Management's Discussion and Analysis of Financial Condition and Results of Operations of Profound Medical Corp. for the Year Ended December 31, 2017

The following Management's Discussion and Analysis ("**MD&A**") prepared as of March 23, 2018 should be read in conjunction with the December 31, 2017 audited consolidated financial statements and related notes of Profound Medical Corp. ("**Profound**", the "**Company**", "**us**" or "**our**"). The audited consolidated financial statements of Profound and related notes 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 MD&A, 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:

- the completion of the TACT Pivotal Clinical Trial (as defined herein) and the timing thereof;
- the submission of an application to the FDA (as defined herein) for approval to market the TULSA-PRO® in the United States;
- the use of proceeds of the 2017 Offering (as defined herein) and 2016 Offering (as defined herein);
- expectations regarding current and future clinical trials and the costs thereof;
- expectations regarding regulatory approvals;
- expectations regarding the safety and efficacy of our products;
- expectations regarding the Company's relationship with Philips (as defined herein);
- expectations regarding the use of our products including treating conditions that our products do not currently treat;
- plans for and timing of expansion of our product and service offerings;
- the Company's mission and future growth plans;
- our ability to attract and develop and maintain relationships with suppliers, manufacturers, distributors, strategic relationships, physicians/clinicians, etc.;
- our ability to attract and retain personnel;
- expectations regarding growth in our product markets and competitive position;
- our ability to raise debt and equity capital to fund future product development;
- anticipated trends and challenges in Profound's business and the markets in which we operate;
- ability to integrate acquired businesses including the Sonalleve® MR-HIFU (as defined herein), new products and services offerings; and
- expectations regarding the additional consideration to be paid to Philips pursuant to the Sonalleve® MR-HIFU Transaction (as defined herein).

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 the Company's Annual Information Form prepared as of March 28, 2017 for the year ended December 31, 2016 (the "**AIF**") available on SEDAR at www.sedar.com, such as:

- successful completion of clinical trial phases with respect to Profound's devices;
- risks related to the integration of business and products acquired by the Company, including the Sonalleve® MR-HIFU, with the current businesses and product offerings of the Company;
- obtaining regulatory approvals in relevant jurisdictions to market Profound's devices;
- risks related to the regulation of Profound, including the healthcare market;
- lack of funding may limit the ability to commercialize and market Profound's products;
- fluctuating input prices, international trade and political uncertainty;
- healthcare regulatory regime may affect financial viability;
- reimbursement models in relevant jurisdictions may not be advantageous;
- risks related to managing growth;
- competition may limit the growth of Profound;
- reliance on third parties and risks related to the transition of manufacturing and installation services;
- 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;
- past performance is not indicative of future performance; and
- history of negative operating cash flow.

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 creating a therapeutics platform that provides the precision of real-time Magnetic Resonance ("**MR**") imaging combined with the safety and ablation power of directional (inside-out) and focused (outside-in) ultrasound technology for the incision-free ablation of diseased tissue.

Profound is commercializing a novel technology, TULSA-PRO®, which combines real-time MR Imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control that is designed to provide precise ablation of the prostate while simultaneously protecting critical surrounding anatomy from potential side effects. TULSA-PRO® is CE marked and Profound is currently conducting a pilot commercial launch of the technology in key European and other CE mark jurisdictions.

Profound is also commercializing Sonalleve® MR high intensity focused ultrasound ("**MR-HIFU**"), an innovative therapeutic platform that combines real-time MR imaging and thermometry with thermal ultrasound to enable precise and incision-free ablation of diseased tissue. Sonalleve® is CE marked for the treatment of uterine fibroids and palliative pain treatment of bone metastases. MR-HIFU, as a technology, has also been shown to have clinical application in other medical conditions, including non-invasive ablation of abdominal cancers and hyperthermia for cancer therapy.

The common shares in the capital of Profound ("**Common Shares**") are listed on the TSX Venture Exchange (TSXV:PRN) and OTCQX Market (PRFMF).

Business Update

Profound's core technology is 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 led 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 2013, Profound announced initiation of the 30 patient TULSA (Transurethral Ultrasound Ablation) study in Canada and subsequently, additional clinical sites were added to include Germany and the United States. In 2014, Profound completed enrollment and treatment of 30 patients ("**Phase 1**") 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 this study, the TULSA-PRO® system demonstrated accurate and precise ablation of targeted prostate tissue, while providing a well-tolerated favourable safety profile with minor impact on urinary, erectile and bowel function at 12 months. In 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 received an Investigational Device Exemption from the United States Food and Drug Administration ("**FDA**") on May 19, 2016, a prerequisite to launching the TULSA-PRO® ablation clinical trial (the "**TACT Pivotal Clinical Trial**"). The TACT Pivotal Clinical 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. Please refer to the AIF for more information. All 110 patients have consented to complete 12 month follow-up visits. On January 31, 2018, Profound announced the completion of patient enrollment in the TACT Pivotal Clinical Trial across 13 research sites in the US, Canada and Europe. The primary safety endpoint is the frequency and severity of adverse events, with additional secondary endpoints focused on quality-of-life side effects commonly associated with current prostate cancer therapies, such as erectile dysfunction and urinary incontinence. As the standard evaluation period for these side effects is 12 months post-treatment, the sample size of evaluable patients is not yet large enough to assess. However, to-date, the Company has received TACT patient follow-up data at 1 month: 105 patients, 3 months: 79 patients, 6 months: 51 patients and 12 months: 12 patients and witnessing a positive trend.

