Management's Discussion and Analysis of Financial Condition and Results of Operations of Profound Medical Corp. for the Year Ended December 31, 2016

The following Management's Discussion and Analysis ("**MD&A**") prepared as of March 6, 2017 should be read in conjunction with the December 31, 2016 audited financial statements and related notes of Profound Medical Corp. ("**Profound**" or the "**Company**"). The audited financial statements of Profound and related notes as at December 31, 2016 and December 31, 2015 and for the years then ended were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). Unless stated otherwise, all references to "$" are to Canadian dollars. In this discussion, unless the context requires otherwise, references to "we" or "our" are references to Profound.

FORWARD-LOOKING STATEMENTS

This MD&A contains "forward-looking statements" which include all statements other than statements of historical fact contained in this MD&A, such as statements that relate to the Company's current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to", "is/are projected to" or the negative of these terms, or other similar expressions intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of our product, expectations regarding the use of our product and revenue, expenses and operations, plans for and timing of expansion of our product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in our product markets, competitive position and our expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound's business and the markets in which we operate.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Profound to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section entitled "Risk Factors" in this MD&A, such as:

- successful completion of clinical trial phases with respect to Profound's device;
- obtaining regulatory approvals in relevant jurisdictions to market Profound's device;
- risks related to the regulation of Profound, including the healthcare markets;
- lack of funding may limit the ability to commercialize and market Profound's product;
- fluctuating input prices, international trade and political uncertainty;
- healthcare regulatory regime may affect financial viability;
- reimbursement models in relevant jurisdictions may not be advantageous;
- competition may limit the growth of Profound;
- if Profound breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business;
- loss of key personnel may significantly harm Profound's business; and
- past performance is not indicative of future performance.

Forward-looking statements contained herein are made as of the date of this MD&A and Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable law. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them.

BUSINESS OVERVIEW

Profound is a Canadian medical device company commercializing a unique, Magnetic Resonance (MR) guided ablation procedure for prostate care. Profound's novel technology, the TULSA-PRO® system, combines real-time MR imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control. It provides a highly precise treatment tailored to patient-specific anatomy and pathology. This method of prostate ablation offers short treatment times and low morbidity, allowing for fast patient recovery.

On June 4, 2015, Profound closed its qualifying transaction (the Transaction) with Profound Medical Inc. (PMI), a biotechnology company developing a treatment to ablate the prostate gland in prostate cancer patients, pursuant to which the shareholders of PMI completed a reverse asset acquisition of Profound.

Profound Medical Corp. common shares are listed on the TSX Venture Exchange (TSXV:PRN).

Business Update

Profound's core technology was based on specific research conducted at Sunnybrook Health Sciences Centre ("**Sunnybrook**"), pursuant to licensing arrangements between Sunnybrook and Profound. In 2010, Profound in collaboration with Sunnybrook, developed working prototypes and completed institutionally sponsored clinical research trials. In 2011, Profound finalized the system design under formal design controls. In 2012, preclinical studies were completed, which lead to the finalization of the development of our clinical stage device

and the successful outsourcing of manufacturing of certain components of the TULSA-PRO® system. In April 2013, Profound announced initiation of the Health Canada approved 30 patient TULSA (Transurethral Ultrasound Ablation) safety and feasibility study. Subsequently, additional clinical sites were added to include Germany and the United States, with approvals from the Federal Institute for Drugs and Medical Devices in Germany in July 2013, and the United States Food and Drug Administration ("**FDA**") in September 2013. In March 2014, Profound completed enrollment and treatment of 30 patients in the TULSA multi-jurisdictional safety and feasibility study. On October 15, 2015, Profound presented 12-month follow-up data at the European Symposium on Focused Ultrasound Therapy held in London, England. The results of this study were also published in the September 2016 issue of European Urology. In the Phase I study, the TULSA-PRO® system demonstrated accurate and precise ablation of targeted prostate tissue, while providing a well-tolerated favorable safety profile with minor impact on urinary, erectile and bowel function at 12 months. On April 11, 2016, Profound announced that it has affixed the CE mark to the TULSA-PRO® system, enabling Profound to market the TULSA-PRO® system in the European Union and in other CE mark jurisdictions. Profound is currently conducting a pilot commercial launch of TULSA-PRO® in key European and other CE mark jurisdictions. Profound also expects to pursue regulatory market clearance in Canada in 2017.

Profound has received an Investigational Device Exemption ("IDE") from the FDA on May 19, 2016, a prerequisite to launching the TACT (TULSA-PRO® Ablation Clinical Trial) Pivotal Trial (as more fully described in the Annual Information Form, dated August 9, 2016 (the "**AIF**")). The TACT Pivotal Trial is a prospective, single-arm pivotal clinical study of 110 patients aimed at further evaluating the safety and efficacy of the TULSA-PRO® system to ablate prostate tissue in patients with localized, organ-confined prostate cancer. The TACT Pivotal Trial is being conducted in 10-14 clinical sites located in the United States, Canada and Europe. The first patient in the TACT Pivotal Trial was treated on September 22, 2016 and a total of 6 patients were treated as of December 31, 2016. Refer to the AIF for a full description of the regulatory approval process under the heading "Government Regulation". If successful, the TACT Pivotal Trial is expected to support Profound's application to the FDA for approval to market the TULSA-PRO® system in the United States. Based on a new predicate device cleared by the FDA in October 2015, Profound intends to pursue a 510(k) submission of the TULSA-PRO® system with the FDA as a Class II device and has engaged in pre-submission consultations with FDA officials in this regard.

2016 HIGHLIGHTS

- Profound entered into a strategic agreement with Siemens to further the development of prostate cancer care
- Profound and Royal Philips sign Sales and Marketing Agreement in MRI-guided therapy for prostate cancer care
- Profound obtained the CE Mark approval for the commercial sale of the TULSA-PRO ® system, in Europe and in other CE Mark Jurisdictions
- Profound and Royal Philips jointly received commercial purchase orders of TULSA-PRO ® system in the United Kingdom and Germany
- Profound successfully signed the first commercial sale purchase order of the TULSA-PRO ® system in Spain
- Profound closed a bought deal financing for gross proceeds of $17,402,000 on November 14, 2016
- Profound received Frost & Sullivan's 2016 New Product Innovation Award

SELECTED ANNUAL INFORMATION

	Year ended December 31		
	2016	2015	2014
	$	**$**	$
Operating expenses	**15,640,414**	11,222,897	4,338,757
Finance costs	**672,301**	5,878,915	3,765,757
Net loss for the year	**16,326,769**	16,375,741	8,204,409
Loss per share			
-Basic	**0.39**	0.69	3.79
-Diluted	**0.39**	0.69	3.79
Total assets	**$23,692,843**	$21,188,916	$2,609,076
Total non-current liabilities	**3,909,489**	5,958,488	2,675,493

The Company reported a net loss of $16,326,769 ($0.39 per share) for the year ended December 31, 2016 as compared to net loss of $16,375,741($0.69 per share) for the year ended December 31, 2015. The increase in loss was primarily related to higher research and development costs resulting from the regulatory filings for marketing approval of the TULSA-PRO ® system in Canada and Europe and the preparation for our TACT Pivotal Trial. The higher operating expenses were offset by lower finance costs in 2016. For the year ended December 31, 2014, the Company recorded a net loss of $8,204,409, which was significantly lower than the preceding years, due to limited funding available to further advance the research and development activities.

The Company reported total assets of $23,692,843 for the year ended December 31, 2016 as compared to $21,188,916 in the comparable period of 2015. The increase was primarily related to the acquisition of inventory, property and equipment and intangible assets. Total non-current liabilities were $2,048,999 lower than in the comparable period of 2015, resulting primarily from the long-term debt and other liability becoming current.

RESULTS OF OPERATIONS

	Three months ended December 31				Twelve months ended December 31			
	2016	2015	Change		2016	2015	Change	
	$	$	$	%	$	$	$	%
Expenses								
Research and development	**2,758,887**	1,538,566	1,220,321	79%	**9,988,693**	5,136,848	4,851,845	94%
Selling, general and administrative	**2,069,198**	1,010,613	1,058,585	105%	**5,651,721**	6,086,049	(434,328)	-7%
Total operating expenses	**4,828,085**	2,549,179	2,278,906	89%	**15,640,414**	11,222,897	4,417,517	39%
Finance costs - net								
Interest and accretion expense	**(10,329)**	276,362	(286,691)	-104%	**829,899**	5,625,257	(4,795,358)	-85%
Interest income	**(33,813)**	(57,399)	23,586	-41%	**(157,598)**	(137,710)	(19,888)	14%
Listing expense	**-**	-	-	-	**-**	2,058,234	(2,058,234)	100%
Loss on recognition of convertible notes	**-**	-	-	-	**-**	2,094,565	(2,094,565)	100%
Change in fair value of convertible notes	**-**	-	-	-	**-**	(334,680)	334,680	-100%
Gain on conversion of convertible notes	**-**	-	-	-	**-**	(1,759,885)	1,759,885	-100%
Gain on extinguishment of long-term debt	**-**	-	-	-	**-**	(63,568)	63,568	-100%
Change in fair value of derivatives	**-**	1,754	(1,754)	-100%	**-**	(2,084,652)	2,084,652	-100%
Preferred share dividend expense	**-**	-	-	-	**-**	481,354	(481,354)	-100%
Total finance costs	**(44,142)**	220,717	(264,859)	-120%	**672,301**	5,878,915	(5,206,614)	-89%
Loss before income taxes	**4,783,943**	2,769,896	2,014,047	73%	**16,312,715**	17,101,812	(789,097)	-5%
Income tax expense (recovery)	**4,674**	-	4,674	100%	**14,054**	(726,071)	740,125	-102%
Net loss for the period	**4,788,617**	2,769,896	2,018,721	73%	**16,326,769**	16,375,741	(48,972)	0%
Item that may be reclassified to profit or loss								
Foreign currency translation adjustment	**821**	-	821	100%	**11,316**	-	11,316	100%
Net loss and comprehensive loss for the period	**4,789,438**	2,769,896	2,019,542	73%	**16,338,085**	16,375,741	(37,656)	0%
Basic and diluted net loss per common share	**0.10**	0.07	0.03	43%	**0.39**	0.69	(0.30)	-43%

Research and Development

Our research and development ("R&D") expenses are comprised of costs incurred in performing R&D activities, including clinical trial and related clinical manufacturing costs, materials and supplies, salaries and benefits, contract research costs, patent procurement costs, and occupancy costs. Our R&D activities occur in clinical R&D. Clinical R&D refers to internal and external activities associated with clinical studies of the TULSA-PRO ® system in humans, and the advancement of the clinical product towards our goal of obtaining regulatory approval to both manufacture and market this product within various jurisdictions.

