \$53.9 million and \$14.2 million, respectively. To date, we have financed our operations principally through placements of our capital stock, issuances of warrants, issuances of convertible promissory notes, use of term loans and receipts of customer deposits for new orders and payments from customers for systems installed. We may, from time to time, seek to raise capital through a variety of sources, including the public equity market, private equity financing, and/or public or private debt. In May 2016, we drew down the additional \$15.0 million in funds from the CRG term loan. In August and September 2016, we issued common stock and warrants to purchase common stock via the 2016 Private Placement for gross proceeds of \$13.8 million. In January 2017, we issued additional common stock and warrants to purchase common stock via the 2017 Private Placement for gross proceeds of \$26.1 million. During the six months ended June 30, 2017, we also raised aggregate gross proceeds of \$39.5 million through our at-the-market offering program in which we sold 6.5 million shares of our common stock at an average market price of \$6.10 per share. We expect that our existing cash and cash equivalents will enable us to conduct our planned operations for at least the next 12 months.

We could potentially use our available financial resources sooner than we currently expect, and we may incur additional indebtedness to meet future operating needs. Adequate additional funding may not be available to us on acceptable terms or at all. In addition, although we anticipate being able to obtain additional financing, we may be unable to do so. Our failure to raise capital as and when needed could have significant negative consequences for our business, financial condition and results of operations. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth in the section titled "Risk Factors."

The following table summarizes our cash flows for the periods presented (in thousands):

	Six Months Ended June 30,				
	2017 2016				
Cash used in operating activities	\$ (23,883)	\$	(20,570)		
Cash used in investing activities	\$ (776)	\$	(5,760)		
Cash provided by financing activities	\$ 64,388	\$	15,092		

#### **Operating Activities**

We have historically experienced negative cash outflows as we developed MRIdian with cobalt systems, MRIdian Linac and expanded our business. Our primary source of cash flow from operating activities is cash receipts from customers including sales of MRIdian systems and, to a lesser extent, up-front payments from customers. Our primary uses of cash from operating activities are amounts due to vendors for purchased components and employee-related expenditures.

During the six months ended June 30, 2017, cash used in operating activities was \$23.9 million as a result of our net loss of \$36.3 million and a \$1.0 million net change in our operating assets and liabilities, partially offset by aggregate non-cash charges of \$13.5 million. The net change in our operating assets and liabilities was primarily a result of an increase in deferred cost of revenue, an increase in inventory, an increase in deposits on purchased inventory, and an increase in prepaid expenses and other assets, partially offset by an increase in customer deposits and deferred revenue, an increase in accounts payable, and a decrease in accounts receivable. Deferred cost of revenue increased \$7.3 million due to the shipment of additional components for MRIdian systems currently being installed. Inventory and deposits on purchased inventory increased \$7.3 million and \$3.0 million, respectively, in anticipation of upcoming shipments and installations of MRIdian systems. Prepaid expenses and other assets increase \$2.1 million increase in customer deposits no new sales contracts. The net change in our operating assets and liabilities were partially offset by a \$13.4 million increase in customer deposits received from new sales contracts and the commencement of installation for two customers in the first six months of 2017. The \$1.8 million change in accounts payable resulted from the timing of payment and collection. Non-cash charges included a \$9.0 million change in the fair value of warrant liability related to the 2017 and 2016 Placement Warrants, \$1.6 million of amortization of debt discount and interest accrual related to the CRG Term Loan, \$1.8 million of stock-based compensation and \$1.0 million of depreciation and amortization expense.

During the six months ended June 30, 2016, operating activities used \$20.6 million in cash as a result of our net loss of \$25.5 million, partially offset by a \$1.5 million net change in our operating assets and liabilities and aggregate non-cash charges of \$3.4 million. The net change in our operating assets and liabilities was primarily a result of an increase in customer deposits and deferred revenue, accounts payable, deferred cost on shipped components, deposits on purchased inventory and accrued expenses and other long-term liabilities, partially offset by the purchase of inventories and accounts receivable. Customer deposits and deferred revenue increased \$2.2 million during the six months ended June 30, 2016 due to five new sales contracts. The increase in accounts payable of \$1.1 million was the result of timing of payments. Deferred cost decreased \$1.2 million due primarily to revenue recognized for VU University Medical Center in 2016. Deposits on purchased inventory decreased \$1.1 million as a result of the timing of placing orders to vendors. Accrued expenses and other long-term liabilities decreased \$0.7 million due primarily to the timing of invoice receipts for

services, inventory and assets purchased. These decreases were offset by an increase of \$3.9 million of inventory purchase and prepayments in anticipation of upcoming shipments and installations of MRIdian systems as well as a \$0.9 million increase in accounts receivable. Non-cash charges primarily included \$1.2 million in stock-based compensation, \$1.1 million in amortization of debt discount and accrued interest related to the CRG Term Loan, \$0.9 million in depreciation and amortization and \$0.2 million of inventory LCM adjustments related to the reduction of the carrying value of inventory to its net realizable value.

### **Investing Activities**

Cash used in investing activities during the six months ended June 30, 2017 of \$0.8 million resulted from capital expenditures to purchase property and equipment.

Cash used in investing activities during the six months ended June 30, 2016 of \$5.8 million primarily resulted from capital expenditures to purchase property and equipment.

#### **Financing Activities**

During the six months ended June 30, 2017, financing activities provided \$64.4 million in cash from \$26.1 million gross proceeds from the 2017 Private Placement, \$39.5 million gross proceeds from our at-the-market offering program and \$0.2 million from the exercise of stock options, partially offset by offering costs of \$1.1 million for our at-the-market offering program and offering costs of \$0.3 million for our 2017 and 2016 Private Placements.

During the six months ended June 30, 2016, financing activities provided \$15.1 million in cash primarily from the net proceeds of \$15.0 million related to the additional CRG draw down and \$0.1 million from the exercise of stock options.

#### CRG Term Loan

In June 2015, we entered the CRG Term Loan for up to \$50.0 million, of which \$30.0 million was made available to us upon closing with the remaining \$20.0 million to be available on or before June 26, 2016 upon meeting certain milestones. We drew down the first \$30.0 million on the closing date in June 2015. In March 2016, the CRG Term Loan was amended with regard to the conditions for borrowing the remaining \$20.0 million available under the CRG Term Loan. We achieved one milestone at March 31, 2016 and borrowed an additional \$15.0 million in May 2016. In April 2017, we executed another amendment to the CRG Term Loan, which included availability of the existing \$5.0 million tranche at ViewRay's option through June 30, 2017, added a \$15.0 million tranche of borrowing capacity available at ViewRay's option through September 30, 2017, extended the interest-only and payment in-kind period, decreased the combined 2016 and 2017 revenue covenant and included a 1.75% increase to the facility fee. The CRG Term Loan is subject to financial covenants and is collateralized by essentially all our assets and limits our ability with respect to additional indebtedness, investments or dividends, among other things, subject to customary exceptions.

At June 30, 2017, we had \$45.0 million in outstanding debt to CRG, which is repayable through June 26, 2020. The CRG Term Loan bears cash interest at a rate of 12.5% per annum and has an interest-payment-only period through March 31, 2020. We were in compliance with all financial covenants under the CRG Term Loan at June 30, 2017. Additional details regarding the CRG Term Loan are included in the section entitled "Notes to Condensed Consolidated Financial Statements – Note 5 – Debt" in the condensed consolidated financial statements.

# 2017 Private Placement

In January 2017, we entered into a Securities Purchase Agreement pursuant to which we sold an aggregate of 10,323,101 shares of common stock which consists of 8,602,589 shares of common stock and warrants to purchase 1,720,512 shares of common stock, or the 2017 Placement Warrants, for total gross proceeds of \$26.1 million, or the 2017 Private Placement. We completed the closing of the 2017 Private Placement on January 18, 2017. The 2017 Placement Warrants have a per share exercise price of \$3.17 per share, are exercisable after six months and expire seven years from the date of issuance.

#### At-The-Market Offering of Common Stock

In January 2017, we issued a base prospectus which covers the offering, issuance and sale by the registrant of up to a maximum aggregate offering price of \$75.0 million of our common stock, preferred stock, debt securities, warrants, purchase contracts and/or units; and we entered into a sales agreement with FBR Capital Markets & Co., or FBR, under which we may sell up to \$25.0 million of our common shares pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act. FBR acted as sales agent on a best efforts basis and used commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between FBR and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement. In April 2017, we agreed to sell up to an additional \$25.0 million of our common stock in accordance with the terms of a sales agreement with FBR and pursuant to an at-the-market offering program in accordance with Rule 415(a)(4) under the Securities Act.



FBR is entitled to compensation of up to 3.0% of the gross sales price per share sold. In connection with the sale of our common stock on our behalf, FBR is deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of FBR is deemed to be underwriting commissions or discounts. The Company has also agreed to provide indemnification and contribution to FBR with respect to certain liabilities, including liabilities under the Securities Act.

As of June 30, 2017, we sold an aggregate of approximately 6.5 million shares of our common stock at an average market price of \$6.10 per share, resulting in aggregate gross proceeds of approximately \$39.5 million.

# **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as of June 30, 2017 or December 31, 2016.

# **Critical Accounting Policies and Estimates**

Our condensed consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates.

There have been no significant changes to our accounting policies during the six months ended June 30, 2017, as compared to the critical accounting policies described in our Annual Report on Form 10-K filed with the SEC on March 17, 2017. We believe that the accounting policies discussed in that Annual Report are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

# JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the JOBS Act. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

# **Recently Issued and Adopted Accounting Pronouncements**

We review new accounting standards to determine the expected financial impact, if any, that the adoption of each such standard will have. For the recently issued accounting standards that we believe may have an impact on our consolidated financial statements, see the section entitled "Notes to Condensed Consolidated Financial Statements – Note 2 – Summary of Significant Accounting Policies" in the condensed consolidated financial statements.

# Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

# Item 4. Controls and Procedures

# **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our CEO and CFO have concluded that as of June 30, 2017, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission (SEC), and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosures.

### **Changes in Internal Control**

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the second quarter of 2017 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

# PART II—OTHER INFORMATION

# Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm business.

We are currently not aware of any pending legal court proceedings to which we are a party or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by any governmental authority.

# Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. The risks described below are not the only risks facing the Company.

# **Risks Related to Our Business and Strategy**

# We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. These factors may raise substantial doubt about our ability to continue as a going concern.

We have historically incurred substantial net losses, including net losses of \$36.3 million and \$25.5 million during the six months ended June 30, 2017 and 2016, respectively. We expect our net losses to continue as a result of ongoing investments in product development and expansion of our commercial operations, including increased manufacturing, and sales and marketing. These net losses have had, and will continue to have, a negative impact on our working capital, total assets and stockholders' equity. Because of the numerous risks and uncertainties associated with our development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability could harm our business, financial condition, results of operations and cash flows.

Further, the net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance quarter-to-quarter and year-to-year, due to factors including the timing of product approval, commercial ramp, clinical trials, any litigation that we may file or that may be filed against us, the execution of collaboration, licensing or other agreements and the timing of any payments we make or receive thereunder. These factors may raise substantial doubt about our ability to continue as a going concern.

# If clinicians do not widely adopt MRI-guided radiation therapy or MRIdian Linac fails to achieve and sustain sufficient market acceptance, we will not generate sufficient revenue and our growth prospects, financial condition and results of operations could be harmed.