If successful, the TACT Pivotal Clinical 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.

On October 26, 2017, Health Canada refused Medical Device License approval of TULSA-PRO® requiring further clinical evidence beyond the Phase I data. Profound management is in the process of evaluating the additional requirements, in terms of required effort and time. From a commercialization strategy perspective, the Canadian market is not considered a priority.

In 2017, Profound made significant reimbursement progress in Germany for TULSA-PRO®. TULSA- PRO® received a dedicated procedure code (OPS code) in Germany, securing an initial Diagnosis-Related Group (DRG) payment of €3,963 per procedure starting in January 1, 2018. Profound continues reimbursement efforts in Germany to build on this initial reimbursement. The Company is also pursuing reimbursement activities for the US market and other key European markets.

Sonalleve® MR-HIFU Transaction

On July 31, 2017, Profound closed an asset and share purchase agreement (the "**Agreement**") with Koninklijke Philips N.V. ("**Philips**") in order to seek to expand the existing collaboration and acquire Philip's Sonalleve® MR-HIFU business (the "**Sonalleve® MR-HIFU Transaction**"), establishing Profound as a market leader in MR-ultrasound ablation therapy.

Under the terms of the Agreement, Philips transferred its Sonalleve® MR-HIFU assets to Profound for upfront consideration of 7,400,000 Common Shares. Under the Agreement, the earn-out provisions include a requirement that Profound pay additional consideration of: (i) 5% of Net Sales occurring after July 31, 2017 for the calendar year 2017; (ii) 6% of Net Sales occurring in the calendar year 2018; and (iii) 7% of Net Sales occurring in calendar years 2019 and 2020. To the extent that the cumulative Net Sales for the full calendar years 2017-2020 exceeds €45,300,000, Profound will be required to pay an additional earn-out equal to 7% of Net Sales for the period beginning after July 31, 2017 through December 31, 2019.

"Net Sales" include the revenues (less any royalties) received by Profound or its affiliates or others on their behalf in respect of the sale or transfer of the Sonalleve® MR-HIFU, any subsequent, successor or next-generation product the treatment technology of which is primarily based on Sonalleve® MR-HIFU and which utilizes intellectual property rights acquired under the Agreement or any future product that combines the technologies of Sonalleve® MR-HIFU and TULSA-PRO® and any amounts received by Profound with respect to service agreements, but does not include any revenues with respect to consumables.

As part of the Sonalleve® MR-HIFU Transaction, Philips and Profound expanded their non-exclusive strategic sales relationship for Profound's TULSA-PRO® system to include distribution of Sonalleve® MR-HIFU. For a limited time following the transition of the Sonalleve® MR-HIFU business to Profound, Philips will also provide other services, including, but not limited to, manufacturing and installation.

The Sonalleve® MR-HIFU Transaction has expanded Profound's core competency in MR-ultrasound ablation therapy. Management believes that Profound is now the only company to provide a therapeutics platform that provides the precision of real-time MR imaging combined with the safety and ablation power of directional (inside-out) and focused (outside-in) ultrasound technology for the incision-free ablation of diseased tissue.

The Company continues to pursue growth opportunities both organically, increasing its existing business by gaining new customers, increasing product and service penetration with existing clients, as well as through transactions in which the Company acquires new operating entities. Over the past year, the Company has enhanced its corporate development capabilities to execute transactions, through significant investments in people, technology and other organizational resources, and has developed techniques, processes and other intellectual capital, all with the objective of creating a powerful combination of real-time MR-guidance imaging platforms and ultrasounds for delivering non-invasive ablative tools to clinicians.

The Company will consider acquisitions ranging in size and structure, but all share the characteristic of having a strong underlying strategic rationale, which include enhancing the Company's position in existing markets or providing entry into new markets, expanding the Company's administrative and technological capabilities, providing new supplier relationships and enhancing the breadth and depth of the Company's product and service offering.

HIGHLIGHTS

- Profound announces fiscal 2017 revenues totaling $4,904,550.
- On November 6, 2017, Profound announced the expanded clinical use of TULSA-PRO® in prostate care to include Benign Prostatic Hyperplasia ("**BPH**").
- On September 20, 2017, Profound completed a bought deal financing pursuant to a short form prospectus (the "**2017 Offering**") for total gross proceeds of $10 million. The 2017 Offering was completed through a syndicate of underwriters led by Echelon Wealth Partners Inc. and including CIBC World Markets Inc.
- On July 31, 2017, Profound completed the Sonalleve® MR-HIFU Transaction, establishing Profound as a market leader in MR-ultrasound ablation therapy.
- Profound obtains Depository and Trust Clearing Corporation (DTC) eligibility for its common shares listed on the OTCQX
- On March 27, 2017, Profound announced that the first TULSA-PRO® patient paid procedure was conducted at the ALTA Klinik ("ALTA") in Bielefeld, Germany.
- Profound announced that the Common Shares are eligible for trading on the OTCQX®.
- Profound and Philips announce first TULSA-PRO® system sale in Finland to Turku University Hospital.