Expenditures for R&D for the three months ended December 31, 2016 were higher by $1,220,321 compared to the three months ended December 31, 2015. This increase was primarily related to development initiatives associated with our TACT Pivotal Trial, such as the ongoing activities related to initiation of clinical site visits, enrollment initiatives and patient treatments. As a result, salaries and benefits increased by $315,415 primarily due to higher headcount and an annual discretionary bonus, which was paid for the first time in 2016. In addition, material expenses increased by $308,017 and clinical trial costs increased by $248,584 compared to the prior period in 2015, respectively.

Expenditures for R&D for the twelve months ended December 31, 2016 were higher by $4,851,845 compared to the twelve months ended December 31, 2015. The increase was primarily related to the preparation of clinical data from the 30 patient TULSA safety and feasibility trial, which was evaluated and submitted for regulatory clearances by the applicable regulatory authority in Canada and Europe for a Medical Device License and CE Mark, respectively. The increase was also due to preparations for an IDE and Institutional Review Board (IRB) submissions to prepare 14 clinical sites for patient enrollment, designed to support a 510(k) submission in the United States to provide a pathway for Class II device classification for the TULSA-PRO ® system. In addition, the increase in R&D expenditures included costs related to the development initiatives associated with the TACT Pivotal Trial. As a result, salaries and benefits increased by $1,398,341, primarily due to increased headcount and an annual discretionary bonus, which was paid for the first time in 2016. Consulting expenses increased by $923,990, validation expenses for clinical trials increased by $708,869 and materials costs increased by $641,941. Other expenses, included an increase of $295,943 with respect to insurance costs for the TACT Pivotal Trial and increased freight costs attributed to shipping products to hospitals. Rent expense increased by $175,564, due to the costs involved in relocating the corporate office into a larger facility. In addition, investment tax credits were lower by $430,825. As per the qualifying transaction that occurred on June 4, 2015, the Company does not qualify for refundable investment tax credits other than Ontario Innovation tax credits.

Selling, General and Administrative

Our selling, general and administrative (SG&A) expenses are comprised of management and business development costs related to the development and commercialization of our TULSA-PRO® system, including salaries and benefits, various management and administrative support functions and other operating and occupancy costs.

SG&A expenses for the three months ended December 31, 2016 were higher by $1,058,585 compared to the three months ended December 31, 2015. The Company formed a German sales office in January 2016 and recruited a new Chief Executive Officer, Mr. Arun Menawat, resulting in an increase to salaries and benefits expense of $312,755. In addition, share option expense increased by $396,918 and rent, office and other expenses increased by $205,759, respectively.

SG&A expenses for the twelve months ended December 31, 2016 were lower by $434,328 compared to the twelve months ended December 31, 2015 primarily due to a marketing expense of $2,303,034 related to the excess of proceeds received on the $4,000,000 secured loan from Knight Therapeutics Inc. ("Knight Loan"), which represented additional value provided to the Company, as a result of the Knight relationship. This was offset by higher salaries and benefits of $617,932, related to the recruitment of new members on the senior management team. In addition, professional and consulting fees increased by $382,251 and office and other expenses increased by $344,631, which included higher insurance premiums due to increased liability limits.

Preferred share dividend expense

The holders of Series A1 preferred shares and A2 preferred shares (collectively, the "Preferred Shares") were, when such Preferred Shares were issued and outstanding, entitled to receive, if, as and when declared by the Board of Directors, cumulative dividends at an annual rate of 8%, compounded annually commencing on their respective date of issuance. The Preferred Shares were converted into common shares of Profound pursuant to the Transaction. Accordingly, there was no preferred share dividend expense for the three and twelve months ended December 31, 2016. The preferred share dividend expense for the twelve months ended December 31, 2015 was $481,354.

Interest and accretion expense

Interest and accretion expense relates to the following (i) the Preferred Shares accreting to their respective redemption prices over their expected life, including accelerated accretion due to the conversion of the Preferred Shares prior to their maturity date, (ii) the Federal Economic Development Agency loan accreting to the principal amount repayable, (iii) the Health Technology Exchange (HTX) loan accreting to the principal amount repayable and its related interest expense, (iv) the Knight Loan accreting to the principal amount repayable and its related interest expense, (v) the convertible notes (the Notes) interest expense, (vi) the bank loan interest expense, and (vii) the 0.5% royalty to Knight.

Interest and accretion expense for the three months ended December 31, 2016 was lower by $286,691 compared to the three months ended December 31, 2015. During the year, the Company revised the fair value of the royalty, using future revenue forecasts for the term of the loan and a discount rate of 18%, and recognized an interest accretion recovery of $249,413.

Interest and accretion expense for the twelve months ended December 31, 2016 was lower by $4,795,358 compared to the twelve months ended December 31, 2015. The decrease is primarily related to accretion expense on the Preferred Shares and convertible notes which terminated with their conversion to common shares on June 4, 2015 pursuant to the terms of the Transaction, partially offset by the Knight Loan which was entered into on April 30, 2015.

Loss on recognition of convertible notes

On January 27, 2015, the Company closed a financing of convertible notes in the principal amount of $1,500,000, with an original maturity date of January 27, 2016. The convertible notes accrued interest at a rate of 12% per annum. All or any part of the convertible notes were convertible at any time after February 20, 2015 at a conversion price per Preferred Share equal to the Preferred Share conversion price at the option of the holder. In the event that a financing occurred, all of the convertible notes would automatically convert into the class or series of Preferred Shares, common shares or units acquired by the new investors at a price per share or unit equal to 75% of the price paid. On April 20, 2015, the convertible notes were amended to eliminate the discount such that the convertible notes would automatically convert at a price per common share or unit equal to 100% of the price paid by the new investors.

The convertible notes represented a financial liability that included embedded derivatives related to the conversion feature that required separation. The Company had elected an accounting policy choice to measure the convertible notes at fair value without separating the embedded derivatives. On initial recognition the fair value of the convertible notes was $3,594,565 and the difference between the fair value and the initial value of $1,500,000, or $2,094,565 was recognized for the year ended December 31, 2015.

Fair value gain on convertible notes

The convertible notes were re-measured at fair value at each period with any changes recognized in finance costs. For the year ended December 31, 2015 a fair value gain on the convertible notes of $334,680 was recognized.

Gain on conversion of convertible notes

The principal and accrued interest on the convertible notes were converted on June 4, 2015 into common shares at $1.50 per common share. On June 4, 2015 the fair value of the Notes was $3,259,885 and the difference between the fair value at June 4, 2015 and the principal value of $1,500,000, or $1,759,885 was recognized for the year ended December 31, 2015.

Change in fair value of derivatives

The Preferred Shares when outstanding, represented a financial liability that includes multiple embedded derivatives that required separation. The embedded derivatives were then measured at fair value at each reporting period with any changes recognized in the consolidated statements of loss and comprehensive loss.

There were no derivatives related to the Preferred Shares as at December 31, 2016. The change in fair value of derivatives for the year ended December 31, 2015 was a gain of $2,084,652.

Income tax expense

During the three and twelve months ended December 31, 2016, the Company recorded an income tax expense of $4,674 and $14,054, respectively, primarily related to taxes in certain foreign jurisdictions.

If holders of Preferred Shares were paid, or were deemed to have been paid, any dividends on such shares, the Company would have become liable for the payment of taxes under Part VI.1 of the Income Tax Act (Canada). On conversion of the Preferred Shares, no dividends were paid or deemed paid, resulting in the reversal of all the accrued Part VI.1 taxes payable. Part VI.1 tax recovery for the year ended December 31, 2015 was $726,071.

Net loss

Net loss for the fourth quarter of 2016 was $4,788,617 or $0.10 per share, compared to a net loss of $2,769,896 or $0.07 per share in the fourth quarter of 2015. The increase in net loss was primarily attributed to an increase in R&D expenses of $1,220,321 and an increase in SG&A expenses of $1,058,585.

Net loss for the year ended December 31, 2016 amounted to $16,326,769 or $0.39 per share, compared to a net loss of $16,375,741, or $0.69 per share for the year ended December 31, 2015. The increase in net loss was primarily attributed to higher R&D expenses of $4,851,845, offset by lower finance costs of $5,206,614 and SG&A expenses of $434,328. Finance costs was significantly lower in 2016, due to costs incurred in 2015 with respect to the qualifying transaction and the acceleration of the accretion on the preferred shares at the time of their conversation to common shares. These expenses were partially offset with a Part VI.1 tax recovery of $726,071 in 2015.

SUMMARY OF QUARTERLY FINANCIAL RESULTS

	2016				2015			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
	$	$	$	$	$	$	$	$
Research and development	**2,758,887**	2,506,112	2,247,697	2,475,997	1,538,566	1,657,700	1,105,381	835,201
Selling, general and administrative	**2,069,198**	1,273,521	1,182,177	1,126,825	1,010,613	1,099,798	3,393,128	582,510
Total operating expenses	**4,828,085**	3,779,633	3,429,874	3,602,822	2,549,179	2,757,498	4,498,509	1,417,711
Finance costs- net								
Preferred share dividend expense	**-**	-	-		-	-	194,256	287,098
Interest and accretion expense	**(10,329)**	302,122	254,145	283,961	276,362	266,603	4,764,823	317,469
Interest income	**(33,813)**	(25,270)	(47,951)	(50,564)	(57,399)	(66,922)	(5,618)	(7,771)
Listing expense	**-**	-	-	-	-	-	2,058,234	-
Loss on recognition of convertible notes	**-**	-	-	-	-	-	-	2,094,565
Change in fair value of convertible notes	**-**	-	-	-	-	-	35,393	(370,073)
Gain on conversion of convertible notes	**-**	-	-	-	-	-	(1,759,885)	-
Gain on extinguishment of long-term debt	**-**	-	-	-	-	-	(63,568)	-
Change in fair value of derivatives	**-**	-	-	-	1,754	-	(224,436)	(1,861,970)
Total finance costs	**(44,142)**	276,852	206,194	233,397	220,717	199,681	4,999,199	459,318
Loss before income taxes	**4,783,943**	4,056,485	3,636,068	3,836,219	2,769,896	2,957,179	9,497,708	1,877,029
Income tax expense (recovery)	**4,674**	4,723	4,657	-	-	-	(798,991)	72,920
Net loss for the period	**4,788,617**	4,061,208	3,640,725	3,836,219	2,769,896	2,957,179	8,698,717	1,949,949
Loss per share								
Basic	**0.10**	0.10	0.09	0.10	0.07	0.08	0.67	0.90
Diluted	**0.10**	0.10	0.09	0.10	0.07	0.08	0.67	0.90

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2016, the Company held cash and short-term investments of $20,833,061 compared to $20,522,520 at December 31, 2015, as summarized below:

	Year ended December 31	
	2016	2015
	$	**$**
Cash	**20,833,061**	10,522,520
Short-term investment	**-**	10,000,000
Total	**20,833,061**	20,522,520

The Federal Economic Development Agency

On April 4, 2012, the Company entered into a $867,000 unsecured, non-interest bearing loan with The Federal Economic Development Agency (FedDev). Repayments of $14,450 commenced on April 1, 2015, followed by 48 monthly instalments of $7,225 from May 1, 2015 to April 1, 2019, and 11 monthly instalments of $45,977 from May 1, 2019 to March 1, 2020. These repayment terms are the result of an amendment to the agreement dated June 2, 2015 and replace the previous repayment terms of 60 monthly payments of $14,450. As at December 31, 2016, the principal balance outstanding on this loan is $708,050 (2015 - $794,750).