Our MRI-guided radiation therapy system, MRIdian, may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or allow us to achieve or maintain profitability. Widespread adoption of MRI-guided radiation therapy depends on many factors, including acceptance by clinicians that MRI-guided radiation therapy is clinically-effective and cost-effective in treating a wide range of cancers, demand by patients for such treatment, successful education of clinicians on the various aspects of this therapeutic approach and coverage and adequate reimbursement for procedures performed using MRI-guided radiation therapy. If we are not successful in conveying to clinicians and hospitals that MRI-guided radiation therapy provides equivalent or superior radiation therapy compared to existing technologies, we may experience reluctance or refusal on the part of clinicians and hospitals to order, and third-party payors to pay for performing, a treatment in which MRIdian is utilized. Our ability to achieve commercial market acceptance for MRIdian or any other future products also depends on the strength of our sales, marketing and distribution organizations. In addition, our expectations regarding clinical benefits and cost savings from using MRIdian may not be accurate. These hurdles may make it difficult to demonstrate to physicians, hospitals and other healthcare providers that MRIdian is an appropriate option for radiation therapy, may be superior to available radiation therapy systems and may be more cost-effective than alternative technologies.

Furthermore, we may encounter difficulty in gaining inclusion in cancer treatment guidelines and gaining broad market acceptance by healthcare providers, third-party payors and patients. Healthcare providers may have difficulty in obtaining adequate reimbursement from government and/or third-party payors for cancer treatment, which may negatively impact adoption of MRIdian.



#### We may not be able to generate sufficient revenue from the commercialization of MRIdian Linac and MRIdian with cobalt to achieve and maintain profitability.

We rely entirely on the commercialization of MRIdian Linac and MRIdian with cobalt to generate revenue. During the six months ended June 30, 2017, we recognized revenue of \$1.9 million from service revenue at certain customer sites and distribution rights revenue from Itochu. In order to successfully commercialize MRIdian Linac and MRIdian with cobalt, we will need to continue to expand our marketing efforts to develop new relationships and expand existing relationships with customers, to receive clearance or approval for MRIdian systems in additional countries, to achieve and maintain compliance with all applicable regulatory requirements and to develop and commercialize new features for MRIdian systems. We cannot assure you that we will be able to achieve or maintain profitability. If we fail to successfully commercialize MRIdian systems, we may never receive a return on the substantial investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance that we have made, as well as further investments we intend to make, which may cause us to fail to generate revenue and gain economies of scale from such investments.

In addition, potential customers may decide not to purchase MRIdian systems, or our customers may decide to cancel orders due to changes in treatment offerings, research and product development plans, difficulties in obtaining coverage or reimbursement for MRI-guided radiation therapy treatment, complications with facility build-outs, utilization of MRI-guided radiation therapy or other cancer treatment methods developed by other parties, lack of financing or the inability to obtain or delay in obtaining a certificate of need from state regulatory agencies or zoning restrictions, all of which are circumstances outside of our control.

In addition, demand for MRIdian systems may not increase as quickly as we predict, and we may be unable to increase our revenue levels as we expect. Even if we succeed in increasing adoption of MRIdian systems by hospitals and other healthcare providers, maintaining and creating relationships with our existing and new customers and developing and commercializing new features for MRIdian systems, we may not be able to generate sufficient revenue to achieve or maintain profitability.

# We are an early, commercial-stage company and have a limited history commercializing MRIdian, which may make it difficult to evaluate our current business and predict our future performance.

We are an early, commercial-stage company and have a limited operating history. We commenced operations as a Florida corporation in 2004 and subsequently reincorporated in Delaware in 2007. However, we did not begin commercial operations until 2013. Our limited history commercializing MRIdian may make it difficult to evaluate our current business and predict our future performance. Any assessment of our profitability or prediction about our future success or viability is subject to significant uncertainty. We have encountered and will continue to encounter risks and difficulties frequently experienced by early, commercial-stage companies in rapidly evolving industries. If we do not address these risks successfully, our business could be harmed.

# If MRIdian does not perform as expected, or if we are unable to satisfy customers' demands for additional product features, our reputation, business and results of operations will suffer.

Our success depends on the market's confidence that MRIdian can provide reliable, high-quality MRI-guided radiation therapy. At June 30, 2017, there were only eight MRIdian with cobalt systems installed, and one other MRIdian with cobalt systems has been delivered and is expected to be installed and start treating patients in early 2018, and therefore we have limited statistics regarding the efficacy or reliability of MRIdian. We believe that our customers are likely to be particularly sensitive to product defects and errors, including functional downtime that limits the number of patients that can be treated using the system or a failure that is costly to repair. For example, in January 2014, we initiated a correction of the system at Washington University in St. Louis due to a defect we identified in an advanced software feature in the treatment planning system of MRIdian. We promptly updated our software to resolve this defect and notified the U.S. Food and Drug Administration, or FDA, of this correction. We cannot assure that similar product defects or other errors will not occur in the future. This could also include the mistreatment of a patient with MRIdian caused by human error on the part of MRIdian's operators or prescribing physicians or as a result of a machine malfunction. We may be subject to regulatory enforcement action or legal claims arising from any defects or errors that may occur. Any failure of MRIdian to perform as expected could harm our reputation, business and results of operations.

Furthermore, the Cobalt-60 radioactive materials used in MRIdian with cobalt systems decay over time, which eventually leads to longer treatment times and may have a negative impact on the number of patients a hospital can treat during a day. U.S. regulations require inspection of Cobalt-60 every five years, at which time customers may consider replacing the Cobalt-60 source. This natural decay or a customer's failure to replace the Cobalt-60 may have a negative impact on MRIdian performance.

In addition, our customers are technologically well informed and at times have specific demands or requests for additional functionality. If we are unable to meet those demands through the development of new features for MRIdian or future products, or those new features or products do not function at the level that our customers expect, or we are unable to increase throughput as expected or we are unable to obtain regulatory clearance or approval of those new features or products, where applicable, our reputation, business and results of operations could be harmed.

# The safety and efficacy of MRIdian with cobalt and MRIdian Linac for certain uses is not currently supported by long-term clinical data, and MRIdian with cobalt and MRIdian Linac may therefore be less safe and effective than initially anticipated.

MRIdian with cobalt and MRIdian Linac have received premarket clearance by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. This process is typically shorter and generally requires the submission of less supporting documentation than the FDA's premarket approval process and does not always require long-term clinical studies. Additionally, to date, we have not been required to complete long-term clinical studies in connection with the sale of MRIdian with cobalt or MRIdian Linac outside the United States. As a result, we currently lack the breadth of published long-term clinical data supporting the efficacy of MRIdian with cobalt or MRIdian Linac and the benefits each offers that might have been generated in connection with other marketing authorization processes. In addition, because MRIdian with cobalt has only been on the market since 2013, and only one MRIdian Linac has been installed at a customer site, we have limited complication or patient survival rate data with respect to treatment using the systems. If future patient studies or clinical testing do not support our belief that MRIdian with cobalt or MRIdian Linac offers a more advantageous treatment for a wide variety of cancer types, market acceptance of these systems could fail to increase or could decrease and our business could be harmed.

If we choose to, or are required to, conduct additional studies, such studies or experience could reduce the rate of coverage and reimbursement by both public and private third-party payors for procedures that are performed with MRIdian with cobalt or MRIdian Linac, slow the market adoption of our product by physicians, significantly reduce our ability to achieve expected revenues and prevent us from becoming profitable. In addition, if future studies and experience indicate that MRIdian with cobalt or MRIdian Linac causes unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls or suspension or withdrawal of FDA clearance, and our reputation with physicians, patients and healthcare providers may suffer.

There have been instances of patients' severe injury or death due to either operator misuse or system malfunction with other radiation therapy systems. If our redundant safety systems do not operate as we expect, or were misused by operators, MRIdian with cobalt or MRIdian Linac could severely injure or kill a patient. This could result in lawsuits, fines or damage to our reputation.

# We may be delayed or prevented from implementing our long-term sales strategy if we fail to educate clinicians and patients about the benefits of MRIdian.

In order to increase revenue, we must increase awareness of the range of benefits that we believe MRIdian offers to both existing and potential customers, primarily cancer clinicians. An important part of our sales strategy involves educating and training clinicians to utilize the entire functionality of MRIdian. In addition, we must further educate clinicians about the ability of MRIdian to treat a wide range of cancer types effectively and efficiently. If clinicians are not properly educated about the use of MRIdian for radiation therapy, they may be unwilling or unable to take advantage of the full range of functionality that we believe MRIdian offers, which could have a negative impact on MRIdian sales. Clinicians may decide that certain tumors can be adequately treated using traditional radiation therapy systems, notwithstanding the benefits of MRIdian. Cobalt-60 systems have historically had certain limitations which have resulted in an increased use of linacs and a decreased use of Cobalt-60 systems. These historical limitations included imprecise radiation dose applications and an unsharp, wide-beam edge. If we do not adequately educate physicians about the functionality of our Cobalt-60 system to address some of the limitations that have affected Cobalt-60 systems, we may be delayed or prevented from implementing our long-term sales strategy. We must also succeed in educating clinicians about the potential for reimbursement for procedures performed using MRIdian. In addition, we need to increase awareness of MRIdian among potential patients, who are increasingly educated about cancer treatment options and therefore impact adoption of new technologies by clinicians. If our efforts to expand sales of MRIdian in the long-term are not successful, our business and results of operations will be harmed.

# We may not be able to gain the support of leading hospitals and key opinion leaders, or to publish the results of our clinical trials in peer-reviewed journals, which may make it difficult to establish MRIdian as a standard of care and achieve market acceptance.

Our strategy includes developing relationships with leading hospitals and key opinion leaders in our industry. If these hospitals and key industry thought leaders determine that MRIdian is not clinically effective or that alternative technologies are more effective, or if we encounter difficulty promoting adoption or establishing MRIdian as a standard of care, our ability to achieve market acceptance of MRIdian could be significantly limited.

We believe that publication of scientific and medical results in peer-reviewed journals and presentation of data at leading conferences are critical to the broad adoption of MRIdian. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving MRIdian sufficiently novel or worthy of publication.

# We have a limited history of manufacturing, assembling and installing MRIdian in commercial quantities and may encounter related problems or delays that could result in lost revenue.

The pre-installation manufacturing processes for MRIdian include sourcing components from various third-party suppliers, subassembly, assembly, system integration and testing. We must manufacture and assemble MRIdian in compliance with regulatory requirements and at an acceptable cost in order to achieve and maintain profitability. We have only a limited history of manufacturing, assembling and installing MRIdian and, as a result, we may have difficulty manufacturing, assembling and installing MRIdian in sufficient quantities in a timely manner. To manage our manufacturing and operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to a year in advance and enter into purchase orders on the basis of these requirements. Our limited manufacturing history may not provide us with sufficient data to accurately predict future component demand and to anticipate our costs effectively.

Further, we have experienced and may in the future experience delays in obtaining components from suppliers and installing our systems at customer sites associated with contractor timing delays, which could impede our ability to manufacture, assemble and install MRIdian on our expected timeline. Alternatively, delays or postponements of scheduled customer installations could lead to excess inventory due to our limited flexibility to postpone or delay component shipments from suppliers. Accordingly, we may encounter difficulties in production of MRIdian, including problems with quality control and assurance, component supply shortages or surpluses, increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements. In addition, if we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenue will also be limited and our reputation could be harmed. If we cannot achieve the required level and quality of production, we may need to make changes in our supply chain or enter into licensing and other arrangements with third parties who possess sufficient manufacturing facilities and capabilities in compliance with regulatory requirements. Even if we outsource necessary production or enter into licensing or other third-party arrangements, the associated cost could reduce our gross margin and harm our financial condition and results of operations.