- On January 31, 2018, the Company announced the completion of patient enrollment in the TACT (TULSA-PRO® Ablation Clinical Trail) pivotal study designed to further evaluate the safety and efficacy of TULSA-PRO® to ablate prostate tissue in patients with localized, organ-confined prostate cancer.
- On March 20, 2018, Profound completed a bought deal financing pursuant to a short form prospectus (the "**2018 Bought Deal Offering**"), for total gross proceeds of $34.5 million.

SELECTED ANNUAL INFORMATION

	Year ended December 31		
	2017	**2016**	**2015**
	$	**$**	**$**
Revenue	4,904,550	-	-
Cost of sales	3,032,208	-	-
Operating expenses	19,499,209	15,640,414	11,222,897
Finance costs	1,121,352	672,301	5,878,915
Net loss for the year	18,748,219	16,326,769	16,375,741
Loss per share			
-Basic	0.31	0.39	0.69
-Diluted	0.31	0.39	0.69
Total assets	27,879,379	23,692,843	21,188,916
Total non-current liabilities	3,013,047	3,909,489	5,958,488

The Company reported a net loss of $18,748,219 ($0.31 per share) for the year ended December 31, 2017 as compared to net loss of $16,326,769 ($0.39 per share) for the year ended December 31, 2016. The increase in loss was primarily related to higher general and administrative legal costs resulting from the Sonalleve® MR-HIFU transaction and sales and marketing costs. For the year ended December 31, 2015, the Company recorded a net loss of $16,375,741, which was similar to the 2016 year end.

The Company reported total assets of $27,879,379 for the year ended December 31, 2017 as compared to $23,692,843 in the comparable period of 2016. The increase was primarily related to increases in inventory, property and equipment, intangible assets and goodwill. Total non-current liabilities were $896,442 lower than in the comparable period of 2016, resulting primarily from the long-term debt becoming current due to the change in repayment terms.

RESULTS OF OPERATIONS

The Company's financial results for the three months and year ended December 31, 2017 reflect the results of the Sonalleve® MR-HIFU Transaction which closed on July 31, 2017.

	Three months ended December 31				Year ended December 31			
	2017	2016	Change		2017	2016	Change	
	$	$	$	%	$	$	$	%
Revenue	1,890,482	-	1,890,482	-	4,904,550	-	4,904,550	-
Cost of sales	1,063,950	-	1,063,950	-	3,032,208	-	3,032,208	-
Gross profit	826,532	-	826,532	-	1,872,342	-	1,872,342	-
Expenses								
Research and development	2,524,405	2,758,887	(234,482)	-8%	9,638,190	9,988,693	(350,503)	-4%
General and administrative	1,456,649	1,521,215	(64,566)	-4%	5,935,215	4,369,288	1,565,927	36%
Selling and distribution	1,174,369	547,983	626,386	114%	3,925,804	1,282,433	2,643,371	206%
Total operating expenses	5,155,423	4,828,085	327,338	7%	19,499,209	15,640,414	3,858,795	25%
Finance costs	169,046	(10,329)	179,375	-1737%	1,249,084	829,899	419,185	51%
Finance income	(38,414)	(33,813)	(4,601)	14%	(127,732)	(157,598)	29,866	-19%
Net finance costs	130,632	(44,142)	174,774	-396%	1,121,352	672,301	449,051	67%
Loss before income taxes	4,459,523	4,783,943	(324,420)	-7%	18,748,219	16,312,715	2,435,504	15%
Income tax expense	69,470	4,674	64,796	1386%	74,123	14,054	60,069	427%
Net loss for the period	4,528,993	4,788,617	(259,624)	-5%	18,822,342	16,326,769	2,495,573	15%
Other comprehensive income (loss)								
Item that may be reclassified to profit or loss								
Foreign currency translation adjustment	(83,767)	821	(84,588)	10303%	(69,245)	11,316	(80,561)	-712%
Net loss and comprehensive loss for the period	4,445,226	4,789,438	(344,212)	-7%	18,753,097	16,338,085	2,415,012	15%
Basic and diluted net loss per common share	0.06	0.10	(0.04)	-40%	0.31	0.39	(0.08)	-21%

Revenue

For the three months ended December 31, 2017, the Company recorded revenues totaling $1,890,482, with $1,738,450 from sale of products and $152,032 from installation and training services, related to the commercial sales of the systems and disposables.

For the year ended December 31, 2017, the Company recorded revenues totaling $4,904,550, with $4,663,986 from sale of products and $240,564 from installation and training services, related to the commercial sales of the systems and disposables. The Company sold the systems and disposables through its partnership agreements with Siemens Healthcare GmbH (Siemens) and Philips.

Results for the three months and year ended December 31, 2016 do not reflect any sale activities and are accordingly not comparable.

Gross Margin

For the three months ended December 31, 2017, the Company recorded cost of sales of $1,063,950, related to the commercial sales of the systems and disposables. These costs include cost of finished goods, inventory provisions, royalties, warranty, freight and direct overhead expenses. The gross margin was lower due to changes in the product mix and overhead allocation due to lower production this quarter.

For the year ended December 31, 2017, the Company recorded cost of sales of $3,032,208, related to the commercial sales of the systems and disposables. These costs include cost of finished goods, inventory provisions, royalties, warranty, freight and direct overhead expenses.

Results for the three months and year ended December 31, 2016 do not reflect any sale activities and are accordingly not comparable.

