PROFOUND MEDICAL CORP

ANNUAL INFORMATION FORM

FOR THE YEAR ENDED DECEMBER 31, 2015

August 9, 2016

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

ANNUAL INFORMATION FORM

In this annual information form (the "**AIF**"), unless otherwise noted or the context indicates otherwise, the "Corporation", the "Company", "Profound", "we", "us" and "our" refer to Profound Medical Corp. and, as the context requires, our principal subsidiaries Profound Medical Inc. and Profound Medical GmbH. All financial information in this AIF is prepared in accordance with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board and is presented in Canadian dollars unless otherwise noted. Unless otherwise stated, all references to "$" are to Canadian dollars and references to "US$" are to United States dollars. Dollar amounts are presented herein in Canadian currency unless otherwise indicated. The information contained herein is dated as of December 31, 2015 (the last day of Profound's most recently completed financial year), unless otherwise stated.

FORWARD-LOOKING STATEMENTS

Certain statements in this AIF may contain "forward-looking statements" within the meaning of applicable securities laws, including the "safe harbour provisions" of the *Securities Act* (Ontario), with respect to Profound. Such statements include all statements other than statements of historical fact contained in this AIF, 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, as well as future or conditional verbs such as "will", "should", "would", and "could" intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its product, expectations regarding the use of its product and its revenue, expenses and operations, plans for and timing of expansion of its product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in its product markets, competitive position and its expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound's business and the markets in which it operates.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, the risks and uncertainties discussed in the "*Risk Factors*" section and elsewhere in thie AIF, such as successful completion of clinical trial phases with respect to Profound's device, obtaining regulatory approvals in relevant jurisdictions to market Profound's device, risks related to the regulation of Profound (including the healthcare markets, lack of funding may limit the ability to commercialize and market Profound's product, fluctuating input prices, international trade and political uncertainty, healthcare regulatory regime in relevant jurisdictions may affect the Company's financial viability, reimbursement models in relevant jurisdictions may not be advantageous), competition may limit the growth of Profound, if the Company breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business, loss of key personnel may significantly harm Profound's business and past performance is not indicative of future performance, and such other risks detailed from time to time in the publicly filed disclosure documents of the Company which are available at www.sedar.com. The Company's forward-looking statements are made only as of the date of this AIF and, except as required by applicable law, 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, and because of the above-noted risks, uncertainties and assumptions, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them.

MARKET AND INDUSTRY DATA

This AIF includes market and industry data obtained from third party sources, industry publications, scientific journals and publicly available information, including iData Research Inc., the Canadian Cancer Society and the American Cancer Society. Profound believes that this market and industry data is accurate and that its estimates and assumptions are reasonable, but there can be no assurance as to the accuracy or completeness thereof. The accuracy and completeness of the market and industry data used throughout this AIF are not guaranteed and Profound does not make any representation as to the accuracy of such information. Although Profound believes it to be reliable, Profound has not independently verified any of the data from third party sources referred to in this AIF, nor analyzed or verified the underlying studies or surveys relied upon or referred to by such sources, or ascertained the underlying economic and other assumptions relied upon by such sources.

GLOSSARY

The following terms have the meanings set out below.

3D	means three-dimensional.
ablation	means to remove or destroy tissue.
ADT	means androgen deprivation therapy.
BDC	means BDC Capital Inc.
BPH	means benign prostatic hyperplasia, a condition where the prostate gland is enlarged and not cancerous.
brachytherapy	means the precise placement of short-range radiation-sources (radioisotopes) directly at the site of the cancerous tumour.
CE Mark	means “Conformité Européenne” and is affixed to a medical device in the European Union by its manufacturer to declare that the medical device complies with applicable EU regulatory requirements and that the appropriate related conformity assessment procedure has been conducted.
CMDCAS	means Canadian Medical Devices Conformity Assessment System.
Common Shares	means the common shares in the capital of Profound.
company	unless specifically indicated otherwise, means a corporation, incorporated association or organization, body corporate, partnership, trust, association or other entity other than an individual.
cryotherapy	means a therapy that uses extreme temperature to destroy benign and malignant tissue by crystallizing.
***de novo* submission**	means the submission of a petition to the FDA to reclassify a novel non-predicated Class III device as a Class I or II device pursuant to Section 513(f)(2) of the *United States Federal Food, Drug and Cosmetic Ac*t.