# We have limited experience in marketing and selling MRIdian, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of MRIdian and we may never generate sufficient revenue to achieve or sustain profitability.

We have limited experience in marketing and selling MRIdian. We have only been selling MRIdian since 2013 and have only eight MRIdian with cobalt systems installed at June 30, 2017, and one other MRIdian with cobalt system that has been delivered and expected to start treating patients in early 2018, and have only treated patients since early 2014. In addition, we have installed only one MRIdian Linac to date. MRIdian is a new technology in the radiation therapy systems sector and our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. We believe it is necessary to maintain a sales force that includes sales representatives with specific technical backgrounds that can support our customers' needs. We will also need to attract and develop sales and marketing personnel with industry expertise. Competition for such employees is intense and we may not be able to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of MRIdian and we may never generate sufficient revenue to achieve or sustain profitability.

# The long sales cycle and low unit volume sales of MRIdian, as well as other factors, may contribute to substantial fluctuations in our operating results and stock price and make it difficult to compare our results of operations to prior periods and predict future financial results.

Because of the relatively small number of systems we expect to install in any period, each installation of a MRIdian will represent a significant percentage of our revenue for a particular period. Additionally, customer site construction, certificate of need and additional zoning and licensing permits are often required in connection with the sale of a MRIdian, any of which may further delay the installation process. When we are responsible for installing a system, we only recognize revenue from the sale of a MRIdian after the system has been installed and accepted by the customer. When a qualified third party is responsible for the installation, we only



recognize revenue when title is transferred. Therefore, if we do not install a MRIdian or transfer title when anticipated, our operating results will vary significantly from our expectations. We have had experiences with customers postponing installation of MRIdian systems due to delays in facility build-outs, which are often lengthy and costly processes for our existing and potential customers. In addition, if our customers delay or cancel purchases, we may be required to modify or terminate contractual arrangements with our suppliers, which may result in the loss of deposits. Due to future fluctuations in revenue and costs, as well as other potential fluctuations, you should not rely upon our operating results in any particular period as an indication of future performance. In addition to the other risks described herein, the following factors may also contribute to these fluctuations:

- timing of when we are able to recognize revenue associated with sales of MRIdian;
- actions relating to regulatory matters, including regulatory requirements in some states for a certificate of need prior to the installation of a MRIdian;
- delays in shipment due to, for example, unanticipated construction delays at customer locations where MRIdian is to be installed, labor disturbances or natural disasters;
- delays in our manufacturing processes or unexpected manufacturing difficulties;
- timing of the announcements of contract executions or other customer and commercial developments;
- timing of the announcement, introduction and delivery of new products or product features by us and by our competitors;
- timing and level of expenditures associated with expansion of sales and marketing activities and our overall operations;
- fluctuations in our gross margins and the factors that contribute to such fluctuations, as described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Quarterly Report;
- our ability to effectively execute on our strategic and operating plans;
- the extent to which MRIdian gains market acceptance and the timing of customer demand for MRIdian;
- our ability to protect our proprietary rights and defend against third-party challenges;
- disruptions in the supply or changes in the costs of raw materials, labor, product components or transportation services; and
- changes in third-party coverage and reimbursement, government regulation or in a customer's ability to obtain financing.

These factors are difficult to forecast and may contribute to fluctuations in our reported revenue and results of operations and variation from our expectations, particularly during the periods in which our sales volume is low. Any such fluctuations in our financial results may cause volatility in our stock price.

Each MRIdian is a major capital equipment item and is subject to a lengthy sales cycle. The time from initial customer contact to execution of a contract can take 18 to 24 months or more. Following execution of a contract, it generally takes nine to 12 months for a customer to customize an existing facility or construct a new vault, which is inclusive of the time from when a customer places the order to when the system is delivered. During this time, facilities support and transitioning, as well as permitting, are typically required, which can take several months. The time required to customize an existing facility prior to installation, including modifications of a standard vault to accommodate an MRI, is currently three months. If a customer does not have an existing vault available, it may take longer to construct a new vault. In some cases customers may request installation for a date later in the future to meet their own clinical or business requirements. Upon the commencement of installation at a customer's facility, it typically takes approximately ninety days to complete the installation and on-site testing of the system, including the completion of acceptance test procedures. If a small number of customers defer installation of a MRIdian for even a short period, recognition of a significant amount of revenue may be deferred to a subsequent period. Because our operating costs are relatively fixed, our inability to recognize revenue in a particular period may impact our profitability in that period. As a result, the inability to recognize revenue in a particular period may make it difficult to compare our operating results with prior periods. The price of a MRIdian requires a portion of our target customers to obtain outside financing before committing to purchase a MRIdian. Such financing may be difficult for our customers to obtain in any given period, if at all. The requirement of site-specific modifications or construction may also delay adoption or overall demand. In addition, while we believe that

### A large portion of our revenue in any given reporting period will be derived from a small number of contracts.

Given that a significant portion of the purchase price for MRIdian will generally be recognized as revenue in a single reporting period, we expect a small number of contracts in any given reporting period to account for a substantial portion of our revenue in any such period, and we expect this trend to continue. Any decrease in revenue from these contracts could harm our operating results. Accordingly, our revenue and results of operations may vary from period to period. We are also subject to credit risk associated with the concentration of our accounts receivable from our customers. If one or more of our customers at any given time were either to terminate their contracts with us, cease doing business with us or to fail to pay us on a timely basis, our business, financial condition and results of operations could be harmed.

### The payment structure we use in our customer arrangements may lead to fluctuations in operating cash flows in a given period.

While our customers typically provide a deposit upon entering into a sales contract with us, the substantial majority of the payment owed for a MRIdian is not due until the time of shipment of a MRIdian or following final acceptance by the customer upon installation. If we miss targeted shipments or our customers do not actively work towards completing installation, our receipt of payments and our operating cash flows could be impacted. In addition, if customers do not adhere to our payments terms, our operating cash flows could be impacted in any given period. Due to these fluctuations in operating cash flows and other potential fluctuations, you should not rely upon our operating results in any particular period as an indication of future performance.

### Amounts included in backlog may not result in actual revenue and are an uncertain indicator of our future earnings.

We define backlog as the accumulation of all orders for which revenue has not been recognized and we consider valid. The determination of backlog includes, among other factors, our subjective judgment about the likelihood of an order becoming revenue and the regulatory approval required in the customer's jurisdiction, if any. Our judgments in this area have been, and in the future may be, incorrect and we cannot assure you that, for any order included in backlog, we will recognize revenue with respect to such order. In addition, orders can be delayed for a number of reasons, many of which are beyond our control, including supplier delays which may cause delays in our manufacturing process, customer delays in commencing or completing construction of its facility, delays in obtaining zoning or other approvals and delays in obtaining financing. We may not be aware of these delays affecting our suppliers and customers and as a result may not consider them when evaluating the contemporaneous effect on backlog. Moreover, orders generally do not have firm dates by when a customer must take delivery, and certain customers may not provide a deposit or letter of credit with the contract, either of which could allow a customer greater flexibility to delay the order without cancelling the contract. We believe the introduction of MRIdian Linac will increase the number of orders we receive and accelerate the conversion of orders in backlog; however, customers with orders in the backlog currently may delay their installation. Further, our backlog could be reduced due to cancellation of orders by customers. Should a cancellation occur, our backlog and anticipated revenue would be reduced unless we were able to replace such order. Reported reductions in our backlog could negatively impact our future results of operations or the price of our common stock.

We evaluate our backlog at least quarterly to determine if the orders continue to meet our criteria for inclusion in backlog. Our criteria include an outstanding and effective written agreement for the delivery of a MRIdian signed by customers, receipt of a minimum customer deposit or a letter of credit, except when the product order is to a government entity or when the product order is from an existing customer with credit to cover the deposit, any changes in customer or distributor plans or financial conditions, the customer's or distributor's continued intent and ability to fulfill the order contract, changes to regulatory requirements, the status of regulatory approval required in the customer's jurisdiction, if any, or reasons for cancellation of order contracts. We may adjust our reported backlog as a result of these factors and due to changes in our judgment about the likelihood of completing an order contract, the timing of shipment of a system for particular projects or the status of our regulatory approval in a particular jurisdiction, where applicable. Projects we once categorized as included within our backlog may be removed if we determine, based on the aforementioned criteria, that a particular order or orders no longer constitute valid backlog. In addition, one or more of our contracts have in the past and may in the future contribute to a material portion of our backlog in any one year. Because revenue will not be recognized until we have fulfilled our obligations to a customer, there may be a significant amount of time from signing a contract with a customer or shipping a system and revenue recognition. We cannot assure you that our backlog will result in revenue on a timely basis or at all, or that any cancelled contracts will be replaced.

# Our ability to achieve profitability depends substantially on increasing our gross margins by reducing costs of MRIdian and improving our economies of scale, which we may not be able to achieve.

We are not, and never have been, profitable. The MRIdian purchase contracts we have entered into to date have been at a range of selling prices. Generally, earlier contracts have been at lower prices and more recent contracts have been at higher prices. Our earlier contracts resulted in negative gross margins. Our ability to enter into contracts at higher selling prices depends on a number of factors including:

- our ability to achieve commercial market acceptance for our system;
- the pricing of competitors' cancer therapy systems;
- availability of coverage and adequate reimbursement by commercial and government payors; and
- our ability to manufacture and install our systems in a timely and cost-effective manner.

We bear the risk of warranty claims on all products we supply, including equipment and component parts manufactured by third parties. We cannot assure you that we will be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in additional costs to us. There is a risk that warranty claims made against us will exceed our warranty reserve and our business, financial condition and results of operations could be harmed.

Our customer contracts provide that our customers commit to purchase a MRIdian for a fixed price, and a MRIdian will generally not be delivered for 11 to 15 months. In some circumstances, delivery can be postponed several months due to customer delays related to construction, vault preparation or concurrent facility expansion, and the cost of product supplies may increase significantly in the intervening time period. In addition, inflation may generally reduce the real value of the purchase price payable upon the achievement of future progress payment milestones. Either of these occurrences could cause our gross margins to decline or cause us to lose money on the sale of a MRIdian.

Moreover, our gross margins may decline in a given period due in part to significant replacement rates for components, resulting in increased warranty expense, negative profit margins on service contracts and customer dissatisfaction. If we are unable to reduce our product costs and improve or maintain quality and reliability, our gross margin may be negatively impacted. Additionally, we may face increased demands for compensation from customers who are not satisfied with the quality and reliability of MRIdian, which could increase our service costs or require us to issue credits against future service payments and negatively impact future product sales. For example, we may have to extend a warranty period due to our failure to meet up-time requirements. We are currently implementing programs to reduce the cost of our MRIdian product; however, we may be unable to reduce our product cost as quickly as we anticipate and in some instances may experience increases in costs from our suppliers.

Even if we are able to implement cost reduction and quality improvement efforts successfully, our service operations may remain unprofitable given the relatively small size and geographic dispersion of our installed base, which prevents us from achieving significant economies of scale for the provision of services. If we are unable to realize increasingly higher gross margins on our MRIdian systems, we may never become profitable.



#### We may not be able to develop new products or enhance the capabilities of MRIdian to keep pace with our industry's rapidly changing technology and customer requirements.

Our industry is characterized by rapid technological changes, new product introductions and enhancements and evolving industry standards. Our business prospects depend on our ability to develop new products and applications for our technology in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of MRIdian. New technologies, techniques or products could emerge that might offer better combinations of price and performance than MRIdian systems. The market for radiation therapy treatment products is characterized by rapid innovation and advancement in technology. It is important that we anticipate changes in technology and market demand, as well as physician, hospital and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis. Nevertheless, we must carefully manage our introduction of new products. If potential customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have no experience in managing product transitions. If we do not successfully innovate and introduce new technology into our anticipated product lines, or effectively manage the transitions of our technology to new product offerings, our business, financial condition and results of operations could be harmed.