Operating Expenses

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 relate to clinical R&D. Clinical R&D refers to internal and external activities associated with clinical studies of the systems in humans, and the advancement of the clinical products towards our goal of obtaining regulatory approval to both manufacture and market these products within various jurisdictions.

For the three months ended December 31, 2017, R&D expenses were lower by $234,482 compared to the three months ended December 31, 2016. Overall, the decrease in R&D spending was attributed to the advanced stages of development of the Company's products. Materials and other expenses decreased by $768,937 and $95,304 respectively. These costs were lower compared to the three months ended December 31, 2016, due to lower R&D initiatives and the in-house manufacturing of disposables. Offsetting these amounts was an increase in clinical trial costs and salaries and benefits by $160,789 and $206,899, respectively, resulting from ongoing activities related to the clinical sites visits, enrollment initiatives and patient treatment. Amortization of intangible assets increased by $272,133 due to the Sonalleve® MR-HIFU Transaction and amortization of the acquired intangible assets.

For the year ended December 31, 2017, R&D expenses were lower by $350,503 compared to the year ended December 31, 2016. Overall, the decrease in R&D spending reflects the advanced stages of development of the Company's products and the ramp-up of commercial operations. Materials, contractors and other expenses were lower by $2,523,608, $136,386 and $204,711, respectively due to lower material costs and R&D initiatives associated with our TACT Pivotal Clinical Trials. Offsetting this amount was an increase in clinical trial costs, salaries and benefits, amortization of intangible assets, consulting fees and travel by $1,311,878, $562,626, $458,980, $80,763 and $66,248, respectively, resulting from ongoing activities related to the initiation of clinical site visits, enrollment initiatives, patient treatment and workforce costs.

General and administrative expenses

Our general and administrative ("**G&A**") expenses are comprised of management costs, including salaries and benefits, various management and administrative support functions and other operating and occupancy costs.

G&A expenses for the three months ended December 31, 2017 were lower by $64,566 compared to the three months ended December 31, 2016. Professional and consulting fees $212,627, due to increased legal fees associated with the Sonalleve® MR-HIFU patents and the inclusion of Sonalleve® MR-HIFU operations. These costs were offset by a decrease in share-based compensation and salaries and benefits by $151,588 and $149,291, respectively, due to the options granted to executive officers in the fourth quarter of 2016 and separation payments to a former executive officer ending in the prior quarter.

G&A expenses for the year ended December 31, 2017 were higher by $1,565,927 compared to the year ended December 31, 2016. Salaries and benefit expenses increased by $88,190, primarily related to a separation payment to a former executive officer and the addition of key executives. In addition, professional and consulting fees increased by $976,380 due to legal fees associated with the Sonalleve® MR-HIFU Transaction and the inclusion of Sonalleve® MR-HIFU operations. Share-based compensation and rent increased by $289,689 and $20,364, respectively, due to new options issued to executive officers while rent was due to relocation to a larger facility in July 2016. Depreciation expense increased by $195,218 primarily due to the new property and equipment for the new facility.

Selling and distribution expenses

Our selling and distribution expenses are comprised of business development costs related to the development and commercialization of our system, including salaries and benefits, management and support functions and other operating and occupancy costs.

Selling and distribution expenses for the three months ended December 31, 2017 were higher by $626,386 compared to the three months ended December 31, 2016. The increase is attributable to the commissions payable provision of $290,203 related to the Siemens shortfall of revenue share payments compared to the minimum amounts contractually required. In addition, salaries and benefits increased by $182,880, resulting from additional direct sales force personnel. Professional and consulting fees, marketing and travel expenses increased by $46,841, $33,056 and $39,770, respectively. These increases relate directly to marketing-related efforts and an increased direct sales force.

Selling and distribution expenses for the year ended December 31, 2017 were higher by $2,643,371 compared to the year ended December 31, 2016. The increase is largely attributable to recognizing commissions payable on commercial sales of $73,046 and a provision of $953,429 related to the estimated shortfall of revenue share payments compared to the minimum amounts contractually required. In addition, shared based compensation and salaries and benefits increased by $32,820 and $650,391, respectively, resulting from additional direct sales force personnel. Professional and consulting fees, marketing, office and other and travel expenses increased by $353,974, $257,074, $90,676 and $231,961, respectively. These increases relate directly to marketing-related efforts and an increased direct sales force.

Finance costs

Finance costs are primarily comprised of interest and accretion expense relate to the following: (i) the Federal Economic Development Agency Loan (as defined herein) accreting to the principal amount repayable; (ii) the Health Technology Exchange Loan (as defined herein) accreting to the principal amount repayable and its related interest expense; (iii) the Knight Loan (as defined herein) accreting to the principal amount repayable and its related interest expense; (iv) the 0.5% royalty liability to Knight Therapeutics Inc. ("**Knight**") accreting to the estimated amount payable; and (v) the change in fair value of the contingent consideration payable to Philips.

Financing costs for the three months ended December 31, 2017 were higher by $179,375 compared to the three months ended December 31, 2016. During the three months ended December 31, 2017, the Company revised the fair value of the royalty liability to Knight, using future revenue forecasts for the term of the Knight Loan and recognized an interest accretion recovery of $3,524. As part of the Sonalleve® MR-HIFU Transaction, the Company is required to repay the Knight Loan at an accelerated rate and therefore recognized $7,134 of accelerated accretion expense. During the period, the Company revised the fair value of the contingent consideration and recognized a change in fair value of $30,236.