The Health Technology Exchange

The Health Technology Exchange (HTX) loans with total proceeds of $1,500,000 are unsecured, bearing interest at 4.50% per annum, with remaining annual repayments on March 31, 2017 for $500,000 and March 31, 2018 for $1,094,698 representing the balance of the obligations under each of the loan agreements including accrued interest to March 31, 2018. As at December 31, 2016, the principal balance outstanding on these loans was $1,300,000 (December 31, 2015 - $1,500,000).

Knight Loan

On April 30, 2015, the Company entered into a $4,000,000, secured loan, bearing interest at 15.0% per annum with Knight Therapeutics Inc. (Knight Loan). Repayments commence on June 30, 2017 with a payment of $1,427,258 followed by seven quarterly instalments of $285,714 plus accrued interest from September 30, 2017 to March 31, 2019, and a final instalment of $2,052,603 on June 3, 2019.

In addition to the Knight Loan, the Company granted to Knight a 0.5% royalty on net sales of Profound for the duration of the Knight Loan. The royalty was initially recorded at fair value and subsequently carried at amortized cost using the effective interest rate method. The initial fair value of the royalty was determined using future revenue forecasts for the term of the Knight Loan and a discount rate of 18%. During the year, the company revised the fair value of the royalty, using future revenue forecasts for the term of the loan and a discount rate of 18%, and recognized an interest accretion recovery of $249,413 (2015 – accretion expense of $38,798). The current portion of this liability as at December 31, 2016 is $39,357 (December 31, 2015 - $nil) and non-current portion is $109,044 (December 31, 2015 - $397,814).

Cash Flow

The Company manages liquidity risk by monitoring actual and projected cash flows and matching the maturity profile of financial assets and liabilities. The cash flow forecast is performed regularly to ensure that the Company has sufficient cash to meet operational needs while maintaining sufficient liquidity. Forecasting takes into consideration the Company's debt financing commitments.

The Company will need additional capital beyond the next 12 months to fund R&D activities and any significant expansion of our operations. Potential sources of capital could include equity and/or debt financings, development agreements or marketing license agreements, the collection of revenues resulting from future commercialization activities and/or new strategic partnership agreements to fund some or all costs of development. There can be no assurance that the Company will be able to obtain the capital sufficient to meet any or all of the Company needs. The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, the market acceptance of our product, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if we raise additional funds by issuing equity securities, our existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Any failure on our part to raise additional funds on terms favorable to us or at all may require us to significantly change or curtail our current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in our not taking

advantage of business opportunities, in the termination or delay of clinical trials for our product, in curtailment of our product development programs designed to identify new products, in the sale or assignment of rights to our technologies, product and/or our inability to file market approval applications at all or in time to competitively market our product.

	Year ended December 31	
	2016	2015
	$	**$**
Cash used in operating activities	**(14,502,266)**	(6,860,211)
Cash provided by (used in) investing activities	**8,912,835**	(9,009,474)
Cash provided by financing activities	**15,899,972**	25,985,710
Net increase in cash and cash equivalents	**10,310,541**	10,116,025

For the twelve months ended December 31, 2016, net cash flows used in operating activities increased to $14,502,266. The principal uses of the 2016 operating cash flows were related to the preparations for an IDE submission and the TACT Pivotal Trial in 14 clinical sites, designed to support a 510(k) submission in the United States to provide a pathway for Class II classification for the TULSA-PRO® system and increases to employee headcount, as the company continues growing.

For the twelve months ended December 31, 2016, net cash flows provided by investing activities was $8,912,835. This was primarily related to the redemption of short term investments, offset by cash outflows related to purchase of research equipment in support of further optimization of the TULSA-PRO® system, ERP implementation, and leasehold improvements at the new office building.

For the twelve months ended December 31, 2016, net cash flows provided by financing activities was $15,899,972. This was primarily related to the issuance of common shares in connection with the bought deal financing for net proceeds of $16,182,997. This was partially offset by the ongoing repayment of HTX and FedDev loans.

Contractual obligations

The following table summarizes the company's significant contractual obligations as at December 31, 2016:

	Carrying amount $	Future cash flows $	Less than 1 Year $	Between 1year and 5 years $	Greater than 5 years $
Accounts payables and accrued liabilities	1,771,427	1,771,427	1,771,427	-	-
Long-term debt	6,637,876	8,616,855	2,877,050	5,731,351	-
Other liability	148,401	230,375	39,357	191,018	-
Total	8,557,704	10,618,657	4,687,834	5,922,369	-

COMMITMENTS

The Company has commitments under operating leases for the rental of office space. On March 28, 2016 the Company signed a lease for new office space and took possession of this office space effective July 1, 2016. Included in prepaid expenses and deposits is an amount of $450,000 related to prepaid rent for this lease that is drawn down at $10,000 per month. The future minimum obligation under these leases are as follows:

	$
No later than 1 year	395,317
Later than 1 year and no later than 5 years	2,056,779
Later than 5 years	2,747,722
	5,199,818

In 2016, the Company signed an agreement that guarantees payment related to revenue sharing of US$3,500,000 over the next five years.

In the event the Company repays the Knight Loan before the end of the term, it would be subject to a prepayment fee. The prepayment fee is the greater of the total unpaid annual interest that would have been payable during the year in which the prepayment is made and (a) $400,000 – If repaid between May 22, 2016 and May 21, 2017; or (b) $200,000 – If repaid between May 22, 2017 to maturity.

All directors and officers of the Company are indemnified by the Company for various items including, but not limited to, all costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors' and officers' liability insurance to mitigate the cost of any potential future lawsuits or actions. The term of the indemnification is not explicitly defined, but is limited to events for the period during which the indemnified party served as a director or officer of the Company. The maximum amount of any potential future payment cannot be reasonably estimated but could have a material adverse effect on the Company.

The Company has also indemnified the underwriters in relation to the bought deal financing and their respective affiliates and directors, officers, employees, shareholders, partners, advisers and agents and each other person, if any, controlling any of the underwriters or their affiliates against certain liabilities.

RELATED PARTY TRANSACTIONS

Key management includes the Company's directors and senior management team. The remuneration of directors and the senior management team were as follows during the years ended December 31:

	Three months ended December 31		**Twelve months ended December 31**	
	2016	2015	**2016**	2015
	$	**$**	**$**	**$**
Salaries and employee benefits	**478,675**	322,505	1,247,563	1,299,855
Directors fees	**28,579**	28,429	63,616	76,092
Share-based compensation	**402,582**	74,655	862,798	594,944
Total	**909,836**	425,589	2,173,977	1,970,891

Executive employment agreements allow for additional payments in the event of a liquidity event, or if the executive is terminated without cause.

Transactions

Research and development expenses include $nil of regulatory professional fees which flowed through a company controlled by an executive officer (2015 - $6,000).

Research and development expenses include $13,333 of director fees related to the Company's US subsidiary paid to an individual related to an executive officer (2015- $nil).

OUTSTANDING SHARES

As at March 6, 2017, the date of this MD&A, the Company had the following securities outstanding:

	Number
Common shares	55,319,327
Share purchase options	6,093,672
Compensation options	576,235

OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

RECENT ACCOUNTING PRONOUNCEMENTS

IFRS 9, Financial Instruments (IFRS 9)

The final version of IFRS 9, Financial Instruments, was issued by the International Accounting Standards Board (IASB) in July 2014 and will replace International Accounting Standard (IAS) 39, Financial Instruments: Recognition and Measurement. IFRS 9 introduces a model for classification and measurement, a single, forward-looking expected loss impairment model and a substantially reformed approach to hedge accounting. The new single, principle-based approach for determining the classification of financial assets is driven by cash flow characteristics and the business model in which an asset is held. The new model also results in a single impairment model being applied to all financial instruments, which will require more timely recognition of expected credit losses. It also includes changes in respect of own credit risk in measuring liabilities elected to be measured at fair value, so that gains caused by the deterioration of an entity's own credit risk on such liabilities are no longer recognized in profit or loss. IFRS 9 is effective for annual periods beginning on or after January 1, 2018, however, is available for early adoption. In addition, the own credit changes can be early applied in isolation without otherwise changing the accounting for financial instruments. The Company is yet to assess the full impact of IFRS 9 and has not yet determined when it will adopt the new standard.

IFRS 15, Revenue from Contracts with Customers (IFRS 15)

This standard replaces IAS 11, Construction Contracts, IAS 18, Revenue, and International Financial Reporting Interpretations Committee 13, Customer Loyalty Programmes. This standard outlines a single comprehensive model for entities to account for revenue arising from contracts with customers. The latest date of mandatory implementation of IFRS 15 is January 1, 2018. The Company has not yet evaluated the impact on the consolidated financial statements and has not yet determined when it will adopt the new standard.

IFRS 16, Leases (IFRS 16)

On January 13, 2016, the IASB published a new standard, IFRS 16, Leases. The new standard will eliminate the distinction between operating and finance leases and will bring most leases on the consolidated balance sheets for lessees. This standard is effective for annual reporting periods beginning on or after January 1, 2019. The company intends to adopt IFRS 16 in its financial statements for the annual period beginning January 1, 2019, and will recognize all of its liabilities for all leases on the consolidated balance sheet.

IFRS 2, Share-based Payment (IFRS 2)

In June 2016, the IASB issued final amendments to IFRS 2, clarifying how to account for certain types of share-based payment transactions. The amendments, which were developed through the IFRS Interpretations Committee, provide requirements on the accounting for: (i) the effect of vesting and non-vesting conditions on the measurement of cash-settled share-based payments; (ii) share-based payment transactions with a net settlement feature for withholding tax obligations; and (iii) a modification to the terms and conditions of a share-based payment that changes the classifications of the transaction from cash-settled to equity-settled. This standard is effective for annual reporting periods beginning on or after January 1, 2018. The company has not yet evaluated the impact on the consolidated financial statements.

RISK FACTORS

The following sets forth certain risks and uncertainties that could have a material adverse effect on the Company's business, financial condition and/or results of operations. Additional risks and uncertainties that the Company is not presently aware of, or that the Company currently deems immaterial, may also impair Profound's business operations. The risks described below address the material factors that may affect Profound's future operating results and financial performance.

Risk factors relating to Profound include, but are not limited to, the following:

Risk Factors Relating to Profound's Business

Profound's business is capital intensive and requires significant investment to conduct research and development, and to fund clinical and regulatory activities necessary to bring its product to market, which capital may not be available in amounts or on terms acceptable to us, if at all.