# We face competition from numerous companies, many of whom have greater resources than we do or offer alternative technologies at lower prices than our MRIdian systems, which may make it more difficult for us to achieve significant market penetration and profitability.

The market for radiation therapy equipment is characterized by intense competition and pricing pressure. In particular, we compete with a number of existing therapy equipment companies, including Elekta AB, Varian Medical Systems, Inc. and Accuray Incorporated. Many of these competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a result, these companies may be better positioned than we are to spend more aggressively on marketing, sales, intellectual property and other product initiatives and research and development activities. In addition, we may compete with certain MRI-linear accelerator research projects that are currently in development and may be commercialized, including projects by the University of Alberta's Cross Cancer Institute and a partnership of the University of Sydney, Ingham Institute and the University of Queensland.

Existing technologies may offer certain advantages compared to the MRI technology used by our MRIdian system. For example, computed tomography, or CT, is known to hold certain potential advantages over MRI technology for use in radiation therapy. Diagnostic CT is currently the most widely adopted imaging modality for treatment planning, and can be used to directly measure the electron density of patient tissues, which enables more accurate dose computation. In addition, CT imaging provides superior imaging of bones and boney anatomy than MRI, which is advantageous when imaging those structures for planning and alignment for treatment. Finally, CT is a less expensive technology than MRI and might be preferred by customers seeking a lower cost solution.

Our current competitors or other potential competitors may develop new products for the treatment of cancer at any time. In addition, competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. If we are unable to develop products that compete effectively against the products of existing or future competitors, our future revenue could be negatively impacted. Some of our competitors may compete by changing their pricing model or by lowering the price of their therapy systems. If these competitors' pricing techniques are effective, it could result in downward pressure on the price of all therapy systems. If we are unable to maintain or increase our selling prices in the face of competition, we may not improve our gross margins.

In addition to the competition that we face from technologies performing similar functions to MRIdian, competition also exists for the limited capital expenditure budgets of our customers. A potential purchaser may be forced to choose between two items of capital equipment. Our ability to compete may also be negatively impacted when purchase decisions are based largely upon price, because MRIdian is a premium-priced system relative to other capital expenditures and alternative radiation therapy technologies. In certain circumstances, a purchaser may decide that an alternative radiation therapy system priced below MRIdian may be sufficient for its patient population given the relative upfront cost savings. In addition to the cost of the MRIdian system, U.S. customers are required to inspect the Cobalt-60 every five years, and our customers may incur significant costs associated with the inspection, replacement and disposal of Cobalt-60.

#### Negative press regarding MRI-guided radiation therapy for the treatment of cancer could harm our business.

The comparative efficacy and overall benefits of MRI-guided radiation therapy are not yet well understood, particularly with respect to certain types of cancer. These types of reports could negatively impact the market's acceptance of MRI-guided radiation therapy, and therefore our ability to generate revenue could be negatively impacted.

### We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not realize the anticipated benefits of any acquisition, strategic alliance or joint venture.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions or joint ventures, we may choose to issue shares of common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

#### **Risks Related to Our Reliance on Third Parties**

### We rely on a limited number of third-party suppliers and, in some cases, sole suppliers, for the majority of our components, subassemblies and materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on several sole suppliers, including Japan Superconductor Technology, Inc., Siemens AG, Best Theratronics Ltd., Tesla Engineering Limited and Quality Electrodynamics, LLC, for certain components of MRIdian. These sole suppliers, and any of our other suppliers, may be unwilling or unable to supply components of MRIdian to us reliably and at the levels we anticipate or are required by the market. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute. Any such interruption could harm our reputation, business, financial condition and results of operations.

If we are required to transition to new third-party suppliers for certain components of MRIdian, we believe that there are only a few other manufacturers that are currently capable of supplying the necessary components. In addition, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Furthermore, if we are required to change the manufacturer of a critical component of MRIdian, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture MRIdian in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of MRIdian or could require that we modify the design of MRIdian. If the change in manufacturer results in a significant change to MRIdian, a new 510(k) clearance from the FDA or similar international regulatory authorization may be necessary, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for MRIdian in a timely manner or cost-effectively.

We cannot assure you that we will be able to secure alternative equipment and materials and utilize such equipment and materials without experiencing interruptions in our workflow. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and components we require for MRIdian, our reputation, business, financial condition and results of operations could be negatively impacted.

In addition, we are in early stages of developing suppliers for components that are specific to MRIdian Linac. The inability of these suppliers to produce reliable components and to sufficiently scale up manufacturing could harm our ability to install MRIdian Linac systems in a timely or cost-effective manner.

#### We depend on third-party distributors to market and distribute MRIdian in international markets.

A significant portion of our backlog is composed of international sales, and we expect a significant amount of our revenue to come from international sales. We depend on a number of distributors for sales in these international markets. We cannot control the efforts and resources our third-party distributors will devote to marketing MRIdian. Our distributors may not be able to successfully market and sell MRIdian and may not devote sufficient time and resources to support the marketing and selling efforts that enable the product to develop, achieve or sustain market acceptance. In some jurisdictions, we rely on our distributors to manage the regulatory process, and we are dependent on their ability to do so effectively. In addition, if a dispute arises with a distributor or if a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor, to seek appropriate regulatory approvals and to train such distributor's personnel to market MRIdian, and our ability to sell and service MRIdian in the region formerly serviced by such terminated distributor could be harmed. Any of our distributors could become insolvent or otherwise become unable to pay amounts owed to us when due. Any of these factors could reduce our revenue from affected international markets, increase our costs in those markets or damage our reputation. In addition, if we are unable to attract additional international distributors, our international revenue may not grow.

#### Failures by our third-party distributors to timely deliver or properly install MRIdian could harm our reputation.

We rely on arrangements with third-party distributors for sales and installation of MRIdian in international markets. As a result of our reliance on third-party distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these distributors become unsatisfactory, including the failure of such distributors to properly install MRIdian, we may experience delays in meeting our customers' product demands and we may not be able to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver, install or service products in a timely manner may damage our reputation and could cause us to lose current or potential customers.

# We rely on third parties to store our inventory and to perform spare parts shipping and other logistics functions on our behalf. A failure or disruption with our logistics providers could harm our business.

Customer service is a critical element of our sales strategy. Third-party logistics providers store most of our spare parts inventory in depots around the world and perform a significant portion of our spare parts logistics and shipping activities. If any of our logistics providers suffers an interruption in its business or experiences delays, disruptions or quality control problems in its operations or we have to change and qualify alternative logistics providers for our spare parts, shipments of spare parts to our customers may be delayed and our reputation, business, financial condition and results of operations could be negatively harmed.

### If third-party payors do not provide coverage and adequate reimbursement to our customers, it could negatively impact sales of MRIdian.

In the United States, hospitals and other healthcare providers who purchase MRIdian generally rely on third-party payors to reimburse all or part of the costs and fees associated with the treatments performed with our system. Accordingly, sales of MRIdian depend, in part, on whether coverage and adequate reimbursement for standard planning methodologies are available to our customers from third-party payors, such as government healthcare insurance programs, including the Medicare and Medicaid programs, private insurance plans, health maintenance organizations and preferred provider organizations. In general, third-party payors in the United States have become increasingly cost-conscious, which has limited coverage for, and reimbursement of, certain procedures such as MRI-guided radiation therapy. Third-party payors have also increased utilization controls related to the use of products such as ours by healthcare providers.

Furthermore, there is no uniform policy on coverage and reimbursement for MRI-guided radiation therapy among third-party payors. Payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of MRIdian.



The Medicare program is increasingly used as a model for how private payors and other governmental payors develop their coverage and reimbursement policies for medical services and procedures. Medicare coverage of advanced and conventional radiation therapies using MRIdian currently varies depending upon the geographic location in which the services are provided. CMS has not adopted national coverage determination for such therapies that would determine coverage nationally. In the absence of such a national coverage determination, Medicare Administrative Contractors, or MACs, with jurisdiction over specific geographic regions have the discretion to determine whether and when the use of MRI-guided radiation therapy will be considered medically necessary and covered in their respective regions. A number of MACs have adopted or proposed local coverage determinations covering MRI-guided radiation therapy. However, these local coverage determinations do not ensure that coverage will be available for MRI-guided radiation therapy for all types of cancer as the coverage policies may limit coverage to only certain types of cancer.

Even if MRI-guided radiation therapy is covered and reimbursed by third-party payors, adverse changes in payors' coverage and reimbursement policies that affect MRIdian could harm our ability to market and sell MRIdian. We cannot be sure that third-party payors will reimburse our customers for procedures using MRIdian at a level that will enable us to achieve or maintain adequate sales and price levels for MRIdian. Without coverage and adequate reimbursement from third-party payors, the market for MRIdian may be limited.

Third-party payors regularly update reimbursement amounts and also, from time to time, revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and ambulatory surgery centers for the radiation treatments performed with MRIdian. Because the cost of MRIdian generally is recovered by the healthcare provider as part of the payment for performing the treatment and not separately reimbursed, these updates could directly impact the demand for MRIdian. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula.

Historically, under the Medicare Physician Fee Schedule, or MPFS, when the application of the formula resulted in lower payment, Congress passed interim legislation to prevent the reductions. In April 2015, however, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, was signed into law, which repealed and replaced the statutory formula for Medicare payment adjustments to physicians. MACRA provided a permanent end to the annual interim legislative updates that had previously been necessary to delay or prevent significant reductions to payments under the Medicare Physician Fee Schedule. MACRA provided for a 0.5% update from July 1, 2015 through December 31, 2015, and for each calendar year through 2019, after which there will be a 0% annual update each year through 2025. In addition, MACRA required the establishment of the Merit-Based Incentive Payment System, beginning in 2019, under which physicians may receive performance-based payment incentives or payment reductions based on their performance with respect to clinical quality, resource use, clinical improvement activities and meaningful use of electronic health records. MACRA also required the Centers for Medicare & Medicaid Services, or CMS, beginning in 2019, to provide incentive payments for physicians and other eligible professionals that participate in alternative payment models, such as accountable care organizations, that emphasize quality and value over the traditional volume-based fee-for-service model. It is unclear what impact, if any, MACRA will have on our business and operating results, but any resulting decrease in payment may result in reduced demand for our services.

CMS also publishes annual updates to HOPPS. These payments are bundled amounts received by our hospital customers for hospital outpatient services, including conventional radiation therapy and IMRT, which may result in lower reimbursement to our customers for procedures performed using MRIdian.

In addition, in 2016, CMS implemented changes to the reimbursement of certain services performed in the freestanding center setting which, to date, have not had any material impact on the services delivered with our products.

Any significant cuts in reimbursement rates or changes in reimbursement methodology or administration for MRI-guided radiation therapy, or concerns or proposals regarding further cuts or changes in methodology or administration, could further increase uncertainty, influence our customers' decisions, reduce demand for MRIdian, cause customers to cancel orders and impact our revenue and harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that adequate reimbursement will be made available with respect to MRIdian under any foreign reimbursement system.

# Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including insider trading and non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants and commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales,

marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

### **Risks Related to Our Financial Condition and Capital Requirements**

### We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new features for MRIdian and new products and expand our operations.