Finance costs for the year ended December 31, 2017 were higher by $419,185 compared to the year ended December 31, 2016. During the year ended December 31, 2017, the Company revised the fair value of the royalty payable to Knight, using future revenue forecasts for the term of the Knight Loan and recognized an interest accretion recovery of $36,438. As part of the Sonalleve® MR-HIFU Transaction, the Company is required to repay the Knight Loan at an accelerated rate and therefore recognized $333,997 of accelerated accretion expense. During the year, the Company revised the fair value of the contingent consideration and recognized a change in fair value of $82,578.

Income tax expense

During the three months and year ended December 31, 2017, the Company recorded an income tax expense of $69,470 and $74,123, respectively, primarily related to taxes in certain foreign jurisdictions.

Net loss

Net loss for the three months ended December 31, 2017 was $4,528,993 or $0.06 per common share, compared to a net loss of $4,788,617 or $0.10 per Common Share for the three months ended December 31, 2016. The decrease in net loss was primarily attributed to a decrease in R&D expenses of $234,482, G&A expenses of $64,566 and an increase in gross profit of $826,532. These decreases were partially offset by an increase in selling and distribution expenses of $626,386 and financing costs of $179,375.

Net loss for the year ended December 31, 2017 was $18,822,342 or $0.31 per common share, compared to a net loss of $16,326,769 or $0.39 per Common Share for the year ended December 31, 2016. The increase in net loss was primarily attributed to an increase in selling and distribution expenses of $2,643,371, G&A expenses of $1,565,927 and an increase in financing costs of $419,185. These increases were offset by a gross profit of $1,872,342.

SUMMARY OF QUARTERLY FINANCIAL RESULTS

	2017				2016			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
	$	$	$	$	$	$	$	$
Revenue	1,890,482	1,465,412	957,139	591,517	-	-	-	-
Cost of Sales	1,063,950	1,185,674	471,359	311,225	-	-	-	-
Gross profit	826,532	279,738	485,780	280,292	-	-	-	-
Operating expenses	5,155,423	5,148,434	5,043,710	4,151,642	4,828,085	3,779,633	3,429,874	3,602,822
Net finance costs	130,632	651,378	98,207	241,135	(44,142)	276,852	206,194	233,397
Loss before income taxes	4,459,523	5,520,074	4,656,137	4,112,485	4,783,943	4,056,485	3,636,068	3,836,219
Income tax expense	69,470	-	2,356	2,297	4,674	4,723	4,657	-
Net loss for the period	4,528,993	5,520,074	4,658,493	4,114,782	4,788,617	4,061,208	3,640,725	3,836,219
Loss per common share								
Basic	0.06	0.09	0.08	0.07	0.10	0.10	0.09	0.10
Diluted	0.06	0.09	0.08	0.07	0.10	0.10	0.09	0.10

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2017, the Company had cash of $11,103,223 compared to $20,833,061 at December 31, 2016.

Subsequent to year end, on March 20, 2018, the Company closed a bought deal financing, resulting in the issuance of 34,500,000 units at a price of $1.00 per unit for gross proceeds of $34,500,000. Each unit consisted of one Common Share and one-half of one warrant, with each whole warrant entitling the holder to acquire one Common Share at an exercise price of $1.40 per Common Share until the date that is five years from the closing of the bought deal financing, subject to accelerated expiry provisions.

Federal Economic Development Agency Loan

Pursuant to a loan agreement dated December 16, 2011, the Federal Economic Development Agency provided the Company with an unsecured and non-interest bearing loan of $867,000 (the "**Federal Economic Development Agency Loan**"). Repayment commenced on April 1, 2015 with a payment of $14,450, 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. As at December 31, 2017, the principal balance outstanding on the Federal Economic Development Agency Loan is $621,350 (December 31, 2016 - $708,050).

Health Technology Exchange Loan

Pursuant to a loan agreement dated May 25, 2011, as amended April 1, 2012, and a loan agreement dated May 31, 2014, the Health Technology Exchange provided the Company with an unsecured loan of $1,500,000 bearing interest at 4.5% per annum (the "**Health Technology Exchange Loan**"). The remaining repayment of $800,000 plus accrued interest is due March 31, 2018. As at December 31, 2017, the principal balance outstanding on the Health Technology Exchange Loan was $800,000 (December 31, 2016 - $1,300,000).

Knight Loan

Pursuant to a loan agreement dated April 30, 2015, Knight provided the Company with a secured loan of $4,000,000 bearing interest at 15% per annum (the "**Knight Loan**"). Repayment commenced on June 30, 2017 with a payment of $1,427,258, followed by 7 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. As at December 31, 2017, the principal balance outstanding on the Knight Loan was $3,428,571 (December 31, 2016 - $4,000,000).

In addition to the Knight Loan, the Company granted Knight a 0.5% royalty on total net sales of all products until the original maturity date 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 ended December 31, 2017, the Company revised the fair value of the royalty, using future revenue forecasts for the term of the Knight Loan and recognized an interest accretion recovery of $36,438 (December 31, 2016 – accretion recovery of $249,413). The current portion of this liability as at December 31, 2017 is $68,922 (December 31, 2016 - $39,357) and non-current portion is $27,972 (December 31, 2016 - $109,044).

As part of the Sonalleve® MR-HIFU Transaction, the Company committed to repay all amounts outstanding under the Knight Loan on or before December 31, 2018.