Profound's business requires substantial capital investment in order to conduct the research and development and to fund the clinical and regulatory activities necessary to bring Profound's product to market and to establish commercial manufacturing, marketing and sales capabilities. As of December 31, 2016, Profound had a cash balance of $20.8 million. Profound will need additional capital to fund its current business activities and expectations and to fund any significant expansion of operations. In order to secure financing, if available, it is likely that Profound would need to sell additional common shares or financial instruments that are exchangeable for or convertible into common shares and/or enter into development, distribution and/or licensing relationships, to fund all or a part of particular programs. Any future equity financing may also be dilutive to existing shareholders. Any future debt financing arrangements Profound enters into would likely contain restrictive covenants that would impose significant operating and, if any, financial restrictions on it. The availability of equity or debt financing will be affected by, among other things, the results of its research and development, its ability to obtain regulatory approvals, the market acceptance of Profound's product, the state of the capital markets generally, strategic alliance agreements, and other relevant commercial considerations. Any additional financing may not be obtained on favourable terms, if at all.

Any additional financing may not be obtained on favourable terms, if at all. If Profound cannot obtain adequate funding on reasonable terms, it may terminate or delay clinical trials, curtail significant regulatory initiatives, and/or sell or assign rights to its technologies, product or product candidates.

Profound's cash outflows are expected to consist primarily of internal and external research and development expenditures to advance Profound's product pipeline in addition to selling, general and administrative expenditures to support its corporate infrastructure. If Profound does not obtain additional capital, there may be substantial doubt about its ability to continue as a going concern and realize assets and pay liabilities as they become due. Depending upon the results of Profound's research and development programs and the availability of financial resources, Profound could decide to accelerate, terminate or reduce certain projects, or commence new ones. Any failure on Profound's part to raise additional funds on terms favourable to it or at all, may require it to significantly change or curtail current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from

operations are generated, and could result in Profound not taking advantage of business opportunities, in the termination or delay of clinical trials for one or more of its product candidates, in curtailment of its product development programs designed to identify new product candidates, in the sale or assignment of rights to Profound's technologies, product or product candidates, and/or Profound's inability to file an application for market clearance in the United States at all or in time to competitively market Profound's product.

Profound has a limited operating history

Profound was formed in June 2008. Profound had no operations prior to then. As Profound continues the development of its product, Profound will continue to incur further losses. There can be no assurance that Profound will ever be able to achieve or sustain profitability or positive cash flow. Its ultimate success will depend on whether its product receives approval in Canada by Health Canada, in the United States by the FDA and/or other applicable regulatory agencies and whether Profound is able to successfully market an approved product. Profound cannot be certain that it will be able to receive approvals for any of its current or future products or that Profound will reach the level of sales and revenues necessary to achieve and sustain profitability. There is no assurance that Profound will be successful and the likelihood of success must be considered in light of its relatively early stage of operations.

Profound has limited experience in assembling and testing the TULSA-PRO® system and no experience in doing so on a commercial scale. To become profitable, Profound must assemble and test the TULSA-PRO® system in commercial quantities in compliance with regulatory requirements and at an acceptable cost. Increasing its capacity to assemble and test its products on a commercial scale will require Profound to improve internal efficiencies. Profound may encounter a number of difficulties in increasing its assembly and testing capacity, including:

- managing production yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, provincial, federal and foreign regulations.

If Profound is unable to satisfy commercial demand for the TULSA-PRO® system due to its inability to assemble and test the device, its ability to generate revenue would be impaired, market acceptance of its products could be adversely affected and customers may instead purchase or use its competitors' products.

Recent and anticipated future losses

Profound has a history of losses and it may never achieve or maintain profitability. Since inception, Profound has incurred significant losses each year and expects to incur significant operating losses as Profound continues product research and development and clinical trials and pursues regulatory approvals. There is no assurance that Profound will ever successfully commercialize its device, or that profitability will ever be achieved or maintained. Even if profitability is achieved, Profound may not be able to sustain or increase profitability.

Development-stage company in an uncertain industry

Profound is in the mid-stage of development. Clinical trial work and remaining validation work must still be completed before Profound's device is ready for use within all of the markets Profound has identified. Profound may fail to obtain regulatory approvals or clearance, enter clinical trials or commercialize the product. Profound does not know whether any of its potential product development efforts will prove to be effective, meet applicable regulatory standards, obtain the requisite regulatory approvals or be capable of being manufactured at a reasonable cost. If Profound's device is approved for sale, there can be no assurance that the device will gain market acceptance among patients, physicians/clinicians and others in the medical community. A failure to gain market acceptance may adversely affect Profound's revenues.

Debt Financing Risk

Profound's Health Technology Exchange loan and Federal Economic Development Agency loan and the Knight Loan agreement contain financial and non-financial covenants, such as requirements that Profound comply with one or more financial ratios and change of control provisions. Complying with such covenants may at times necessitate that Profound must forego other favourable business opportunities, such as acquisitions. Moreover, Profound's failure to comply with any of these covenants would likely constitute a default under such facilities and agreements and could give rise to an acceleration of some, if not all, of Profound's then outstanding indebtedness, which would have a material adverse effect on its business. Profound's indebtedness may grow as Profound's business grows and/or Profound makes new acquisitions. If Profound's income from operations underperforms, Profound may have to utilize cash flow or capital resources to fund its debt service payments. If Profound's cash flow and capital resources are insufficient to service amounts owed under Profound's current or any future indebtedness, as applicable, Profound may be forced to reduce or delay capital expenditures, dispose of assets, issue equity or incur additional debt to obtain necessary funds, or restructure its debt, any or all of which could have a material adverse effect on Profound's business, financial condition and results of operations. In addition, Profound cannot guarantee that it would be able to take any of these actions on terms acceptable to it, or at all; that these actions would enable Profound to continue to satisfy its capital requirements; or that these actions would be permitted under the terms of Profound's various debt agreements. The Knight Loan agreement contains covenants with respect to capital expenditures and other indebtedness, maintaining minimum cash balances at all times and certain financial covenants in relation to the twelve-month period ending on June 30, 2019 and for periods thereafter, in addition to covenants with respect to permitted distributions. Profound has granted a security interest over all assets (including the shares of Profound). Events of default under the Knight Loan agreement include any covenant breach, failure to maintain minimum required net assets at all times, cross defaults to other agreements, a failure to comply with certain financial tests as to, among other items, minimum revenues over certain specified periods, a change of control of Profound, the common shares becoming subject to a cease trade order in effect for more than 20 business days or Profound being on the list of reporting issuers in default maintained by the Ontario Securities Commission for 20 consecutive business days. The enforcement by Knight of its rights and remedies pursuant to the terms of the Knight Loan agreement and associated documentation could result in Knight, its agent or any third party purchaser thereof owning all assets of Profound, including all share capital of Profound.

Clinical trials may not demonstrate a clinical benefit of Profound's device, may not support its product candidate claims or may result in the discovery of adverse side effects.

Before obtaining regulatory clearances or approvals for the commercial sale of the TULSA-PRO® system, Profound must demonstrate through clinical trials that the device is safe and effective for its intended use or, to receive 510(k) clearance in the United States, that the device is substantially equivalent to an existing predicate device for its intended use. Obtaining product clearance or approval and conducting the requisite clinical trials is a long, expensive and uncertain process and is subject to delays and failures at any stage. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Profound will be required to demonstrate through well-controlled clinical trials that its device is sufficiently safe and effective for its intended use in a diverse population before it can seek regulatory clearances or approvals for commercial sale. Data obtained from a clinical trial can be insufficient to demonstrate to the regulatory authority that the TULSA-PRO® system is sufficiently safe and effective for its intended use or that it is substantially equivalent to a predicate device. The data from a clinical trial may be inadequate to support clearance or approval of an application to the regulatory authorities for numerous reasons including, but not limited to:

- prevalence and severity of adverse events and other unforeseen safety issues;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines;
- the interim or final results are insufficient, inconclusive or unfavourable as to safety or efficacy; and
- the FDA or other regulatory authorities concluding that a clinical trial design is inadequate to demonstrate safety and efficacy.

In addition, a regulatory authority may disagree with Profound's interpretation of the data from its clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety and efficacy for a particular use, or to demonstrate substantial equivalence to a predicate device, and may require it to pursue additional clinical trials, which would increase costs and could further delay clearance of the Profound device. The data Profound collects from its current trials and other trials may not be sufficient to support clearance or approval by the regulatory authorities of the TULSA-PRO® system. Regulatory authorities may refuse to grant exemptions to pursue additional clinical trials. Profound, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including the risk of death, or that Profound's device is not manufactured under acceptable conditions or with acceptable quality. Further, success in preclinical studies and early clinical trials does not mean that future clinical trials will be successful because medical devices and/or treatment options in later

stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other regulatory authorities despite having progressed through initial clinical trials. Profound cannot be sure that the later trials will replicate the results of prior trials.

Even if Profound's clinical trials are completed as planned, there can be no certainty that trial results will support Profound's product candidate claims or that the FDA or foreign authorities will agree with Profound's conclusions regarding them or agree that they are adequate to support approval. The clinical trial process may fail to demonstrate that Profound's product candidates are safe and effective for the proposed indicated uses, which could cause Profound to abandon a product candidate and may delay development of others. Any delay or termination of Profound's clinical trials will delay the filing of its product submissions and, ultimately, its ability to commercialize the TULSA-PRO® system and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile. In addition, Profound's clinical trials for the TULSA-PRO® system involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

If the TULSA-PRO® system does not prove to be safe and effective, or substantially equivalent to a predicate device, in clinical trials to the satisfaction of the relevant regulatory authorities, if the clinical studies do not support Profound's product candidate claims or if they result in the discovery of adverse side effects, Profound's business, financial condition and results of operation could be materially adversely affected.

If clinical trials are conducted in a manner that fails to meet all FDA regulations and requirements, the FDA may delay approval or the deficiencies may be so great that the FDA could refuse to accept all or part of Profound's data or trigger enforcement action.

Clinical trials are generally required to support PMA approval and de novo classification and are sometimes required to support 510(k) clearance. Such trials, if conducted in the United States, generally require an investigational device exemption application, or IDE, to be approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non significant risk device eligible for more abbreviated IDE requirements. As noted above, the FDA has granted IDE approval with respect to the Pivotal Trial. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board ("**IRB**") for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, Profound must also obtain the patients' informed consent that complies with FDA requirements, state and federal privacy regulations and human subject protection regulations. Profound, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Additionally, Profound may decide at any time, for business or other reasons, to terminate a study. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device for its intended use or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Following completion of a study, Profound would need to collect, analyze and present the data in an appropriate submission to the FDA. Even if a study is completed and submitted to the FDA, the results of clinical testing may not demonstrate the safety and efficacy of the device for its intended use, or may be equivocal or otherwise not be sufficient to obtain clearance or approval of Profound's product. In addition, the FDA may perform a bioresearch monitoring inspection of a study and if it finds deficiencies, Profound will need to expend resources to correct those deficiencies, which may delay clearance or approval or the deficiencies may be so great that the FDA could refuse to accept all or part of the data or could trigger enforcement action.