Based on our current business plan, we believe that our existing cash and cash equivalents, together with cash receipts from sales of MRIdian systems and the plan to raise additional capital from various sources from time to time, will enable us to conduct our planned operations for at least the next 12 months. If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including because of lower demand for MRIdian as a result of lower than currently expected rates of reimbursement from commercial third-party payors and government payors or due to other risks described herein, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to increase market adoption of MRIdian and address competitive developments;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for MRIdian systems;
- fund development and marketing efforts of any future products and technologies, including MRIdian Linac, or additional features to then-current products;
- acquire, license or invest in new technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve gross margins;
- our rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of MRIdian;
- the cost of research and development activities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to MRIdian.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to certain components contained within MRIdian, or grant licenses on terms that are not favorable to us.

### We have incurred, and will continue to incur significant costs as a result of operating as a public company and our management expects to continue to devote substantial time to public company compliance programs.

As a public company, we have incurred, and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or SEC, and the NASDAQ Stock Market. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have devoted, and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, and further regulations will continue to cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring additional accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our principal estatements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, our common stock may not be able to remain eligible for quotation on The NASDAQ Global Market.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could harm our business.

### Compliance with recently adopted rules of the SEC relating to "conflict minerals" may require us and our suppliers to incur substantial expense and may result in disclosure by us that certain minerals used in products we manufacture or contract to manufacture are not "DRC conflict free."

Section 1502 of the Dodd-Frank Act required the SEC to promulgate rules requiring disclosure by a public company of any "conflict minerals" (tin, tungsten, tantalum and gold) necessary to the functionality or production of a product manufactured or contracted to be manufactured by the public company. The SEC adopted final rules in 2012 that took effect at the end of January 2013. Because we manufacture or contract to manufacture a product that contains tin, tungsten, tantalum or gold, we will be required under these rules to determine whether those minerals are necessary to the functionality or production of MRIdian and, if so, conduct a country of origin inquiry with respect to all such minerals. If any such minerals may have originated in the Democratic Republic of the Congo, or DRC, or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those

conflict minerals to determine if they originated in one of the covered countries and, if so, whether they financed or benefited armed groups in the covered countries. Disclosures relating to the products that may contain conflict minerals, the country of origin of those minerals and whether they are "DRC conflict free" must be provided in a Form SD (and accompanying conflict minerals report, if required, to disclose the diligence undertaken by us in sourcing the minerals and our conclusions relating to such diligence). If we are required to submit a conflict minerals report, after 2015 that report must be audited by an independent auditor pursuant to existing government auditing standards. Compliance with this new disclosure rule may be very time-consuming for management and our supply chain personnel (as well as time-consuming for our suppliers) and could involve the expenditure of significant amounts of money by us and them. Disclosures, mandated by this new rule, which can be perceived by the market to be "negative," may cause customers to refuse to purchase MRIdian. We cannot assure you that the cost of compliance with the rule will not harm our business, financial condition or results of operations.

#### Our loan and security agreement with Capital Royalty Partners II L.P., Capital Royalty Partners II - Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P., or together with their successors by assignment, CRG, contains operating and financial covenants that may restrict our business and financing activities.

At June 30, 2017, we had \$45.0 million in outstanding debt to CRG. Borrowings under our loan and security agreement with CRG are secured by substantially all of our personal property, including our intellectual property. Our loan and security agreement restricts our ability to, among other things:

- dispose of or sell our assets;
- make material changes in our business;
- merge with or acquire other entities or assets;
- incur additional indebtedness;
- create liens on our assets;
- pay dividends;
- make investments; and
- pay off subordinated indebtedness.

The operating and financial restrictions and covenants in our loan and security agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under our loan and security agreement. If not waived, future defaults could cause all of the outstanding indebtedness under our loan and security agreement to become immediately due and payable and terminate all commitments to extend further credit.

If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

#### Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

At December 31, 2016, we had federal net operating loss carryforwards, or NOLs, of \$210.4 million, which begin to expire in the year ending December 31, 2024, and \$131.1 million related to state net operating loss carryforwards, which begin to expire in the year ending December 31, 2019. We also had federal and state research and development tax credit carryforwards of \$2.9 million and \$255 thousand, respectively, which expire at various dates through the year ending December 31, 2024. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We believe we have experienced at least one ownership change in the past. We are currently analyzing the tax impacts of such ownership change on our federal NOLs and credit carryforwards. Future changes in our stock ownership, including this or future offerings, as well as other changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be limited under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future tax benefits of such assets.



#### We face risks related to the current global economic environment, which could delay or prevent our customers from obtaining financing to purchase MRIdian and implement the required facilities, which could harm our business, financial condition and results of operations.

The state of the global economy continues to be uncertain. The current global economic conditions and uncertain credit markets and concerns regarding the availability of credit pose a risk that could impact customer demand for MRIdian, as well as our ability to manage normal commercial relationships with our customers, suppliers and creditors, including financial institutions. If the current global economic environment deteriorates, our business could be negatively affected.

### Risks Related to Administrative, Organizational and Commercial Operations and Growth

### We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We anticipate growth in our business operations. This future growth could create a strain on our organizational, administrative and operational infrastructure, including manufacturing operations, quality control, technical support and customer service, sales force management and general and financial administration. We may not be able to maintain the quality of or installation timelines of MRIdian or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

# If we are unable to support demand for MRIdian and our future products, including ensuring that we have adequate resources to meet increased demand, or we are unable to successfully manage the evolution of our MRI-guided radiation technology, our business could be harmed.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for manufacturing, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. We will also need to purchase additional equipment, some of which can take several months or more to procure, set up and validate, and increase our manufacturing, maintenance, software and computing capacity to meet increased demand. We cannot assure you that any of these increases in scale, expansion of personnel, purchase of equipment or process enhancements will be successfully implemented.

# The loss of our President and Chief Executive Officer or Chief Scientific Officer or our inability to attract and retain highly skilled scientists and salespeople could negatively impact our business.

Our success depends on the skills, experience and performance of our President and Chief Executive Officer, Chris A. Raanes, and our Chief Scientific Officer and founder, James F. Dempsey, Ph.D. The individual and collective efforts of these employees will be important as we continue to develop MRIdian and as we expand our commercial activities. The loss or incapacity of existing members of our executive management team could negatively impact our operations if we experience difficulties in hiring qualified successors. Our executive officers have employment agreements; however, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time.

Our commercial, manufacturing and research and development programs and operations depend on our ability to attract and retain highly skilled engineers, scientists and technicians. We may not be able to attract or retain qualified managers, engineers, scientists and technicians in the future due to the competition for qualified personnel among medical device businesses, particularly in California and Ohio. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, manufacturing and research and development programs. All of our employees are at-will, which means that either we or the employee may terminate his or her employment at any time.

### If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale and use of MRIdian could lead to the filing of product liability claims were someone to allege that MRIdian did not effectively treat the conditions its users were intending to target, caused other serious medical conditions or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon the information we provide in the ordinary course of our business activities, such as customer support or operating instructions. A product liability claim could result in substantial damages and be costly and time-consuming for us to defend.



We maintain product liability insurance, but the amounts of insurance coverage may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could lead to regulatory investigations, product recalls or withdrawals, damage our reputation or cause current vendors, suppliers and customers to terminate existing agreements and potential customers and partners to seek other suppliers of radiation therapy systems, any of which could negatively impact our results of operations.

### Sanctions against Russia, and Russia's response to those sanctions, could harm our business, financial condition and results of operations.

Due to Russia's recent military intervention in Ukraine and annexation of Crimea, the United States and the European Union, or EU, have imposed sanctions on certain individuals and one financial institution in Russia and have proposed the use of broader economic sanctions. In response, Russia has imposed entry bans on certain U.S. lawmakers and officials. We have engaged a third-party distributor and are currently in discussions with potential customers in Russia. If the United States or the EU were to impose sanctions on Russian businesses, or if Russia were to take retaliatory action against U.S. companies operating in Russia, our sales and marketing efforts in Russia could be harmed.

#### The results of the United Kingdom's referendum on withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom, or the U.K., elected to withdraw from the EU in a national referendum, also known as Brexit. In March 2017, the U.K. Prime Minister began the process for the U.K. to withdraw from the EU. Negotiations are expected to commence to determine the future terms of the U.K.'s relationship with the EU, including, among other things, the terms of trade between the U.K. and the EU. The effects of Brexit will depend on any agreements the U.K. reaches to retain access to EU markets either during a transitional period or more permanently. Nevertheless, the referendum has created significant uncertainty about the future relationship between the U.K. and the EU, including with respect to the laws and regulations that will apply as the U.K. determines which EU laws to replace or replicate in the event of a withdrawal, including those governing manufacturing, labor, environmental, data protection/privacy, competition, medical sales and advertising and other matters applicable to the medical device industry. The referendum has log given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market inquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and results of operations and results of operations.

#### We face risks associated with our international business.

In addition to our marketing and sales of MRIdian in the United States, we also market MRIdian in North America, Europe and the Pacific Rim, with contracts signed with customers and distributors in Taiwan, Turkey, Korea, China, the United Arab Emirates, Hong Kong, Japan, Italy and Russia. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- having to comply with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and antimoney laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market MRIdian and future product enhancements for MRIdian including but not limited to, MRIdian Linac;
- changes in uncertainties relating to foreign rules and regulations that may impact our ability to sell MRIdian, perform services or repatriate profits to the United States;
- tariffs, export or import restrictions, restrictions on remittances abroad, imposition of duties or taxes that limit our ability to move MRIdian out of these countries or interfere with the import of essential materials into these countries;
- limitations on our ability to enter into cost-effective arrangements with distributors of MRIdian, or at all;
- fluctuations in foreign currency exchange rates;
- imposition of limitations on production, sale or export of MRI-guided radiation therapy systems in foreign countries;
- imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;

- differing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- imposition of differing labor laws and standards;
- economic, political or social instability in foreign countries and regions;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

We expect that we will begin expanding into other target markets; however, we cannot assure you that our expansion plans will be realized, or if realized, be successful. We expect each market to have particular regulatory and funding hurdles to overcome and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business. If we expend significant time and resources on expansion plans that fail or are delayed, our reputation, business and financial condition may be harmed.

### Our results may be impacted by changes in foreign currency exchange rates.

Currently, the majority of our international sales contracts are denominated in U.S. dollars. We pay certain of our suppliers in a foreign currency under the terms of their supply agreements, and we may pay other suppliers in the future in foreign currency. As a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making MRIdian less competitive in international markets or our costs could increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

### We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior that is required by U.S. laws or by corporate policies. We are subject to the risk that we, our U.S. employees or our employees located in other jurisdictions or any third parties such as our sales agents and distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA and the Bribery Act of 2010, or the U.K. Anti-Bribery Act. In addition, we operate in certain countries in which the government may take an ownership stake in an enterprise and such government ownership may not be readily apparent, thereby increasing potential anti-corruption law violations. Any violation of the FCPA and U.K. Anti-Bribery Act or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations. In addition, we have internal ethics policies with which we require our employees to comply in order to ensure that our business is conducted in a manner that our management deems appropriate. If these anti-corruption laws or internal policies were to be violated, our reputation and operations could also be substantially harmed. Further, detecting, investigating and resolving actual or alleged violations is expensive and can consume significant time and attention of our senior management.

# We are subject to export restrictions and laws affecting trade and investments, and the future sale of our MRIdian system may be further limited or prohibited in the future by a government agency or authority.