Cash Flow

The Company manages liquidity risk by monitoring actual and projected cash flows. A cash flow forecast is performed regularly to ensure that the Company has sufficient cash to meet operational needs while maintaining sufficient liquidity.

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 products, 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 products, 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 products.

	Three months ended		Year ended	
	December 31, 2017	**December 31, 2016**	**December 31, 2017**	**December 31, 2016**
	$	**$**	**$**	**$**
Cash used in operating activities	(4,579,490)	(4,779,266)	(14,854,460)	(14,502,266)
Cash provided by (used in) investing activities	168,368	(116,373)	(997,428)	8,912,835
Cash provided by (used in) financing activities	(793,083)	16,161,322	6,122,050	15,899,972
Net (decrease) increase in cash	(5,204,205)	11,265,683	(9,729,838)	10,310,541

Net cash used in operating activities for the three months ended December 31, 2017 was $4,579,490 versus $4,779,266 for the three months ended December 31, 2016. The principal uses of the operating cash flows during this period were related to additional costs associated to the commercialization of the products, sales and marketing initiatives, increased workforce costs and trade and other receivables.

Net cash used in operating activities for the year ended December 31, 2017 was $14,854,460 versus $14,502,266 for the year ended December 31, 2016. The principal uses of the 2017 operating cash flows were related to additional costs associated to the commercialization of the products, sales and marketing initiatives, increased workforce costs and trade and other receivables.

Net cash flows provided by (used in) investing activities for the three months ended December 31, 2017 was $168,368 versus $(116,373) for the three months ended December 31, 2016. This change was primarily related to fewer purchases of property and equipment and the cash acquired during the three months ended December 31, 2017 compared to 2016.

Net cash flows provided by (used in) investing activities for the year ended December 31, 2017 was $(997,428) versus $8,912,835 for the year ended December 31, 2016. This change was primarily related to transaction costs associated with the Sonalleve® MR-HIFU Transaction, fewer purchases of property and equipment and the sale of short-term investments in the amount of $10,000,000 which occurred in the three months ended December 31, 2016 but did not have a corresponding amount in 2017.

Net cash flows provided by (used in) financing activities for the three months ended December 31, 2017 were $(793,083) versus $16,161,322 for the three months ended December 31, 2016. These cash flows related to repayments on the Federal Economic Development Agency Loan and the Knight Loan and the receipts from the 2016 and 2017 Offering's.

Net cash flows used in financing activities for the year ended December 31, 2017 were $6,122,050 versus $15,899,972 for the year ended December 31, 2016. These cash flows related to repayments on the Federal Economic Development Agency Loan, the Health Technology Exchange Loan and the Knight Loan and cash receipt of the gross proceeds from the 2017 Offering less cash transactions costs paid.

Contractual obligations

The following table summarizes the company's significant contractual obligations

	Year ended December 31, 2017				
	Carrying amount $	**Future cash flows $**	**Less than 1 Year $**	**Between 1year and 5 years $**	**Greater than 5 years $**
Accounts payables and accrued liabilities	5,081,704	5,081,704	5,081,704	-	-
Long-term debt	5,145,089	5,802,658	5,268,011	534,647	-
Other liability	1,830,944	2,161,552	419,121	1,742,431	-
Total	12,057,737	13,045,914	10,768,836	2,277,078	-

Use of Proceeds

2017 Offering

The Company received net proceeds of $8,913,868 from the 2017 Offering. The following table compares the intended use of net proceeds with the actual expenditures as at December 31, 2017, by which time the proceeds from the 2017 Offering were partially expended.

	Estimated per 2017 Offering	**Total spending as at December 31, 2017**
To support certain costs and expenses of the TACT Pivotal Clinical Trial		
Equipment costs (e.g., TULSA-PRO® system and disposables)	$100,000 to $200,000	$699,500
Patient enrollment costs (based on an agreed amount for each patient with the participating hospitals)	$1,200,000 to $2,200,000	$1,332,100
Increased personnel requirements and employee travel expenses related to support of the clinical procedures for patients	$500,000 to $1,200,000	$1,218,800
Ongoing expansion of infrastructure to execute on global sales and marketing plans with respect to the TULSA-PRO® system and recently acquired Sonalleve® MR-HIFU system		

TULSA-PRO® sales and marketing activities	$1,000,000 to $2,400,000	$1,018,700
Sonalleve® MR-HIFU sales and marketing activities	$800,000 to $1,200,000	$917,500
For general corporate purposes, including working capital and scheduled payments under the Knight Loan and other indebtedness	$1,800,000 to $5,500,000	$894,800
Totals		$6,081,400

Although it is intended the remainder of the net proceeds from the 2017 Offering (being $2,832,468) will be used as set out above based on the current knowledge and planning of the Company's management, there may be circumstances where, for sound business reasons, a reallocation of funds may be deemed prudent or necessary and the use of proceeds may vary materially from that set forth above.

2016 Offering

The Company received net proceeds of $16,182,997 from the public offering of Common Shares completed on November 14, 2016 (the "**2016 Offering**"). The following table compares the intended use of net proceeds with the actual expenditures as at December 31, 2017, by which time the proceeds from the 2016 Offering were expended.