EBRT	means External Beam Radiation Therapy.
European Union	means an organization created in 1993 with the aim of achieving closer economic and political union between the member states of Europe and currently comprising Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.
FDA	means the United States Food and Drug Administration, the regulatory authority in the United States that regulates companies that manufacture, repackage, relabel, distribute and/or import food, drugs and/or devices sold in the United States.
Genesys	means Genesys Ventures II LP.
Gleason score	means the histological assessment of prostate tissue using a tumour grading system which describes how aggressive a prostate cancer is on a scale from 1 (least aggressive) to 5 (most aggressive). The Gleason score is a combination of the two most common growth patterns observed in a biopsy specimen.
HDR	means high dose radiation.
HIFU	means High Intensity Focus Ultrasound.
HMO	means Health Maintenance Organizations.
IFRS	means the International Financial Reporting Standards issued by the International Accounting Standards Board.
IDE	means investigational device exemption; an approved IDE means that the Institutional Review Board of a clinical site and the FDA have approved the sponsor's clinical study application.
Knight	means Knight Therapeutics Inc.
Knight Loan Agreement	means the loan agreement entered into on April 30, 2015 between Profound and Knight pursuant to which Knight agreed to provide Profound a four-year secured loan bearing interest at an effective annual rate of 15.0% and in connection with which Profound granted to Knight a 0.5% royalty on net sales of Profound for the duration of such loan.
MCO	means Managed Care Organizations.
Medical Device License	means the license for marketing approval of a medical device in Canada.
Mira	means Mira IV Acquisition Corp., a corporation incorporated under the OBCA.
Mira Subco	means Mira IV Subco Inc., a wholly-owned subsidiary of Mira incorporated under the OBCA.

MR	means magnetic resonance.
MRI	means magnetic resonance imaging.
OBCA	means the *Business Corporations Act* (Ontario), as amended, together with all regulations promulgated pursuant thereto.
Options	means options issued under the Share Option Plan.
QSR	means Quality System Regulations.
Person	means a company or individual.
Pivotal Trial	means a clinical trial or study intended to provide evidence and reasonable assurance of safety and efficacy for a device marketing approval.
PMA	means the Pre-Market Approval application process for marketing approval in the United States.
PMI	means Profound Medical Inc.
Private Placement	means the brokered private placement of 16,005,885 Subscription Receipts for aggregate gross proceeds of $24,008,827.50, which closed on April 30, 2015.
Promoter	means a promoter as prescribed by applicable Securities Laws.
Qualifying Transaction	has the meaning given under the heading "*Corporate Structure – Name, Address and Incorporation*".
radical prostatectomy	means a surgical procedure that involves the removal of the whole prostate gland.
Securities Laws	means securities legislation, securities regulation and securities rules, as amended, and the policies, notices, instruments and blanket orders in force from time to time that are applicable to an issuer.
Share Option Plan	means the share option plan of Profound dated June 4, 2015, as amended.
Shareholder	means a holder of a Common Share.
Subscription Receipts	means the subscription receipts issued by Profound in connection with the Private Placement, with each such subscription receipt being exchangeable for one Common Share.
Sunnybrook	means the Sunnybrook Health Sciences Centre.
Sunnybrook License	has the meaning given under the heading "*Proprietary Protection*".
TSX-V	means the TSX Venture Exchange.
TULSA	means Transurethral ULtraSound Ablation.
TULSA-PRO	means the Transurethral ULtraSound Ablation device.

TURP	means a transurethral resection of the prostate, a surgical procedure that removes portions of the prostate gland through the penis.
UA	means ultrasound applicator.
U.S. PTO	means the United States Patent and Trademark Office.
urinary rectal fistula	means an abnormal channel between the bladder and rectum resulting in the potential for leakage of urine from the urinary tract into surrounding tissues.