As a global company headquartered in the United States, our MRIdian system is subject to U.S. laws and regulations that may limit, restrict or require a license to export (and reexport from other countries) our MRIdian system and related product and technical information due to its use of hazardous materials, including Cobalt-60, lead and depleted uranium. We are also subject to the export and import laws of those foreign jurisdictions to which we sell or from which we re-export our MRIdian system. Compliance with these laws and regulations could significantly limit our operations and our sales in the future and failure to comply, even indirectly, could result in a range of penalties, including restrictions on exports of our MRIdian system for a specified time period, or forever, and severe monetary penalties. In certain circumstances, these restrictions may affect our ability to interact with any of our future foreign subsidiaries and otherwise limit our trade with third parties, including suppliers and customers, operating inside and outside the United States. In addition, if we introduce new products, we may need to obtain licenses or approvals from the United States and other governments to ship them into foreign countries. Failure to receive the appropriate approvals may mean that our commercial efforts and expenses related to such efforts may not result in any revenue, which could harm our business.



#### We depend on our information technology systems, and any failure of these systems could harm our business.

We depend on information technology and telecommunications systems for significant elements of our operations. We have developed propriety software for the management and operation of MRIdian by our customers. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, contract management, regulatory compliance and other infrastructure operations. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including sales and marketing, manufacturing operations, customer service support, billing and reimbursement, research and development activities and general administrative activities.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems or those used by our third-party service providers could prevent us from providing maintenance and support services to our customers, conducting research and development activities and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could harm our business.

#### Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

We conduct a significant portion of our activities, including administration and data processing, at facilities located in California, Ohio and other areas that have experienced major earthquakes, tornadoes and other natural disasters. A major earthquake, tornado or other disaster (such as a major fire, hurricane, flood, tsunami, volcanic eruption or terrorist attack) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' damaged manufacturing facilities; these delays could be lengthy and costly. If any of our customers' facilities are negatively impacted by a disaster, shipments of MRIdian could be delayed. Additionally, customers may delay purchases of MRIdian until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could delay or prevent blocking shipment from these ports could delay or prevent shipments and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases, such as ebola or influenza, could harm our operations, those of our suppliers and customers and the ability to travel, which could harm our business, financial condition and results of operations.

#### **Risks Related to Intellectual Property**

# Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling MRIdian or impact our stock price.

There is considerable intellectual property litigation and contested patent disputes in the medical device area. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize MRIdian in its current or an updated form, launch new products and enter new markets, we expect that competitors may claim that MRIdian infringes their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. Although we are presently unaware of any basis by which a third-party would be justified in making such claims, in the future, we may receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Third parties may have obtained, and may in the future obtain, patents under which such third parties may claim that the use of our technologies constitutes patent infringement.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include contested post-grant proceedings such as oppositions, inter partes review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office or foreign patent offices. The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.



We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against any of these claims or in any of such proceedings. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a negative impact on our cash position and stock price. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement or misappropriation against us, we may be required to pay damages, obtain one or more licenses from third parties or be prohibited from selling certain products, all of which could have a negative impact on our cash position, business and financial condition.

In addition, we may be unable to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in product introductions while we attempt to develop alternative methods or products. Defense of any lawsuit or adversarial proceeding or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of MRIdian or future products could impact our ability to grow and maintain profitability and harm our business.

# If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect MRIdian, others could compete against us more directly, which could harm our business, financial condition and results of operations.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Specifically, we hold a license to four issued U.S. patents, 15 issued foreign patents (eight of which were issued in Great Britain, Germany, France and the Netherlands as a result of two applications filed and allowed through the European Patent Office), one pending U.S. application and five pending foreign applications as of July 18, 2017. We own an additional 18 issued U.S. patents, 30 issued foreign patents (10 of which were issued in Great Britain, Germany, France, Italy and the Netherlands as a result of two applications filed and allowed through the European Patent Office), 22 pending U.S. applications and 80 pending foreign applications as of July 18, 2017. Assuming all required fees are paid, individual patents or patent applications owned or licensed by us will expire between 2021 and 2037. We also have a joint ownership interest with Case Western Reserve University in one issued patent and one U.S. application. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect MRIdian, any additional features we develop for MRIdian or any new products. Other parties may have developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. U.S. patents and patent applications may also be subject to supplemental examination or contested post-grant proceedings such as inter partes review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in district court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. These proceedings could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own or exclusively license may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to commercialize MRIdian.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If any of these developments were to occur, they each could have a negative impact on our sales.

Our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering MRIdian are invalidated or found unenforceable, our financial position and results of operations could be negatively impacted. In addition, if a court found that valid, enforceable patents held by third parties covered MRIdian, our financial position and results of operations could be harmed.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect MRIdian or any other products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize MRIdian on a substantial scale before our relevant patents expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

# If we are not able to meet the requirements of our license agreement with the University of Florida Research Foundation, Inc., we could lose access to the technologies licensed thereunder and be unable to manufacture, market or sell MRIdian.

We license patents and patent applications from the UFRF, covering our combination of MRI and radiation therapy, and other key technologies, incorporated into MRIdian under a license agreement that requires us to pay royalties to UFRF. In addition, the license agreement obligates us to pursue an agreed development plan and to submit periodic reports and restricts our ability to take actions to defend the licensed patents. The license agreement terminates when the underlying patents expire in 2025, although UFRF has the right to unilaterally terminate the agreement if we do not meet our royalty payment obligations, including minimum royalty payments of \$50,000 per quarter, or if we fail to satisfy other development and commercialization obligations related to our utilization of the technology. If UFRF were to terminate the agreement or if we were to otherwise lose the ability to exploit the licensed patents, our competitive advantage could be reduced, we may not be able to find a source to replace the licensed technology and we may be prevented from selling MRIdian. The license agreement reserves to UFRF the initial right to defend or prosecute any claim arising with respect to the licensed technology. If UFRF does not vigorously defend the patents, we may be required to engage in expensive patent litigation to enforce our rights and any competitive advantage we have based on the licensed technology may be hampered. Any of these events could harm our business, financial condition and results of operations.

#### Recent changes in U.S. patent laws may limit our ability to obtain, defend or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for companies to challenge the validity of competitor patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could therefore increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Moreover, if such challenges occur with regard to our UFRF-licensed patents, as indicated above, we have only limited rights to control the defense.

#### If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. For example, significant elements of MRIdian are based on unpatented trade secrets and know-how that are not publicly disclosed. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

#### We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

#### Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's technology, we may be limited in our ability to capitalize on the market potential of these intellectual property rights. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business.

#### Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employeer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

### **Risks Related to Regulatory Matters**

# MRIdian and our operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

MRIdian is a medical device that is subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance, or possible PMA approval. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market MRIdian for the provision of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment is indicated. An element of our strategy is to continue to upgrade MRIdian to incorporate new software and hardware enhancements. We expect that such upgrades, as well as other future modifications, may require new 510(k) clearance; however, future upgrades may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In August 2016, we filed for FDA 510(k) clearance for the MRIdian Linac and received FDA clearance in February 2017. In June 2017, we received 510(k) clearance to market RayZR, our high resolution MLC.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that MRIdian is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared product on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) clearance process, the FDA initiated an evaluation, and in January 2011, announced several proposed actions intended to reform the clearance process. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. More recently, the FDA issued draft guidance in August 2016 intended to assist industry in determining when a change to a previously 510(k)-cleared product requires a new premarket notification to be submitted to the FDA. Once finalized, this guidance will replace the 1997 guidance on the same topic. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell MRIdian and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of MRIdian; and
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze will remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget, or OMB, in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An understaffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In order to sell MRIdian in member countries of the European Economic Area, or EEA, MRIdian must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to MRIdian, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the



intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. We have the right to affix the CE mark to MRIdian with cobalt since November 2014 and MRIdian Linac since September 2016. If we fail to remain in compliance with applicable European laws and directives, we would not be able to continue to affix the CE mark to MRIdian Linac, which would prevent us from selling MRIdian with cobalt or MRIdian Linac within the EEA. We will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell MRIdian with cobalt and MRIdian Linac.

# Modifications to MRIdian and our future products may require new 510(k) clearances or PMA approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market MRIdian for the provision of stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body where radiation treatment is indicated. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA.

In February 2017, we received a 510(k) premarket clearance from the FDA to market the MRIdian system that contains MRIdian Linac. As we make other changes or enhancements to our MRIdian system, we will need to determine whether additional FDA clearance is required or not. However, the FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to MRIdian in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) clearance process may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) notification for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. For example, the FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) for modifications or changes to a previously cleared device and issued draft guidance in August 2016 to assist device manufacturers in making this determination. When finalized, this guidance will replace the FDA's long-standing guidance issued in 1997 on the same topic. We cannot guarantee whether the FDA's approach in future guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. The FDA continues to review its 510(k) clearance process, which could result in additional changes to regulatory requirements or guidance documents, which could increase the costs of compliance or restrict our ability to maintain current clearances.

# If treatment guidelines for cancer radiation therapies change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for MRIdian.

If treatment guidelines for cancer radiation therapies or the standard of care evolves, we may need to redesign MRIdian and seek new clearances or approvals from the FDA for MRIdian. Our 510(k) clearance from the FDA is based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of MRIdian could be diminished and our business could suffer. For example, competition by other forms of cancer treatment, in particular personalized medicine approaches in targeting drugs and biologics, could reduce the use of radiation therapy as a standard of care in certain indications.



# The misuse or off-label use of MRIdian with cobalt or MRIdian Linac may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Clinicians or physicians may misuse MRIdian with cobalt or MRIdian Linac or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If MRIdian with cobalt or MRIdian Linac is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. In addition, any of the events described above could harm our business.

In addition, MRIdian with cobalt and MRIdian Linac have been cleared by the FDA for specific treatments. We train our marketing and direct sales force to not promote MRIdian with cobalt and MRIdian Linac for uses outside of the FDA-cleared indications for use, known as "off-label uses." For example, MRIdian with cobalt and MRIdian Linac have not been indicated for diagnostic use. We cannot, however, prevent a physician from using MRIdian with cobalt or MRIdian Linac off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use MRIdian with cobalt or MRIdian Linac off-label. Furthermore, the use of MRIdian with cobalt or MRIdian Linac for indications other than those cleared by the FDA or authorized by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

# Our MRIdian systems may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our MRIdian systems, or a recall of our MRIdian systems either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that MRIdian may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of MRIdian. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of MRIdian or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. For example, in January 2014, we initiated a correction of the system at Washington University in St. Louis due to a defect we identified in an advanced software feature in the treatment planning system of MRIdian. We promptly updated our software to resolve this defect and notified the FDA of this correction, but the FDA has not formally classified this correction as a recall. We cannot assure you that similar product defects or other errors will not occur in the future. Recalls involving MRIdian could be particularly harmful to our business, financial condition and results of operations because it is currently our only product.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for MRIdian in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

# If we or our distributors do not obtain and maintain international regulatory registrations or approvals for MRIdian, we will not be able to market and sell MRIdian outside of the United States.

Sales of our devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling MRIdian or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. We have applied for and received regulatory approval in Europe, the United Arab Emirates, Taiwan, Korea, Japan, China and Italy, where regulatory approval is required in addition to the CE mark. We currently have orders to deliver MRIdian to customers in the United States, Taiwan, China, Korea, Italy, Germany, Belgium, the Netherlands, the United Kingdom, France and the United Arab Emirates, which we include in our backlog due to the status of each sales order and our regulatory approval processes in these countries. Complying with foreign regulatory approvals in each country in which we plan to market MRIdian or that we will be able to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations or approvals may significantly differ from FDA requirements. If we modify MRIdian, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell MRIdian in that country, which could harm our business.