	Estimated per 2016 Offering	**Total spending as at December 31, 2017**
To support certain costs and expenses of the TACT Pivotal Clinical Trial	$3,200,000 to $6,400,000	$3,879,900(1)
Ongoing expansion of infrastructure to execute on European sales and marketing plans	$3,200,000 to $6,400,000	$3,053,500
For general corporate purposes, including working capital	$3,400,000 to $9,800,000	$9,249,597
Totals		$16,182,997

Note:

(1) Actual spending from the net proceeds of the 2016 Offering on the TACT Pivotal Clinical Trial for the period indicated was as follows: (i) approximately $1,833,900 for setup costs (e.g., contracting with each participating hospital, training-related travel); (ii) approximately $625,500 for equipment costs (e.g., TULSA-PRO® system and disposables); and (iii) approximately $1,420,500 for employees and their travel expenses related to support of the clinical procedures for patients.

Non-IFRS Financial Measures

Non-IFRS measures are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS. These measures are defined with reference to the nearest comparable IFRS measure in order that a reconciliation to the nearest comparable IFRS measure can be completed. Accordingly, these measures may not be comparable to similar measures presented by other companies. We use non-IFRS measures in order to provide additional financial information to complement the closest IFRS measures in order to provide investors with a further understanding of our operations from management's perspective. Investors should not consider that these non-IFRS measures are a substitute for analyses of the financial information that we report under IFRS. We use these non-IFRS measures in order to provide investors with a supplemental measure of our operating performance and thus highlight trends in our business that may not otherwise be apparent when relying solely on IFRS measures.

The Company's working capital (defined as current assets less current liabilities) is a non-IFRS financial measure. The working capital as at December 31, 2017 is set forth in the table below. The Company defines working capital as current assets less current liabilities, with the exclusion of deferred revenue. Deferred revenue represents the excess of amounts billed and revenue earned on service contracts. The amount is amortized into income as services are rendered, in accordance with the revenue recognition policies described in the Company's financial statements.

Deferred revenue is a non-cash liability and therefore management believes that adding back the deferred revenue provides a more accurate reflection of the liquidity and working capital position of the Company.

	December 31, 2017	December 31, 2016
	$	$
Current assets	17,602,066	22,477,129
Less: current liabilities	10,725,193	4,947,127
Working Capital	6,876,873	17,530,002
Add back: Deferred revenue	241,316	-
Net working capital	7,118,189	17,530,002

Working capital has decreased by $10,411,813 to a surplus of $7,118,189 at December 31, 2017 compared to the surplus of $17,530,002 at December 31, 2016. The change in working capital is due to an increase in current liabilities of $5,778,066, which was primarily the result of an increase in long term debt and accounts payable as a result of the change in the repayment terms of the Knight Loan and accounts payable owing to Philips for manufactured goods. The decrease in working capital was also caused by a lower cash balance by $9,729,838 due to the repayments of the Knight Loan, clinical trial expenses and vendor balances; offset by an increase in trade and other receivables of $3,985,322, which was the result of increased revenue in the fourth quarter.

COMMITMENTS & CONTIGENCIES

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 $330,000 related to prepaid rent for this lease that is drawn down at $10,000 per month starting effective October 1, 2016. The future minimum obligation are as follows:

	$
No later than 1 year	431,396
Later than 1 year and no later than 5 years	2,203,851
Later than 5 years	2,169,254
	4,804,501

In 2016, the Company signed an agreement that includes revenue sharing with a minimum amount payable 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 $200,000.

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 Offerings 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:

	Three months ended		Year ended	
	December 31, 2017	December 31, 2016	December 31, 2017	December 31, 2016
	$	$	$	$
Salaries and employee benefits	234,765	478,675	1,021,568	1,247,563
Termination benefits	-	-	138,125	-
Directors fees	26,503	28,579	88,232	63,616
Share-based compensation	323,452	402,582	1,220,655	862,798
Total	584,720	909,836	2,468,580	2,173,977

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

OUTSTANDING SHARES

As at March 23, 2018, the date of this MD&A, the Company had the following securities outstanding:

	Number
Common shares	107,617,377
Share purchase options	5,180,591
Warrants	22,250,000

OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements other than those disclosed in this MD&A.

RECENT ACCOUNTING PRONOUNCEMENTS

IFRS 9, Financial Instruments (IFRS 9)

The final version of IFRS 9, Financial Instruments, was issued by the IASB in July 2014 and will replace IAS 39, Financial Instruments - Recognition and Measurement (IAS 39). 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.

The Company has reviewed its financial assets and financial liabilities with respect to new guidance under IFRS 9. Accordingly, the Company has determined the new guidance is not expected to affect the classification and measurement of its financial assets and financial liabilities.

The new impairment model requires the recognition of impairment provisions based on expected credit losses, rather than incurred credit losses alone, as is the case under IAS 39. For the Company, this applies primarily to financial assets classified at amortized cost. Based on the assessments undertaken to date, the Company does not expect a significant increase in the trade receivables provision for impairment.

The new standard also introduces expanded disclosure requirements and changes in presentation. These are expected to change the nature and extent of the Company's disclosures about its financial instruments, particularly in the year of the adoption of the new standard.

The Company will adopt the standard on the effective date of January 1, 2018. The standard will be implemented retrospectively with no restatement of comparatives following the specific transitional requirements listed in the standard related to classification and measurement and impairments.

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 (IFRIC) 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 determined it will apply this standard on a fully retrospective basis.