CORPORATE STRUCTURE

Name, Address and Incorporation

Profound Medical Corp. is the company resulting from a "three-cornered" amalgamation involving Mira, Mira IV Subco and PMI. PMI was formed by articles of incorporation under the OBCA on June 13, 2008 under the name "Profound Medical Inc.". Mira was formed by articles of incorporation under the OBCA on July 16, 2014 under the name Mira IV Acquisition Corp., and following its initial public offering, was a "capital pool company" listed on the TSX-V. As a capital pool company, Mira had no assets other than cash and did not carry on any operations. On June 3, 2015, the Company changed its name to Profound Medical Corp. and completed a consolidation of its share capital on the basis of one post-consolidation common share for every 13.6363 pre-consolidation common shares. PMI completed its qualifying transaction pursuant to the policies of the TSX-V by way of reverse takeover of Mira by the shareholders of PMI on June 4, 2015 (the "**Qualifying Transaction**").

The Company's head and registered office is located at 2400 Skymark Avenue, Unit 6, Mississauga, Ontario, L4W 5K5.

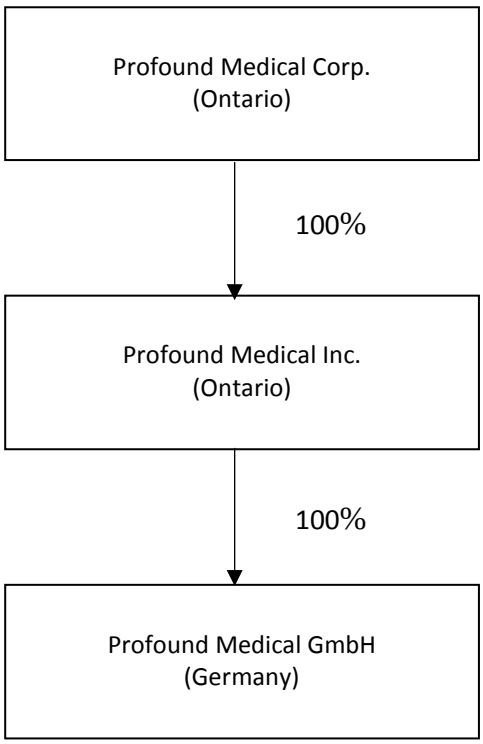
Inter-Corporate Relationships

Profound operates its business through its wholly-owned principal subsidiaries, Profound Medical Inc. and Profound Medical GmbH.

Profound Medical Inc. was incorporated under the OBCA on June 13, 2008 and amalgamated with Mira IV Subco Inc. on June 4, 2015 as part of the Qualifying Transaction.

Profound Medical GmbH was established in Germany on January 12, 2016 as a wholly-owned direct subsidiary of PMI.

The following diagram illustrates the organizational structure of Profound and its principal subsidiaries, their respective jurisdictions of incorporation and the percentage of voting and non-voting securities owned by Profound Medical Corp. as of the date of this AIF.



GENERAL DEVELOPMENT OF THE BUSINESS

The following is a summary of the general development of Profound's business:

2013

In April 2013, PMI announced initiation of the Health Canada approved 30 patient multi-center TULSA safety and feasibility study of its device. In July 2013, approval was received from the Federal Institute for Drugs and Medical Devices in Germany to expand clinical sites of the TULSA safety and feasibility study into Germany. In August 2013, the FDA granted IDE approval to further expand the TULSA safety and feasibility study into the United States.

2014

In March 2014, PMI completed enrollment and treatment of 30 patients in the TULSA multi-jurisdictional safety and feasibility study.

On September 24, 2014, Mira completed an initial public offering of 10,000,000 common shares at a price of $0.10 per share for gross proceeds to Mira of $1,000,000.

On November 5, 2014, Mira and PMI announced that they had entered into a Letter of Intent with a view to completing the Qualifying Transaction.

2015

On January 27, 2015, PMI closed a bridge financing transaction for aggregate gross proceeds of $1,500,000 pursuant to which PMI issued (i) a secured convertible promissory note to BDC with a principal amount of $1,000,000; and (ii) a secured convertible promissory note to Genesys with a principal amount of $500,000.

On April 29, 2015, Mira, Mira IV Subco and PMI entered into an amalgamation agreement with respect to the Qualifying Transaction. On April 30, 2015, Profound completed a private placement pursuant to which it sold 16,005,885 Subscription Receipts at a price of $1.50 per Subscription Receipt for aggregate gross proceeds of $24,008,827.50.