Regulatory clearance or approval by the FDA does not ensure marketing authorization by regulatory authorities in other countries, and authorization for marketing by one or more foreign regulatory authorities does not ensure marketing authorization will be granted by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining marketing authorization in one country may have a negative effect on the regulatory process in others.

## We must manufacture MRIdian in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of MRIdian must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of MRIdian. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. MRIdian is also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

We cannot guarantee that we or any subcontractors will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of MRIdian. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with MRIdian or manufacturing processes could result in, among other things:

- warning letters or untitled letters;
- fines, injunctions or civil penalties;
- suspension or withdrawal of approvals or clearances;
- seizures or recalls of MRIdian;
- total or partial suspension of production or distribution;
- administrative or judicially imposed sanctions;
- FDA's refusal to grant pending or future clearances or approvals for MRIdian;
- clinical holds;
- refusal to permit the import or export of MRIdian; and
- criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of MRIdian. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

# Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for MRIdian or to produce, market or distribute MRIdian after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices or the reimbursement thereof. In addition, the FDA or Nuclear Regulatory Commission, or NRC, regulations and guidance are often revised or reinterpreted by the FDA or NRC in ways that may significantly affect our business and our MRIdian systems. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) clearance process, the FDA initiated an evaluation, and in January 2011, announced several proposed actions intended to reform the clearance process. In addition, as part of FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance or approval. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute MRIdian or future products. For example, the FDA. Once finalized, this guidance will replace the 1997 guidance on the same topic. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- additional testing prior to obtaining clearance or approval;
- changes to manufacturing methods;
- recall, replacement or discontinuance of MRIdian or future products; or
- additional record keeping.

Any of these changes could require substantial time and cost and could harm our business and our financial results.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation and the In-Vitro Diagnostic Medical Devices Regulation, which repeal and replace the Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation and In-Vitro Diagnostic Devices Regulation, among other things, are intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and in vitro diagnostic devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will, however, only become applicable three years after publication while the In-Vitro Diagnostic Medical Devices Regulation will only become applicable five years after publication. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are
  placed on the market.

These modifications may have an impact on the way we conduct our business in the EEA.

## Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers' activities and our own activities involve the controlled storage, use and disposal of hazardous materials, including Cobalt-60, lead and depleted uranium. We and our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We



currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials, but we do reserve funds to address these claims at both the federal and state levels. Although we believe that our safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations.

# If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information.

In particular, the U.S. Department of Health and Human Services has promulgated rules governing the privacy and security of individually identifiable health information under the Health Insurance Portability and Accountability Act of 1996, or HIPPA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. These privacy and security rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information, limiting most uses and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose, and requiring administrative, technical and physical safeguards. Although we are not a covered entity under HIPAA, we have entered into agreements with certain covered entity customers, such as health care providers, under which we are considered to be a "business associate" under HIPAA. As a business associate, we are contractually bound and may also be directly responsible under HIPAA, as amended by HITECH, to implement policies, procedures and reasonable and appropriate security measures to protect any individually identifiable health information we may create, receive, maintain or transmit on behalf of covered entities. We may also be subject to state laws protecting the confidentiality of medical records where those state laws have stricter provisions than HIPAA. Our failure to protect or secure any individually identifiable health information received on behalf of customers could subject us to civil and criminal liability, including the imposition of monetary fines, and adverse publicity, and could harm our business and impair our ability to attract new customers.

#### We are subject to federal and state fraud and abuse laws and health information privacy and security laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our relationships with providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing
  remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which
  payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual
  knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services
  resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- HIPAA, which created federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false
  statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or
  specific intent to violate it to have committed a violation;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any thirdparty payor, including commercial insurers;
- state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and
- state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

These laws, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. We have a variety of arrangements with our customers that could implicate these laws. Due to the breadth of these laws, the narrowness of statutory exceptions and safe harbors available, and the range of interpretations to which they are subject to, it is possible that some of our current or future practices might be challenged under one or more of these laws. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business, financial condition and results of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could negatively impact our ability to operate our business and our results of operations.

### Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the Affordable Care Act:

- requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, which, due to
  subsequent legislative amendments, has been suspended from January 1, 2016 to December 31, 2017, and, absent further legislative action, will be reinstated
  starting January 1, 2018;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- establishes an Independent Payment Advisory Board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

We expect that the new presidential administration and U.S. Congress will seek to modify, repeal, or otherwise invalidate all or certain provisions of, the Affordable Care Act. Since taking office, President Trump has continued to support the repeal of all or portions of the Affordable Care Act. In January 2017, the House and Senate passed a budget resolution that authorizes congressional committees to draft legislation to repeal all or portions of the Affordable Care Act and permits such legislation to pass with a majority vote in the Senate. President Trump also recently issued an executive order in which he stated that it is his administration's policy to seek the prompt repeal of the Affordable Care Act and directed executive departments and federal agencies to waive, defer, grant exemptions from, or delay the implementation of the provisions of the Affordable Care Act to the maximum extent permitted by law. There is still uncertainty with respect to the impact President Trump's administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include the Budget Control Act of 2011, which resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken, as well as the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.



We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for MRIdian or additional pricing pressure.

### **Risks Related to Ownership of Our Common Stock**

### The price of our common stock may be volatile and may be influenced by numerous factors, some of which are beyond our control.

Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- commercial success and market acceptance of MRIdian;
- success of our competitors in discovering, developing or commercializing products;
- ability to commercialize or obtain regulatory approval for MRIdian, or delays in commercializing or obtaining regulatory approval;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;
- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- business disruptions caused by earthquakes, tornadoes or other natural disasters; and
- changes in the manner that investors and securities analysts who provide research on us to the marketplace analyze the value of our common stock.

In addition, the stock markets in general, and the markets for medical device companies in particular, have experienced extreme volatility that have been often unrelated to the operating performance of the issuer. These broad market fluctuations may negatively impact the price or liquidity of our common stock. In the past, when the price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business.

# We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An "emerging growth company" can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended

transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

#### Future sales of our common stock or securities convertible or exchangeable for our common stock may cause our stock price to decline.

If our existing stockholders or optionholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any applicable legal restrictions on resale lapse, the price of our common stock could decline. The perception in the market that these sales may occur could also cause the price of our common stock to decline. At June 30, 2017, we have outstanding a total of 58,915,205 shares of common stock.

In addition, based on the number of shares subject to outstanding awards under our 2008 Stock Option and Incentive Plan, or 2008 Plan, the number of shares subject to outstanding awards or available for issuance under our 2015 Equity Incentive Award Plan, or 2015 Plan, and our 2015 Employee Stock Purchase Plan, or 2015 ESPP, at June 30, 2017, 3,202,296 shares, 6,739,123 shares and 1,103,481 shares, respectively, of common stock that are either subject to outstanding options, outstanding but subject to vesting or reserved for future issuance under the 2008 Plan, 2015 Plan and 2015 ESPP will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act, which includes, for shares held by directors, executive officers and other affiliates, volume limitations under Rule 144 under the Securities Act. The 2015 Plan or 2015 ESPP are sold, or if it is perceived that they will be sold, by the award recipients in the public market, the price of our common stock could decline.

# You may experience dilution of your ownership interests because of the future issuance of additional shares of our common or preferred stock or other securities that are convertible into or exercisable for our common or preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders and the purchasers of our common stock offered hereby. We are authorized to issue an aggregate of 300,000,000 shares of common stock and 10,000,000 shares of "blank check" preferred stock. We may issue additional shares of our common stock or other securities that are convertible into or exercisable for our common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of our common stock may create downward pressure on the trading price of the common stock. We may need to raise additional capital in the near future to meet our working capital needs, and there can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with these capital raising efforts, including at a price (or exercise prices) below the price you paid for your stock.

# Our operating results for a particular period may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our operating results will be affected by numerous factors, including:

- variations in the level of expenses related to MRIdian with cobalt, MRIdian Linac or future development programs;
  - level of underlying demand for MRIdian and any other products we develop;
  - addition or termination of clinical trials or funding support;
  - receipt, modification or termination of government contracts or grants, and the timing of payments we receive under these arrangements;
  - our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
  - any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; and
- regulatory developments affecting MRIdian with cobalt, MRIdian Linac or our competitors.

If our operating results for a particular period fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that comparisons of our financial results from various reporting periods are not necessarily meaningful and should not be relied upon as an indication of our future performance.



### Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock at June 30, 2017, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 69% of our common stock. Accordingly, these stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise.

### Provisions of our charter documents or Delaware law could delay or prevent an acquisition of the company, even if such an acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal
  of a director;
- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;
- an advance notice requirement for stockholder proposals and nominations;
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to
  amend specific provisions of our certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of the company. Furthermore, our certificate of incorporation specifies that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in such action.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

## We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. In addition, our current loan and security agreement with CRG contains, and our future loan



arrangements may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

#### If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on the company. If no securities or industry analysts commence coverage of the company, the price for our common stock could be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of the company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

The risks above do not necessarily comprise all of those associated with an investment in the Company. This Quarterly Report contains forward-looking statements that involve unknown risks, uncertainties and other factors that may cause the actual results, financial condition, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set out above.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Not applicable.

#### Item 3. Defaults Upon Senior Securities.

Not applicable.

### Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

Not applicable.

### Item 6. Exhibits.

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.



### 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 hereunto duly authorized.

Dated: August 7, 2017

Dated: August 7, 2017

### VIEWRAY, INC.

By: /s/ Chris A. Raanes Name: Chris A. Raanes Title: Chief Executive Officer (Principal Executive Officer)

By: /s/ Ajay Bansal

Name: Ajay Bansal Title: Chief Financial Officer (Principal Financial Officer)

Exhibit		Incorporated by Reference			Filed	
Number	Description	Form	Exhibit	Date Filed	Herewith	
2.1	Agreement and Plan of Merger and Reorganization, dated as of July 23, 2015, by and among ViewRay Inc., Acquisition Sub and ViewRay Technologies, Inc.	S-1/A	2.1	12/16/15		
3.1	Amended and Restated Certificate of Incorporation.	S-1/A	3.1	12/16/15		
3.2	Amended and Restated Bylaws.	S-1/A	3.2	12/16/15		
10.1	Amendment No. 2 to Term Loan Agreement, dated as of April 12, 2017, by and among ViewRay Technologies, Inc. (formerly known as ViewRay Incorporated), Capital Royalty Partners II L.P., Capital Royalty Partners II (Cayman) L.P., Parallel Investment Opportunities Partners II L.P. and CRG Issuer 2015-1.		Х			
31.1	Certification of Principal Executive Officer Required under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				Х	
31.2	Certification of Principal Financial Officer under Securities Exchange Act Rule 13a-14(a) and 15d-14(a).				Х	
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).				Х	
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. 1350 and Securities Exchange Act Rule 13a-14(b).			Х		
101	Interactive Data Files of Financial Statements and Notes.				Х	
101.INS	Instant Document				Х	
101.SCH	XBRL Taxonomy Schema Document				Х	
101.CAL	XBRL Taxonomy Calculation Linkbase Document				Х	
101.DEF	XBRL Taxonomy Definition Linkbase Document				Х	
101.LAB	XBRL Taxonomy Label Linkbase Document				Х	
101.PRE	XBRL Taxonomy Presentation Linkbase Document				Х	

### AMENDMENT NO. 2 TO TERM LOAN AGREEMENT

THIS AMENDMENT NO. 2 to Term Loan Agreement, dated as of April 12, 2017 (this "*Amendment*") is made among ViewRay Technologies, Inc., a Delaware corporation (formerly known as ViewRay Incorporated) ("*Borrower*") and the lenders listed on the signature pages hereof under the heading "LENDERS" (each a "*Lender*" and, collectively, the "*Lenders*"), with respect to the Loan Agreement referred to below.