Management has assessed the effects of applying the new standard on the Company's consolidated financial statements. The Company does not expect the adoption of IFRS 15 to have a material impact on the consolidated financial statements.

The new standard also introduces expanded disclosure requirements. These are expected to change the nature and extent of the Company's disclosures about its contracts with customers and associated revenue recognition upon adoption of 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 sheet 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 consolidated financial statements for the annual period beginning January 1, 2019 and will recognize assets and liabilities for all leases, except for its low value leases, on the consolidated balance sheet on adoption.

IFRIC 23, Uncertainty over Income Tax Treatments (IFRIC 23)

On June 7, 2017, the IASB issued IFRIC 23. IFRIC 23 clarifies the application of recognition and measurement requirements in IAS 12, Income Taxes, when there is uncertainty over income tax treatments. The IFRIC 23 interpretation specifically addresses whether an entity considers uncertain tax treatments separately; the assumptions an entity makes about the examination of tax treatments by taxation authorities; how an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates; and how an entity considers changes in facts and circumstances. IFRIC 23 is effective for annual periods beginning on or after January 1, 2019, with earlier application permitted. The Company is currently evaluating the impact of adopting this interpretation on the consolidated financial statements.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company's 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 products 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 products to market and to establish commercial manufacturing, marketing and sales capabilities. As of December 31, 2017, Profound had a cash balance of $11.1 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 products, 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. 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 products.

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 products 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 approved products. 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® and Sonalleve® systems and no experience in doing so on a commercial scale. To become profitable, Profound must assemble and test the TULSA-PRO® and Sonalleve® systems 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 its products 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 devices,

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 devices are 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 products. 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 devices are approved for sale, there can be no assurance that the devices 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, 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 devices, 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 systems, 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 devices are 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 devices are 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 systems are 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 systems. 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 devices are 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. 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 ("**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.

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® and Sonalleve® *systems 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 devices have 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 systems, but may be unable to do so if the systems do 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 devices will prove to be safe and effective in clinical trials or that it will receive 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 for 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 TACT Pivotal Clinical 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 systems 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.

Sonalleve® MR-HIFU Transaction

On July 31, 2017, the Company closed the Sonalleve® MR-HIFU Transaction. Achieving the benefits of the Sonalleve® MR-HIFU Transaction depends in part on successfully consolidating functions and integrating operations and procedures of the business acquired pursuant to the Sonalleve® MR-HIFU Transaction with those of the Company in a timely and efficient manner, as well as the Company's ability to realize the anticipated growth opportunities and synergies from combining the acquired business and operations with those of Profound. Profound relies on Philips to manufacture and install Sonalleve® and will need to transition such services in the future. The integration of the acquired business and transition of manufacturing and installation services will require substantial management effort, time and resources and may divert management's focus from other strategic opportunities and operational matters. *Third-party reimbursement*

Even after regulatory approvals or clearance is obtained, successful commercialization of such devices will depend largely upon the cost 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 devices 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 devices. 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 products 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 devices may not achieve or maintain expected levels of market acceptance

Even if Profound is able to obtain regulatory approvals or clearances for its devices, 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 products 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 devices as a method of ablation of prostate tissue, uterine fibroids, bone metastases or ultimately (pending the relevant approvals) treatment for localized prostate cancer, uterine fibroids and bone metastases, 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 products relative to those of its competitors;
- acceptance and adoption of its products by physicians/clinicians and the medical community;
- ability to market Profound's products effectively at the patient, physician/clinician and medical community level; and
- acceptance of Profound's products 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 partner may not be as successful in promoting Profound's products 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 products are 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 products, 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 ("**QSR**") and International Standards Organization ("**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 or 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 its system

The TULSA-PRO® and Sonalleve® systems 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 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 developed proprietary automated manufacturing test equipment to improve quality and provide scalability as demand grows and is assembled and tested in-house. 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 outsource 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® and Sonalleve® systems 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 products 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 favourable 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 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 and the Sonalleve® system with one MRI manufacturer. As not all hospital and treatment facilities utilize MRIs that are compatible with the TULSA-PRO® and Sonalleve®, 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 systems by such facilities. Accordingly, Profound intends to expand compatibility of the systems 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 systems, 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 systems 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 products 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, Sonalleve® 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 products 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® or Sonalleve® systems 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 devices will face competition from existing and new prostate ablation, uterine fibroids ablation, palliative pain treatment of bone metastases 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 products, 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 devices. These developments could render Profound's medical devices 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 products

The market may not accept Profound's products and may continue to use the incumbent products. The TULSA-PRO® and Sonalleve® systems 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® and Sonalleve® systems 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 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.

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

If Profound fails to maintain positive working relationships with physicians/clinicians, Profound's devices may not be developed and marketed in line with the needs and expectations of the professionals who Profound expects will use and support the devices, which could cause a decline in earnings and profitability. The research, development, marketing and sales of the devices are 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 devices. 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 continues 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 products 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 launches. 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 products. There can be no assurance 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 devices 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 devices 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 ("**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 payers 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 directors' and officers' 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 devices 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 products are, or are 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 products are 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 products, 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 products.

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

A significant portion of Profound's revenues, 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 multiple issued United States patents and several 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 devices 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 USPTO 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 USPTO 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 USPTO, 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 USPTO 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.

Additional information relating to the Company is available on SEDAR at www.sedar.com, including the AIF.