Clinical trials recruitment

Clinical trials for Profound's device will require that Profound identify and enroll a large number of patients requiring ablation of prostate tissue. Profound may not be able to enroll a sufficient number of patients to complete its clinical trials or may not be able to complete its trials in a timely manner. Patient enrollment is a function of many factors including, but not limited to, design of the study protocol, size of the patient population, eligibility criteria for the study, the perceived risks and benefits of the therapy under study, the patient referral practices of physicians and the availability of clinical trial sites. If Profound has difficulty enrolling a sufficient number of patients to conduct Profound's clinical trials as planned, it may need to delay or terminate ongoing clinical trials. Profound may also be unable to adequately monitor patients after treatment for a variety of reasons, including the failure of the patient to complete the clinical trial, resulting in delays.

If Profound is unable to obtain, or experiences significant delays in obtaining, FDA clearances or approvals or equivalent third country approvals for the TULSA-PRO® *system or future products or product enhancements, Profound's ability to commercially distribute and market its products could suffer.*

Profound's products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities and notified bodies. Profound's device has not received regulatory clearance or approval for commercial sale in the United States or Canada. The process of obtaining FDA clearances or approvals, or equivalent third country approvals to market a medical device can be costly and time consuming, and Profound may not be able to obtain these clearances or approvals on a timely basis, if at all. Profound expects to eventually generate a significant portion of its revenues from sales of the TULSA-PRO™ system, but may be unable to do so if the TULSA-PRO® system does not prove to be safe and effective for its intended use in clinical trials to the satisfaction of the relevant regulatory authorities in the United States, Canada or other countries. No assurance can be given that Profound's device will prove to be safe and effective in clinical trials or that it will receive the regulatory approval. Furthermore, no assurance can be given that current regulations relating to regulatory approval will not change or become more stringent.

Profound believes, based on non-binding discussions with the FDA, that there are suitable predicate devices for the TULSA-PRO™ system or use in the ablation of prostate tissue. As such, Profound intends to follow a 510(k) path for regulatory clearance of its device. Based on its discussions with the FDA, Profound has determined it will need to submit clinical data with its 510(k) premarket notification to support this indication. Profound will collect data from the 110 patient Pivotal Trial designed to demonstrate substantial equivalence for the intended use of device. There is no guarantee that the FDA will clear a submission for 510(k) clearance for the device.

Profound may not obtain the necessary regulatory clearances, approvals, or equivalent third country approvals to market the TULSA-PRO™ system or future products in the United States, the European Union, Canada or elsewhere. Any delay in, or failure to receive or maintain, regulatory clearance, approval or other products under development would adversely affect Profound's ability to utilize its technology, thereby adversely affecting operations and could prevent the Company from generating revenue from these products or achieving profitability. Any failure to obtain regulatory approval would materially adversely affect Profound's business, financial condition and results of operations.

Third-party reimbursement

Even after regulatory approvals or clearance is obtained, successful commercialization of such devices will depend largely upon the costs of the device and the availability of reimbursement for the procedure and medical costs associated with the use of the device from government authorities and private health insurers and other organizations, such as HMOs and MCOs. Profound expects that its device will be purchased by health-care providers, clinics, and hospitals that will subsequently bill various third-party payers. These expectant payers carefully review and increasingly challenge the prices charged for medical devices, procedures and services. Provincial government sponsored health programs in Canada and similar programs in the United States and the European Union reimburse hospitals a pre-determined fixed amount for the costs associated with a particular procedure based on the patient's discharge diagnosis and similarly reimburse the surgeon or physician based on the procedure performed, without taking into consideration the actual costs incurred by either party or the actual cost of the device. New products are being increasingly scrutinized with respect to whether or not they will be covered by the various health plans and at what level of reimbursement. Economic research studies will need to be conducted to evaluate whether Profound's product and approach is superior from a long term cost containment standpoint. Third-party payers may determine that Profound's products are unnecessary, not cost-effective, too experimental or are primarily intended for non-approved indications. These issues could have a material adverse effect on Profound's business, results of operations and financial condition. Profound is unable to predict if additional legislation or regulation impacting the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on Profound's business.

Profound's device may not achieve or maintain expected levels of market acceptance

Even if Profound is able to obtain regulatory approvals or clearances for its device, the success of those products is dependent upon achieving and maintaining market acceptance. New medical devices that appear promising in development may fail to reach the market or may have only limited or no commercial success. Levels of market acceptance for Profound's product could be impacted by several factors, many of which are not within Profound's control, including but not limited to:

- safety, efficacy, convenience and cost-effectiveness of Profound's device as a method of ablation of prostate tissue, or ultimately (pending the relevant approvals) treatment for localized prostate cancer, compared to products of Profound's competitors or other forms of treatment;
- scope of approved uses and marketing approval or clearance;
- timing of market approvals and market entry;
- difficulty in, or excessive costs to, manufacture;
- infringement or alleged infringement of the patents or intellectual property rights of others;

- availability of alternative products from Profound's competitors;
- acceptance of the price of Profound's product relative to those of its competitors;
- acceptance and adoption of its product by physicians/clinicians and the medical community;
- ability to market Profound's product effectively at the patient, physician/clinician and medical community level; and
- acceptance of Profound's product by government and third-party payers for adequate reimbursement.

In addition, the success of any new product will depend on Profound's ability to either successfully build Profound's in-house sales capabilities or to secure new, or to realize the benefits of future arrangements with, third-party marketing or distribution partners. Seeking out, evaluating and negotiating marketing or distribution agreements may involve the commitment of substantial time and effort and may not ultimately result in an agreement. In addition, the third-party marketing or distribution partners may not be as successful in promoting Profound's product as anticipated. If Profound is unable to commercialize new products successfully, whether through a failure to achieve market acceptance, a failure to build Profound's own in-house sales capabilities, a failure to secure new marketing partners or to realize the benefits of Profound's arrangements with existing marketing partners, there may be a material adverse effect on Profound's business, financial condition and results of operations and it could cause the market value of the Common Shares to decline.

In addition, by the time any products are ready to be commercialized, the proposed market for these products may have changed. Profound's estimates of the number of patients who have received or might have been candidates to use a specific product may not accurately reflect the true market or market prices for such products or the extent to which such products, if successfully developed, will actually be used by patients. Profound's failure to successfully introduce and market Profound's products that are under development would have a material adverse effect on Profound's business, financial condition, and results of operations.

Even if Profound's product is approved by regulatory authorities, if Profound or its suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements or if Profound experiences unanticipated problems with its product, it could be subject to restrictions or withdrawal from the market.

Any product for which Profound obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, Profound and its suppliers are required to comply with the FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which Profound obtains clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. Profound and its contract manufacturers have been, and anticipate in the future being, subject to such inspections. The failure by Profound of one of its suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, withdrawal, detention or seizure of Profound's products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying Profound's requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- suspension, variation, or withdrawal of Profound's CE Certificates of Conformity;
- refusals to allow imports and/or to issue documentation necessary to facilitate exports;
- refusal to grant export approval for Profound's product; or
- imposition of civil, administrative or criminal penalties.

If any of these actions were to occur, it would harm Profound's reputation and cause product sales and profitability to suffer and may prevent Profound from generating revenue. Furthermore, key component suppliers may not currently be, or may not continue to be, in compliance with all applicable regulatory requirements, which could result in Profound's failure to produce its products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce Profound's potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that Profound's promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that Profound cease or modify training or promotional materials or subject Profound to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider Profound's training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, Profound may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of its products, and Profound must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to its products. Later discovery of previously unknown problems with its products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device Profound manufactures or distributes, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would have a material adverse effect on Profound's business, financial condition, and results of operations.

Profound relies on third parties to manufacture components of TULSA-PRO® *system*

The TULSA-PRO® system consists of common electronic components, proprietary capital equipment and proprietary disposables. Profound purchases standard electronic components from a number of third party vendors. The capital equipment consists of custom system electronics, treatment delivery console, fluid circuits and an MRI compatible robotic positioning system. Printed circuit boards and assemblies and custom mechanical parts are outsourced to approved local suppliers. Capital equipment is assembled and tested in-house.

Disposables consist of the urethral applicator ("**UA**"), an endo-rectal cooling device and associated accessories. Due to sterility requirements used in connection with the TULSA-PRO® system, the UA must be manufactured under clean conditions. Profound has successfully transferred manufacturing of the UA to an ISO-13485 certified contract medical device manufacturer experienced with assembly of handheld surgical instruments and catheter-based products pursuant to a manufacturing agreement. Profound has developed proprietary automated manufacturing test equipment to improve quality and provide scalability as demand grows and has identified and contracted with local suppliers for the manufacture and supply of the other disposables and their sub-assemblies. The endo-rectal cooling device, which does not require sterilization, is assembled and tested in-house.

Profound cannot be certain that manufacturing sources will continue to be available or that Profound can continue to out-source the manufacturing of Profound's devices on reasonable or acceptable terms. Any loss of a manufacturer or any difficulties that could arise in the manufacturing process could significantly affect Profound's supply of devices. If Profound is unable to supply sufficient amounts of its products to its customers on a timely basis, Profound's market share could decrease and, correspondingly, Profound's revenues would decrease.

If Profound does not negotiate long-term contracts, its suppliers will likely not be required to provide us with any guaranteed minimum production levels. As a result, there can be no assurance that Profound will be able to obtain sufficient quantities of product in the future. In addition, Profound's reliance on third-party manufacturers and suppliers involves a number of risks, including, among other things:

- contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of Profound's products or cause delays in shipments of products;
- Profound or its contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, Profound's suppliers may have excess or inadequate inventory of materials and components;
- Profound or its contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- Profound or its contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of Profound's products;

- Profound may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from Profound or their other customers;
- fluctuations in demand for products that Profound's contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components in a timely manner;
- suppliers or contract manufacturers may wish to discontinue supplying components or services for risk management reasons;
- Profound may not be able to find new or alternative components or reconfigure its system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- contract manufacturers and suppliers may encounter financial hardships unrelated to Profound's demand, which could inhibit their ability to fulfill orders and meet Profound's requirements.

If any of these risks materialize, it could significantly increase costs and impact Profound's ability to meet demand for its products. If Profound is unable to satisfy commercial demand for the TULSA-PRO® system in a timely manner, its ability to generate revenue would be impaired, market acceptance of its products could be adversely affected, and customers may instead purchase or use competitors' products.

Profound's contract manufacturers must comply with applicable Health Canada, EMA and FDA regulations, which include quality control and quality assurance requirements, as well as the corresponding maintenance of records and documentation and manufacture of devices according to the specifications contained in the applicable regulatory file. If Profound's contract manufacturers do not or cannot comply with these requirements, the availability of devices could be reduced.