### RECITALS

WHEREAS, the Borrower and the Lenders are parties to a Term Loan Agreement, dated as of June 26, 2015 (as amended by that certain Amendment No. 1 to Term Loan Agreement, dated as of March 24, 2016, the "*Loan Agreement*").

WHEREAS, the parties hereto desire to amend the Loan Agreement on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements, provisions and covenants contained herein, the parties agree as follows:

### SECTION 1. Definitions; Interpretation.

(a) **Terms Defined in Loan Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement.

(b) **Interpretation**. The rules of interpretation set forth in **Section 1.03** of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

### SECTION 2. Amendment of Loan Agreement. Subject to Section 3, the Loan Agreement is hereby amended as follows:

(a) The definition of "Commitment Period" in **Section 1.01** of the Loan Agreement is hereby amended and restated to read in its entirety as follows:

""*Commitment Period*" means the period from and including the first date on which all of the conditions precedent set forth in **Section 6.01** have been satisfied (or waived by the Lenders) and through and including the earlier of (i) September 30, 2017 and (ii) the date on which Borrower shall have provided written notice to Lenders of Borrower's termination of the Commitment Period."

(b) The definition of "FATCA" in **Section 1.01** of the Loan Agreement is hereby amended and restated to read in its entirety as

follows:

		<b>""FATCA</b> " means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof and any agreements entered into pursuant to Section 1471(b)(1) of the Code, any intergovernmental agreement entered into in connection with the implementation of such Sections of the Code and any fiscal or regulatory legislation, rules or practices adopted pursuant to such intergovernmental agreement."
follows:	(c)	The definition of "Fee Letter" in <b>Section 1.01</b> of the Loan Agreement is hereby amended and restated to read in its entirety as
		"" <i>Fee Letter</i> " means that amended and restated fee letter agreement dated as of April 12, 2017 among Borrower and the Lenders party thereto."
entirety as	(d) follows:	The definition of "Interest-Only Period" in Section 1.01 of the Loan Agreement is hereby amended and restated to read in its
		"" <i>Interest-Only Period</i> " means the period from and including the First Borrowing Date and through and including the nineteenth (19th) Payment Date following the First Borrowing Date ( <i>i.e.</i> , March 31, 2020)."
follows:	(e)	The definition of "PIK Period" in <b>Section 1.01</b> of the Loan Agreement is hereby amended and restated to read in its entirety as
		"" <b>PIK Period</b> " means the period beginning on the First Borrowing Date through and including, the earlier to occur of (i) the nineteenth (19th) Payment Date after the First Borrowing Date ( <i>i.e.</i> , March 31, 2020), and (ii) the date on which any Default shall have occurred (provided that if such Default shall have been cured or waived, the PIK Period shall resume until the earlier to occur of the next Default and the nineteenth (19th) Payment Date after the First Borrowing Date ( <i>i.e.</i> , March 31, 2020)."
	(f)	The following sentence shall be added to the end of <b>Section 5.03(a)</b> of the Loan Agreement:
		"For purposes of this Section 5.03, the term "applicable law" includes FATCA."
	(g)	Section 6.03 of the Loan Agreement shall be amended and restated to read in its entirety as follows:
		<b>"6.03 Conditions to Subsequent Borrowings.</b> The obligation of each Lender to make a Loan as part of any Borrowing subsequent to the second Borrowing made under <b>Section 6.02</b> is subject to the following conditions precedent:

		(a) <b>Borrowing Date</b> . Any such Borrowing shall occur on or prior to September 30, 2017.				
	amount o one Borr	(b) <b>Amount of Borrowing</b> . The amount of any such Borrowing shall be no less than 00. The aggregate amount of all Borrowings under this <b>Section 6.03</b> shall be \$20,000,000 minus the aggregate f Borrowings previously drawn under this <b>Section 6.03</b> ; <i>provided, however, that</i> if Borrower does not make at least owing on or prior to June 30, 2017, then the aggregate amount of all Borrowings under this <b>Section 6.03</b> shall be 000 minus the aggregate amount of Borrowings previously drawn under this <b>Section 6.03</b> .				
	(c) <b>Borrowing Milestone</b> . Borrower shall have maintained a public market capitalization amount of at least \$175,000,000 for the ten Business Day period immediately preceding the relevant Borrowing Notice Date, and provided evidence thereof in the relevant Notice of Borrowing."					
clause (g):	(h)	Section 9.06 of the Loan Agreement shall be amended by deleting the current clause (g) and replacing it with the following				
		"(g) to pay any (i) fees, taxes or expenses in connection with an initial public offering of Borrower's common stock on a nationally recognized securities exchange and (ii) fees or expenses in connection with sales of Borrower's common stock incurred in the ordinary course of business; and"				
"60,000,00	(i) 00."	Section 10.02(b) of the Loan Agreement shall be amended by replacing the number "80,000,000" therein with the number				
SECTION	13.	Conditions of Effectiveness. The effectiveness of Section 2 shall be subject to the following conditions precedent:				
connection Agreement	(a) Borrower shall have paid or reimbursed Lenders for Lenders' reasonable out of pocket costs and expenses incurred in onnection with this Amendment, including Lenders' reasonable out of pocket legal fees and costs, pursuant to <b>Section 12.03(a)(i)(z)</b> of the Loan Agreement.					
	(b)	The representations and warranties in <b>Section 4</b> shall be true and correct on the date hereof.				
Borrower.	(C)	Lenders shall have received a copy of the Fee Letter, dated the date hereof (the " <i>Fee Letter</i> "), executed and delivered by				
SECTION	<b>4</b> .	Representations and Warranties; Reaffirmation.				
	(a)	Borrower hereby represents and warrants to each Lender as follows:				

(i) Borrower has full power, authority and legal right to make and perform this Amendment. This Amendment is within Borrower's corporate powers and has been duly authorized by all necessary corporate and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by Borrower and constitutes a legal, valid and binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by (a) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (b) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law). This Amendment (x) does not require any consent or approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (y) will not violate any applicable law or regulation or the charter, bylaws or other organizational documents of Borrower and its Subsidiaries or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, (z) will not violate or result in an event of default under any material indenture, agreement or other instrument binding upon Borrower and its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person.

(ii) No Default has occurred or is continuing or will result after giving effect to this Amendment.

(iii) The representations and warranties made by or with respect to Borrower in **Section 7** of the Loan Agreement are true in all material respects (taking into account any changes made to schedules updated in accordance with **Section 7.20** of the Loan Agreement or attached hereto), except that such representations and warranties that refer to a specific earlier date were true in all material respects on such earlier date.

(iv) There has been no Material Adverse Effect since the date of the Loan Agreement.

(b) Borrower hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents to which it is a party remain in full force and effect, undiminished by this Amendment, except as expressly provided herein and in the Fee Letter. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

### SECTION 5. Governing Law; Submission to Jurisdiction; Waiver of Jury Trial.

(a) **Governing Law**. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; *provided that* Section 5-1401 of the New York General Obligations Law shall apply.

(b) **Submission to Jurisdiction**. Borrower agrees that any suit, action or proceeding with respect to this Amendment or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in

Houston, Texas or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 5** is for the benefit of the Lenders only and, as a result, no Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by applicable Laws, the Lenders may take concurrent proceedings in any number of jurisdictions.

(C) **Waiver of Jury Trial**. Borrower and each Lender hereby irrevocably waives, to the fullest extent permitted by applicable LAW, any and all right to trial by jury in any suit, action or proceeding arising out of or relating to this Amendment, the other Loan Documents or the transactions contemplated hereby or thereby.

### SECTION 6. Miscellaneous.

(a) **No Waiver**. Nothing contained herein shall be deemed to constitute a waiver of compliance with any term or condition contained in the Loan Agreement or any of the other Loan Documents or constitute a course of conduct or dealing among the parties. Except as expressly stated herein, the Lenders reserve all rights, privileges and remedies under the Loan Documents. Except as amended hereby and as amended and restated by the Fee Letter, the Loan Agreement and other Loan Documents remain unmodified and in full force and effect. All references in the Loan Documents to the Loan Agreement shall be deemed to be references to the Loan Agreement as amended hereby.

(b) **Severability**. In case any provision of or obligation under this Amendment shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(c) **Headings**. Headings and captions used in this Amendment (including the Exhibits, Schedules and Annexes hereto, if any) are included for convenience of reference only and shall not be given any substantive effect.

(d) **Integration**. This Amendment constitutes a Loan Document and, together with the other Loan Documents, incorporates all negotiations of the parties hereto with respect to the subject matter hereof and is the final expression and agreement of the parties hereto with respect to the subject matter hereof.

(e) **Counterparts**. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart.

(f) **Controlling Provisions**. In the event of any inconsistencies between the provisions of this Amendment and the provisions of any other Loan Document, the provisions of this Amendment shall govern and prevail. Except as expressly modified by this Amendment and by the Fee Letter, the Loan Documents shall not be modified and shall remain in full force and effect.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

### VIEWRAY TECHNOLOGIES, INC.

By <u>/s/ Ajay Bansal</u> Ajay Bansal Chief Financial Officer

### CAPITAL ROYALTY PARTNERS II L.P.

By CAPITAL ROYALTY PARTNERS II GP L.P., its General Partner By CAPITAL ROYALTY PARTNERS II GP LLC, its General Partner

By <u>/s/ Nathan Hukill</u> Name:

Title:

Nathan Hukill Authorized Signatory

### CAPITAL ROYALTY PARTNERS II (CAYMAN) L.P.

By CAPITAL ROYALTY PARTNERS II (CAÝMAN) GP L.P., its General Partner By CAPITAL ROYALTY PARTNERS II (CAYMAN) GP LLC, its General Partner

By <u>/s/ Nathan Hukill</u>	
Name:	Nathan Hukill
Title:	Authorized Signatory

Witness: <u>/s/ Nicole Nesson</u> Name: Nicole Nesson

### PARALLEL INVESTMENT OPPORTUNITIES PARTNERS II L.P.

By PARALLEL INVESTMENT OPPORTUNITIES PARTNERS II GP L.P., its General Partner By PARALLEL INVESTMENT OPPORTUNITIES PARTNERS II GP LLC, its General Partner

By <u>/s/ Nathan Hukill</u> Name: Title:

Nathan Hukill Authorized Signatory

CRG ISSUER 2015-1

By CRG SERVICING LLC, as Administrator

By /s/ Nathan Hukill

Name: Nathan Hukill Title: President I, Chris A. Raanes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ViewRay, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2017

/s/ Chris A. Raanes

Chris A. Raanes Title: Chief Executive Officer and President (Principal Executive Officer) I, Ajay Bansal, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ViewRay, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2017

/s/ Ajay Bansal Ajay Bansal Title: Chief Financial Officer (Principal Financial Officer)

### CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER UNDER SECTION 906

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of ViewRay, Inc., a Delaware corporation (the "Company"), does hereby certify that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

#### VIEWRAY, INC.

Dated: August 7, 2017

By: /s/ Chris A. Raanes Name: Chris A. Raanes Title: Chief Executive Officer (Principal Executive Officer)

### CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER UNDER SECTION 906

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of ViewRay, Inc., a Delaware corporation (the "Company"), does hereby certify that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 2017 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

#### VIEWRAY, INC.

Dated: August 7, 2017

 
 By:
 /s/ Ajay Bansal

 Name:
 Ajay Bansal

 Title:
 Chief Financial Officer (Principal Financial Officer)