If Profound encounters delays or difficulties with contract manufacturers, delivery of Profound's products could be delayed. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to Profound's products that are subject to FDA and other regulatory clearances or approvals. Similarly, in the European Union, the introduction of new or alternative manufacturers or suppliers could be considered to constitute a substantial change to Profound's quality system or result in design changes to Profound's product which could affect compliance with the Essential Requirements laid down in Annex I to the Council Directive 93/42/EEC concerning medical devices. These changes must be notified to Profound's notified body before implementation. The notified body will then assess the changes and verify whether they affect the products' conformity with the Essential Requirements laid down in Annex I to the Directive. If the assessment is favorable the notified body will issue a new CE Certificate of Conformity or an addendum to the existing certificates attesting compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive. We may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede Profound's ability to manufacture its products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of Profound's products, suffer damage to our reputation, and experience a material adverse effect on Profound's business, financial condition, and results of operations.

Profound depends on single-source suppliers for some of the components in its products. The loss of these suppliers could prevent or delay shipments of Profound's products or delay its clinical trials or otherwise adversely affect Profound's business.

Profound intends to, at least initially, rely on a single source for the manufacture of the UA and associated accessories. Establishing additional or replacement suppliers for these components will take a substantial amount of time and could result in increased costs and impair Profound's ability to produce its products, which would adversely impact Profound's business, operating results and prospects. In addition, some of Profound's products, which are acquired from third parties, are highly technical and are required to meet exacting specifications, and any quality control problems that Profound experiences with respect to the products supplied by third-party vendors could adversely and materially affect Profound's reputation, its attempts to complete its clinical trials or commercialization of its products and adversely and materially affect Profound's business, operating results and prospects. Profound may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities and the failure of Profound's suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including, warning letters, product recalls, termination of distribution, product seizures, or civil penalties.

Profound's reliance on third-party manufacturers and other third parties in other aspects of our business may reduce any profits earned from Profound's products and may negatively affect future product development.

Profound currently intends to partner with one or more companies to commercialize products manufactured by QSR compliant and FDA registered contract manufacturers and, in connection therewith, Profound will likely be required to enter into manufacturing, licensing and distribution arrangements with third parties. These arrangements will likely reduce our product profit margins. In addition,

the identification of new product candidates for development may require the entering into licensing or other collaborative agreements with others, including medical device and pharmaceutical companies and research institutions. These collaborative agreements may require the payment of license fees, milestone payments or royalties or granting rights, including marketing rights, to one or more parties. Any such arrangement will reduce Profound's profits. Moreover, these arrangements may contain covenants restricting product development or business efforts in the future.

Profound has designed the TULSA-PRO® system to be capable of integration with magnetic resonance imaging (MRI) of two major MRI manufacturers. As not all hospital and treatment facilities utilize MRIs that are compatible with the TULSA-PRO®, such facilities would be required to acquire compatible MRI technology, which may involve additional capital expenditure and which could restrict or delay utilization of the TULSA-PRO® system by such facilities. Accordingly, Profound intends to expand compatibility of the TULSA-PRO® system with other MRIs in the future.

Scaling issue due to growth

As Profound expands its manufacturing capabilities in order to meet its growth objectives, it may not be able to produce sufficient quantities of products or maintain consistency between differing lots of consumables. If Profound encounters difficulties in scaling its manufacturing operations as a result of, among other things, quality control and quality assurance issues and availability of components and raw material supplies, it will likely experience reduced sales of its products, increased repair or re-engineering costs due to product returns, defects and increased expenses due to switching to alternate suppliers, and reputational damage, any of which would reduce revenues and gross margins.

Profound's reliance on its suppliers and contract manufacturers could harm its ability to meet demand for its product in a timely and cost effective manner. Profound's reliance on suppliers and contract manufacturers exposes it to risks including, among other things:

- the possibility that one or more suppliers or assemblers that do not have supply agreements with Profound could terminate their services at any time without penalty;
- natural disasters that impact suppliers;
- the potential obsolescence of, and/or inability of suppliers to obtain, required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
- the inability to qualify alternate sources without impacting performance claims of products;
- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and
- increases in prices of raw materials and key components.

If any of these risks materialize, it could significantly increase Profound's costs and impact Profound's ability to meet demand for its products. If Profound is unable to satisfy commercial demand for the TULSA-PRO® system or supply its clinical trials in a timely manner, Profound's ability to generate revenue would be impaired, market acceptance of Profound's products could be adversely affected, commercialization could be delayed and customers may instead purchase or use its competitors' products. In addition, Profound could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult. The introduction of new or alternative manufacturers or suppliers also may require design changes to the TULSA-PRO® system that are subject to FDA and other regulatory clearances or approvals. Profound may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede Profound's ability to manufacture its products in a timely manner. As a result, Profound could incur increased production costs, experience delays in deliveries of its products, suffer damage to its reputation, and experience a material adverse effect on Profound's business, financial condition, and results of operations.

Profound may rely on third parties to perform distribution, clinical trial planning and execution, regulatory and sales and marketing services for its device

Profound may rely on third parties to provide distribution, clinical trial planning and execution, regulatory and sales and marketing services for its device in certain geographic regions. In connection with the Knight Loan Agreement, Profound has entered into a product sales, marketing and distribution agreement with Knight pursuant to which Knight will act as exclusive distributor of the Company's TULSA-PRO® system in Canada for an initial 10 year term, renewable for successive 10 year terms by either party. Profound may be unable to find suitable partners, external consultants or service providers to provide such services outside of Canada or such arrangements may not be available on commercially reasonable terms. There can be no assurances that Profound will be able to enter

into manufacturing or other collaborative arrangements with third parties on acceptable terms, if at all. Further, Profound may engage third parties that may cease to be able to provide these services, or may not provide these services in a timely or professional manner. Accordingly, Profound may not be able to successfully manage such services, execute clinical trials or generate revenues from its devices in such regions, which may result in decreases in sales. If Profound fails to establish such arrangements when, and as necessary, it could be required to undertake these activities at its own expense, which would significantly increase capital requirements and may delay the development, manufacturing and commercialization of Profound's product. If Profound is unable to address these capital requirements, it would likely be forced to sell or abandon its business. Additionally, any delay or interruption in the process or in payment could result in a delay delivering product to its customers, which could have a material adverse effect on Profound's business, financial condition and operating results.

These arrangements will likely reduce Profound's product profit margins. In addition, the identification of new product candidates for development may require that Profound enter into licensing or other collaborative agreements with others, including medical device and pharmaceutical companies and research institutions. These collaborative agreements may require that Profound pay license fees, make milestone payments or pay royalties or grant rights, including marketing rights, to one or more parties. Any such arrangement will reduce Profound's profits. Moreover, these arrangements may contain covenants restricting Profound's product development or business efforts in the future.

Profound's product may in the future be subject to product recalls that could harm its reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. Profound may initiate voluntary recalls involving its products in the future that it determines do not require notification of the FDA. If the FDA disagrees with Profound's determinations, they could require Profound to report those actions as recalls. A future recall announcement could harm Profound's reputation with customers and negatively affect its sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In the European Union, incidents must be reported to the relevant authorities of the European Union Member States, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. In addition, other foreign governmental bodies have the authority to require the recall of products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by Profound or one of its distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of the TULSA-PRO® system or any future products would divert managerial and financial resources and have an adverse effect on its financial condition and results of operations.

If Profound's product causes or contributes to a death or a serious injury, or malfunctions in certain ways, it will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device was to recur. If Profound fails to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against it. Similar enforcement action could be taken by the competent authorities in the EU if the company does not comply with its medical devices vigilance obligations. In addition, Profound's notified body could decide to suspend or withdraw the company's CE Certificates of Conformity. Any such adverse event involving the TULSA-PRO® system also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, audit or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of personnel time and capital, distract management from operating the business and may harm the Profound's reputation and could have a material adverse effect on Profound's business, financial condition and operating results.

Profound may be subject to fines, penalties or injunctions if it is determined to be promoting the use of its products for unapproved or "off-label" uses.

If the FDA determines Profound is promoting the use of its products for unapproved or "off-label" uses, the FDA could require Profound to stop promoting its products for specific procedures until Profound obtains FDA clearance or approval for them. In addition, if the FDA determines that Profound's promotional materials or training constitutes promotion of an unapproved use, it could request that Profound modify its training or promotional materials or subject Profound to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider Profound's promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, Profound's reputation could be damaged and adoption of the products would be impaired.

The markets in which Profound proposes to operate are highly competitive and subject to rapid and significant technological change

Profound's device will face competition from existing and new prostate ablation and prostate cancer treatment options. Many of Profound's competitors have greater financial resources and development and selling and marketing capabilities. Profound may face further competition from medical equipment/supply companies that focus their efforts on developing and marketing products that are similar in nature to its product, but that in some instances offer improvements of Profound's devices. Profound's competitors may succeed in developing technologies and products that are more effective or less expensive to use than Profound's device. These developments could render Profound's medical device uncompetitive, which would have a material adverse effect on Profound's business, financial condition and operating results. In addition, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products. They may also establish exclusive collaborative or licensing relationships with Profound's competitors.

Further, this industry is also subject to changing industry standards, market trends and customer preferences and to competitive pressures which can, among other things, necessitate revisions in pricing strategies, price reductions and reduced profit margins. The success of Profound will depend, in part, on its ability to secure technological superiority in its product and operations and maintain such superiority in the face of new technologies. No assurance can be given that further modification of product offerings of Profound will not be required in order to meet demands or to make changes necessitated by developments made by competitors that might render services and operations of Profound less competitive. The future success of Profound will be influenced by its ability to continue to adapt its device. Although Profound has committed resources to research and develop its device, there can be no assurance that these efforts will be successful.

Market not accepting of the product

The market may not accept Profound's product and may continue to use the incumbent products. The TULSA-PRO® system may not be adopted as Profound expects and its treatment may not be considered an advantage by some or all physicians/clinicians, adversely affecting Profound's ability to see its product become profitable. Profound's competitors may be more effective at commercializing products that eat into any market share that the TULSA-PRO™ system may have achieved.

Profound depends on key managerial personnel for its continued success

Profound is highly dependent upon qualified managerial personnel. Profound's anticipated growth will require additional expertise and the addition of new qualified personnel. There is intense competition for qualified personnel in the medical device field. Therefore, Profound may not be able to attract and retain the qualified personnel necessary for the development of Profound's business. Profound must continue to retain, motivate and recruit executives, including Profound's Chief Executive Officer, Steven Plymale, and other key employees. The loss of the services of existing personnel, as well as the failure to recruit additional key managerial personnel in a timely manner, would harm Profound's business development programs, and Profound's ability to manage day-to-day operations, attract collaboration partners, attract and retain other employees, generate revenues, and could have a material adverse impact on Profound's business, financial condition and results of operations.

Profound currently maintains key-man insurance on its Chief Executive Officer, Steven Plymale, and its Vice-President of Engineering, Ron Kurtz, but not on its other executive officers or employees. The policies on Mr. Plymale and Mr. Kurtz are term policies, each with one million dollar benefits to Profound. Although it would not solve the potential problem of a loss of the services of any particular

employee, Profound may seek key-man insurance on other key individuals to help in the case of such an event. The loss of the services of any of the executive officers identified in this AIF could have a material impact on Profound.

A period of significant growth can place a strain on management systems

Profound expects to increase its staffing from 48 to approximately 60 employees by 2018. This significant growth will put significant demands on Profound's processes, systems and people. There can be no assurance that Profound will be able to effectively manage such growth. If Profound is unable to successfully manage and support its growth and the challenges and difficulties associated with managing a larger, more complex business, this could cause a material adverse effect on Profound's business, financial position and results of operations.

The continuing development of Profound's device depends upon Profound maintaining strong relationships with physicians/clinicians

If Profound fails to maintain positive working relationships with physicians/clinicians, Profound's device may not be developed and marketed in line with the needs and expectations of the professionals who Profound expects will use and support the device, which could cause a decline in earnings and profitability. The research, development, marketing and sales of the device is dependent upon Profound maintaining working relationships with physicians/clinicians. Profound relies on these professionals to provide considerable knowledge and experience regarding the development, marketing and sale of the device. Physicians/clinicians assist Profound as researchers, marketing and product consultants, inventors and public speakers. If Profound is unable to maintain strong relationships with these professionals and continue to receive their advice and input, the development and marketing of the device could suffer, which could have a material adverse effect on Profound's business, financial condition and operating results.

Research and development of products carries substantial technical risk

Future growth will depend on, among other factors, Profound's ability to successfully develop new products and make product improvements to meet evolving market needs. Profound may not be able to successfully commercialize future products and as a consequence, its ability to expand the product portfolio to generate new revenue opportunities may be severely limited. Although Profound believes it has the scientific and technical resources available to improve its product and develop new products, future products will nevertheless be subject to the risks of failure inherent in the development of products based on innovative technologies. There can be no assurance that Profound will be able to successfully develop future products and tests, which would prevent Profound from introducing new products in the marketplace and negatively impact its ability to grow revenues and become profitable.

Achievement of development goals in time frames announced and expected

Profound sets goals for and makes public statements regarding the timing of the accomplishment of objectives material to its success, such as the commencement and completion of clinical trials and anticipated regulatory submission and approval dates and time of product launch. The actual timing of these events can vary dramatically due to factors such as delays or failures in Profound's clinical trials or the uncertainties inherent in the arrangements sufficient to commercialize its product. There can be no assurance that Profound's clinical trials will be completed, that Profound will make regulatory submissions or receive regulatory approvals as planned. Failure to achieve one or more of these milestones would have a material adverse effect on Profound's business, financial conditions and results of operations.

Profound's business is subject to limitations imposed by government regulations

The preclinical and clinical trials of any products developed by Profound and the manufacturing, labeling, sale, distribution, export or import, marketing, advertising and promotion of any of those products are subject to rigorous regulation by federal, provincial, state and local governmental authorities. Profound's medical devices are principally regulated in the United States by the FDA, in Canada by Health Canada (particularly, the Therapeutic Products Directorate), in the European Union by the EMA and by other similar regulatory authorities in other jurisdictions. Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products. Following several widely publicized issues in recent years, the FDA and similar regulatory authorities in other jurisdictions have become increasingly focused on product safety. This development has led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials and for more detailed analysis of trial results. Consequently, the process of obtaining regulatory approvals/clearance, particularly from the FDA, has become more costly, time consuming and challenging than in the past. Any product developed by Profound or its future collaborative partners, if any, must receive

all relevant regulatory approvals or clearances from the applicable regulatory authorities before it may be marketed and sold in a particular country.

Any of Profound's products that receive regulatory approval could be subject to extensive post-market regulation that could affect sales, marketing and profitability

With respect to any products for which Profound obtains regulatory clearance or approval, it will be subject to post-marketing regulatory obligations, including requirements by the FDA, Health Canada, EMA and similar agencies in other jurisdictions to maintain records regarding product safety and to report to regulatory authorities serious or unexpected adverse events. The occurrence of unanticipated serious adverse events or other safety problems could cause the governing agencies to impose significant restrictions on the indicated uses for which the product may be marketed, impose other restrictions on the distribution or sale of the product or require potentially costly post-approval studies. In addition, post-market discovery of previously unknown safety problems or increased severity or significance of a pre-existing safety signal could result in withdrawal of the product from the market and product recalls. Compliance with extensive post-marketing record keeping and reporting requirements requires a significant commitment of time and funds, which may limit Profound's ability to successfully commercialize approved products.

Legislative or regulatory reform of the healthcare systems in which Profound intends to operate may affect Profound's ability to sell its device profitably and could adversely affect its business

The government and regulatory authorities in the United States, Canada, the European Union and other markets in which Profound expects to sell its device may propose and adopt new legislation and regulatory requirements relating to medical product approval criteria, manufacturing and marketing requirements. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Profound's business and products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact Profound's operations and could have a material adverse effect on Profound's business, financial condition and results of operations.

For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon Profound and delay Profound's ability to obtain new 510(k) clearances or PMA approvals or increase the costs of compliance. Any change in the laws or regulations that govern the clearance and approval processes relating to Profound's products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for Profound's products would have a material adverse effect on Profound's business, financial condition and operating results.

Another example can be found in the European Union. On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the European Union. These proposals are intended to strengthen the medical devices rules in the European Union. On May 25 2016, the Council of the European Union issued a press release to announce that the European Commission, the European Parliament and the Council had reached an agreement concerning the text of the proposed Regulation on medical devices and the proposed Regulation on in vitro diagnostic medical devices. Final adoption of the Regulations is anticipated in late 2016 or early 2017. The Regulations, which are expected to substantially impact medical devices manufacturers, will be applicable from late 2019 at the earliest. When adopted the proposed new legislation may prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly. These pressures are particularly strong given the ongoing effects of the recent global economic and financial crisis, including the continuing debt crisis in certain countries in Europe, and the risk of a similar crisis in the United States. As a result, Profound's businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. In recent years, national, federal, provincial, state and local officials and legislators have proposed, or are reportedly considering proposing, a variety of price based reforms to the healthcare systems in the United States, the European Union and other countries. Some proposals include measures that would limit or eliminate

payments for certain medical procedures and treatments or subject pricing to government control. Furthermore, in certain foreign markets, the pricing or profitability of healthcare products is subject to government controls and other measures that have been prepared by legislators and government officials. While Profound cannot predict whether any such legislative or regulatory proposals or reforms will be adopted, the adoption of any such proposals or reforms could adversely affect the commercial viability of Profound's existing and potential products.

In March 2010, the President of the United States, Barack Obama, signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. Certain provisions of the law will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the law. The legislation imposes new taxes on medical device makers in the form of a 2.3% excise tax on all medical device sales in the United States. Under the legislation, the total cost to the medical device industry is expected to be approximately US$20 billion over 10 years. The new tax could materially and adversely affect Profound's business, cash flows and results of operations. The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending beginning in 2014. Profound cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursement for Profound's products or reduce medical procedure volumes could adversely affect Profound's business and results of operations.

Other legislation or regulatory proposals may adversely affect Profound's revenues and profitability

Existing and proposed changes in the laws and regulations affecting public companies may cause Profound to incur increased costs as it evaluates the implications of new rules and responds to new requirements. Failure to comply with the new rules and regulations could result in enforcement actions or the assessment of other penalties. The new laws and regulations could make it more difficult to obtain certain types of insurance, including director's and officer's liability insurance, and Profound may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for Profound to attract and retain qualified persons to serve on Profound's board of directors, or as executive officers. Profound may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause Profound's general and administrative costs to increase beyond what it currently has planned. Profound is presently evaluating and monitoring developments with respect to these rules, and it cannot predict or estimate the amount of the additional costs it may incur or the timing of such costs.

Rising insurance costs could negatively impact Profound's profitability

The cost of insurance, including director and officer, worker's compensation, property, product liability and general liability insurance, has risen significantly in recent years and is expected to continue to increase. In response, Profound may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and Profound's increased risk due to increased deductibles and reduced coverages, could have a negative impact on Profound's business, financial condition and results of operations.

Profound may be subject to product liability claims, which can be expensive, difficult to defend and may result in large judgments or settlements

The use of medical devices for treatment of humans, whether in clinical trials or after marketing clearance approval is obtained, can result in product liability claims. Product liability claims can be expensive, difficult to defend and may result in large judgments or settlements against Profound. In addition, third party collaborators and licensees may not protect Profound from product liability claims.

Profound currently maintains product liability insurance in connection with the use of Profound's device in clinical trials. Profound may not be able to obtain or maintain adequate protection against potential liabilities arising from such use. If Profound is unable to obtain sufficient levels of insurance at acceptable cost or otherwise protect against potential product liability claims, Profound will be exposed to product liability claims. A successful product liability claim in excess of Profound's insurance coverage could harm Profound's financial condition, results of operations and prevent or interfere with Profound's product commercialization efforts. In addition, any successful

claim may prevent Profound from obtaining adequate product liability insurance in the future on commercially desirable terms. Even if a claim is not successful, defending such a claim may be time-consuming and expensive.

Use of product in unapproved circumstances could expose Profound to liabilities

The marketing approval from regulators of Profound's product is, or is expected to be, limited to specific indications. Profound is prohibited by law from marketing or promoting any unapproved use of its products. Physicians/clinicians, however, in most jurisdictions, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training Profound will provide to physicians and other health care professionals will be limited to cleared/approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if its product is used in ways or for procedures that are not approved.

Unexpected product safety or efficacy concerns may arise

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as product liability, consumer fraud and/or other claims. This could have a material adverse effect on Profound's business, financial condition and results of operations.

Customer misuse could result in lack of adoption

There is a risk that customers may misuse the product, such as not following the instructions for use, not using it on the intended patient population, using it with unapproved MRI machines, using it with unapproved or modified hardware or software, or misuse by inadequately trained staff. Customers may also initiate their own clinical studies which may be poorly designed or controlled. This may result in negative publications, negative sentiment or adverse events, thereby limiting future sales of the product.

Risks related to "fraud and abuse" laws, anti-bribery laws, environmental laws and privacy and security regulations

Profound's business is subject to the Foreign Corrupt Practices Act of 1977 ("FCPA") in the United States, which generally prohibits companies and company employees from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. The FCPA also requires companies to maintain accurate books and records and internal controls. In addition, Profound is subject to other anti-bribery laws of the nations in which Profound conducts business that apply similar prohibitions as the FCPA (e.g., The Bribery Act 2010 in the United Kingdom, the Corruption of Foreign Public Officials Act in Canada and the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions of the Organisation for Economic Co-operation and Development). Profound's employees or other agents may, without Profound's knowledge and despite Profound's efforts, engage in prohibited conduct under Profound's policies and procedures and the FCPA or other anti-bribery laws to which Profound may be subject. If Profound's employees or other agents are found to have engaged in such practices, Profound could suffer severe penalties and other consequences that may have a material adverse effect on its business, financial condition and results of operations.

Profound is also subject to various privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") in the United States. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions (e.g. health care claims information and plan eligibility, referral certification and authorization, claims status, plan enrolment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states, provinces and other countries have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws could result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could have a material adverse effect on Profound's business, financial condition and operating results.

Foreign currency risk

Profound expects that a significant portion of its revenues, if and when realized, expenses, current assets and current liabilities will be denominated in Euros, United States dollars and other foreign currencies but its financial statements are expressed in Canadian dollars. A decrease in the value of such foreign currencies relative to the Canadian dollar could result in decreases in revenues from currency exchange rate fluctuations. To date, Profound has not hedged against risk associated with foreign exchange rate exposure.

Also, the price of Common Shares may be independently impacted by the exchange rate alone as the market price of Profound's securities will be denominated in Canadian dollars while some of the financial results of Profound's operations will be denominated in foreign currency. Consequently, the market price of Profound's securities may be negatively affected by adverse changes in exchange rates.

Risk Factors Relating to Intellectual Property

If Profound breaches any of the agreements under which Profound licenses rights to its technology from third parties, Profound could lose license rights that are important to its business. Certain of Profound's license agreements may not provide an adequate remedy for their breach by the licensor

Profound licenses certain development and commercialization rights for its device, and expects to enter into similar licenses in the future. For instance, Profound licenses exclusive rights from Sunnybrook that enable it to use, manufacture, distribute and sell the device. Under this license, Profound is subject to various obligations, including a milestone payment of $250,000 upon obtaining FDA clearance, and legal costs associated with patent application preparation, filing and maintenance. Subject to certain buy out provisions as defined in the license, Profound has the option to acquire ownership of the licensed technology and intellectual property. In addition, Profound has a further option to acquire rights to improvements to the relevant technology and intellectual property. If Profound fails to comply with any of these obligations or otherwise breaches this agreement, Sunnybrook may have the right to terminate. Loss of this license or the exclusivity rights provided therein could have a material adverse effect on Profound's business, financial condition and operating results

Profound's proprietary rights may not adequately protect Profound's technologies

Profound's commercial success will depend on its ability to obtain patents (or exclusive rights thereto) and/or regulatory exclusivity and to maintain adequate protection for Profound's technologies in Canada, the United States and other countries. As of the date hereof, Profound owns or has exclusive rights to six issued United States patents and at least six pending United States patent applications. Profound or its licensors will be able to protect such proprietary rights from unauthorized use by third parties only to the extent that Profound's proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Profound applies for patents covering its technologies as Profound deems appropriate. However, Profound may fail to apply for patents on important technologies in a timely fashion, or at all. Profound's existing patent applications and any future patents Profound may obtain may not be sufficiently broad to prevent others from utilizing Profound's technologies or from developing competing products and technologies. In addition, Profound cannot guarantee that:

- Profound or its licensors were the first to make the inventions covered by each of Profound's issued patents and pending patent applications;
- Profound or its licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of Profound's or its licensors' technologies;
- any of Profound's or its licensors' pending patent applications will result in issued patents;
- any of Profound's or its licensors' patents will be valid or enforceable;
- any patents issued to Profound or its licensors and collaboration partners will provide Profound with any competitive advantages, or will not be challenged by third parties;
- Profound will develop or in-license additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on Profound's business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent, the scope of Profound's or its licensors' coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. Profound's or its licensors' ability to maintain and solidify Profound's or its licensors' proprietary position for Profound's product will depend on Profound's or its licensors' success in obtaining effective claims and enforcing those claims once granted. Profound's or its licensors' issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, and the rights granted under any such issued patents may not provide Profound with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a medical device, it is possible that, before

Profound's device can be commercialized, any relevant patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Protection afforded by United States patents may be adversely affected by recent or future changes to patent related statutes in the United States and to U.S. PTO rules. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of Profound's patent applications and the enforcement or defense of Profound's issued patents. On September 16, 2011, the Leahy-Smith Act was signed into law in the United States. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO 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. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of Profound's business. However, the Leahy-Smith Act and its implementation, as well as any future changes to patent law in the United States or otherwise, could increase the uncertainties and costs surrounding the prosecution of Profound's or its licensors' patent applications and the enforcement or defense of Profound's or its licensors' issued patents, all of which could have a material adverse effect on Profound's business, financial condition and operating results.

Moreover, Profound or its licensors may be subject to a third party preissuance submission of prior art to the U.S. PTO, or become involved in opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions, challenging Profound's or its licensors' patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, Profound's or its licensors' patent rights, allow third parties to commercialize Profound's technology or product and compete directly with Profound, without payment to Profound, or result in Profound's inability to manufacture or commercialize product without infringing third party patent rights. In addition, if the breadth or strength of protection provided by Profound's or its licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with Profound to license, develop or commercialize current or future products. Other changes to the patent statutes may adversely affect the protection afforded by United States patents and/or open United States patents up to third party attack in non-litigation settings.

Profound also relies on trade secrets to protect some of its technology, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While Profound uses reasonable efforts to protect its trade secrets, Profound or Profound's collaboration partners' employees, consultants, contractors or scientific and other advisors may unintentionally or wilfully disclose Profound's proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than courts in the United States to protect trade secrets. If Profound's competitors independently develop equivalent knowledge, methods and know-how, Profound would not be able to assert Profound's trade secrets against them and Profound's business could be harmed.

Profound may not be able to protect its intellectual property rights throughout the world

Filing, prosecuting and defending patents on all of Profound's product candidates and products, when and if Profound has any, in every jurisdiction would be prohibitively expensive. Competitors may use Profound's technologies in jurisdictions where Profound or Profound's licensors have not obtained patent protection to develop Profound's own products. These products may compete with Profound's products, when and if Profound has any, and may not be covered by any of Profound's or its licensors' patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of the United States and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, may not favour the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of Profound's patents. Proceedings to enforce Profound's or its licensors' patent rights in foreign jurisdictions could result in substantial cost and divert Profound's efforts and attention from other aspects of Profound's business.

The patent protection for Profound's technologies may expire before Profound is able to maximize their commercial value which may subject us to increased competition and reduce or eliminate Profound's opportunity to generate product revenue

The patents for Profound's technologies have varying expiration dates and, when these patents expire, Profound may be subject to increased competition and may not be able to recover its development costs. In some of the larger economic territories, such as the

United States and the European Union, patent term extension/restoration may be available to compensate for time taken during aspects of the product candidate's regulatory review. However, Profound cannot be certain that an extension will be granted or, if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. If Profound or its licensors are unable to obtain patent term extension/restoration or some other exclusivity, Profound could be subject to increased competition and Profound's opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, Profound may not have sufficient time to recover Profound's development costs prior to the expiration of Profound's or its licensors' patents in the United States or elsewhere.

Profound may incur substantial costs as a result of litigation or other proceedings relating to enforcement of Profound's or its licensors' patent and other intellectual property rights and Profound may be unable to protect Profound's rights to, or use of, Profound's technology

If Profound chooses to go to court to prevent a third party from using the inventions claimed in Profound's or its licensors' patents, that third party has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. Even if Profound were successful in stopping the infringement of these patents, these lawsuits are expensive and would consume time and other resources. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that Profound does not have the right to prevent the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to prevent the other party on the ground that such other party's activities do not infringe Profound's rights.

Profound may be subject to lawsuits from, liable for damages to, or be required to enter into license agreements with, a third party that claims Profound infringed its patents or otherwise misused its proprietary information

If Profound wishes to use the technology in issued and unexpired patents owned by others, Profound will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of these patents or incur the risk of litigation in the event that the owner asserts that Profound infringed these patents. The failure to obtain a license to technology or the failure to challenge an issued patent owned by others that Profound may require to develop or commercialize Profound's product candidates may have a material adverse impact on Profound.

In addition, if a third party asserts that Profound infringed its patents or other proprietary rights, Profound could face a number of risks that could seriously harm Profound's results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from Profound's business;
- substantial damages for past infringement, including possible treble damages, which Profound may have to pay if a court determines that Profound's product candidates or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing Profound's technologies unless the third party licenses Profound's patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, Profound may have to pay substantial royalties or lump sum payments or grant cross licenses to Profound's patents or other proprietary rights to obtain that license.

The coverage of patents is subject to interpretation by the courts and the interpretation is not always uniform. If Profound is sued for patent infringement, Profound would need to demonstrate that its products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and Profound may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Patent laws in the United States as well as the laws of some foreign jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent is subsequently issued and certain other conditions are met. While Profound believes that there may be multiple grounds on which to challenge the validity of United States patents and the foreign counterparts possibly relevant to Profound's business, Profound cannot predict the outcome of any invalidity challenge. Alternatively, it is possible that Profound may determine it prudent to seek a license from a patent holder to avoid potential litigation and other potential disputes. Profound cannot be sure that a license would be available to it on acceptable terms, or at all.

Because some patent applications in the United States or other countries may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after

filing and because publications in the scientific literature often lag behind actual discoveries, Profound cannot be certain that others have not filed patent applications for technology covered by Profound's or its licensors' issued patents or Profound's pending applications or Profound's licensors' pending applications, or that Profound or its licensors were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to Profound's may have priority over Profound's or its licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a United States patent application on an invention similar to Profound's, Profound may elect to participate in or be drawn into an interference or other proceeding declared by the U.S. PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that such efforts would be unsuccessful, resulting in a loss of Profound's United States patent position with respect to such inventions.

Profound may also be subject to damages resulting from claims that Profound or its employees or consultants have wrongfully used or disclosed alleged trade secrets of third parties. Many of Profound's employees were previously employed, and certain of Profound's consultants are currently employed, at universities or medical device companies, including Profound's competitors or potential competitors. Although Profound has not received any claim to date, Profound may be subject to claims that Profound, or these employees or consultants, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these current or former employers. Litigation may be necessary to defend against these claims. If Profound fails in defending such claims, in addition to paying monetary damages, Profound may lose valuable intellectual property rights or personnel. Profound may be subject to claims that employees of Profound's partners or licensors of technology licensed by Profound have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Profound may become involved in litigation to defend against these claims. If Profound fails in defending such claims, in addition to paying monetary damages, Profound may lose valuable intellectual property rights or personnel.

Some of Profound's competitors may be able to sustain the costs of complex patent litigation more effectively than Profound can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on Profound's ability to raise the funds necessary to continue Profound's operations. Profound cannot predict whether third parties will assert these claims against Profound or against its licensors, or whether those claims will harm Profound's business. If Profound or its licensors are forced to defend against these claims, whether they are with or without any merit, whether they are resolved in favour of or against Profound or its licensors, Profound may face costly litigation and diversion of management's attention and resources. As a result of these disputes, Profound may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to Profound, if at all, which could have a material adverse effect on Profound's business, financial conditions and results of operations.