On June 3, 2015, and prior to the completion of the Qualifying Transaction, Mira changed its name to "Profound Medical Corp." and completed a consolidation of its share capital on the basis of one post-consolidation common share for every 13.6363 pre-consolidation common shares. As a result of the Qualifying Transaction, which proceeded by way of a "three-cornered" amalgamation involving Mira, Mira IV Subco and PMI, PMI became a wholly-owned subsidiary of Profound. Following the completion of the Qualifying Transaction, a total of 39,442,337 Common Shares were issued and outstanding.

On June 8, 2015, the shares of Profound commenced trading on the TSX-V under the ticker symbol PRN.

On July 21, 2015, Royal Philips (NYSE:PHG) (AEX:PHIA) and Profound announced a joint development agreement to support Profound's proprietary TULSA-PRO™ system designed to ablate benign and malignant prostate tissue utilizing Royal Philips' Ingenia and Achieva 3T MRI systems.

On October 15, 2015, the Company presented 12-month follow-up data of the TULSA-PRO™ Phase I Clinical Trial at the European Symposium on Focused Ultrasound Therapy, held in London, England. The study demonstrated the clinical safety and precision of Profound's TULSA-PRO™ system for the ablation of the prostate gland, with low toxicity and a well-tolerated safety profile.

On November 2, 2015, the Company announced the hiring of Hartmut Warnken as Vice President, International Sales.

On November 17, 2015, Shameze Rampertab resigned as the Chief Financial Officer of Profound. Rashed Dewan, Profound's Corporate Controller, assumed Mr. Rampertab's responsibilities as Profound's interim Chief Financial Officer.

On November 27, 2015, Profound announced that it was named *Life Science Company of the Year* by Life Sciences Ontario.

Recent Developments

On January 12, 2016, Profound established Profound Medical GmbH in Germany, as a wholly-owned subsidiary of PMI. The purpose of Profound Medical GmbH is to conduct marketing and sales activity in the European Union.

On February 29, 2016, Profound announced that it had entered into a strategic collaboration agreement with Siemens Healthcare GmbH, aimed at advancing the commercial launch of Profound's TULSA-PRO™ system. Profound and Siemens will each invest approximately US$2,000,000 on marketing and sales resources in support of the marketing and sale of TULSA-PRO™ system.

On April 11, 2016, Profound announced that it has affixed the CE mark to the TULSA-PRO™ system following receipt of a CE Certificate of Conformity from its notified body in the European Union. The CE mark affixed to the medical device enables Profound to market TULSA-PRO™ system in the European Union and in other jurisdictions accepting CE marked medical devices such as Norway, Iceland, Liechtenstein and Switzerland.

On April 28, 2016, Profound announced a sale of its TULSA-PRO™ system to ResoFus Alomar, a medical clinic in Barcelona, Spain, noting that this was the Company's first commercial sale.

On May 11, 2016, Profound announced a sales and marketing agreement with Royal Philips. Under the terms of the agreement, Profound and Royal Philips will collaborate in the commercialization of the TULSA-PRO™ system in Europe, followed by Canada, the United States and other markets, subject to regulatory clearance in those jurisdictions.

On May 19, 2016, Profound announced that the FDA granted IDE approval with respect to the multicenter Pivotal Trial. The objective of this trial is to evaluate the efficacy of the TULSA-PRO™ system in ablating tissue in patients with localized prostate cancer.

On June 20, 2016, Profound announced the first sale of the TULSA-PRO™ system in the United Kingdom to University College London and University College London Hospitals NHS Foundation Trust. This marked the first sale under the Company's collaboration with Royal Philips.

On June 21, 2016, Profound announced the first sale of the TULSA-PRO™ system in Germany to University Hospital of Cologne, also resulting from the collaboration with Royal Philips.

Significant Acquisitions

Other than in connection with the Qualifying Transaction, Profound did not complete any significant acquisitions during the most recently completed fiscal year.

THE BUSINESS

General

The Company was founded for the purpose of ultimately developing and commercializing a unique, minimally invasive treatment for prostate cancer. Profound's novel technology combines magnetic resonance imaging guidance and ultrasound energy to provide thermal ablative therapy to the prostate gland delivered through the urethra. Profound is currently focused on the development and commercialization of the TULSA-PRO™ system, its transurethral ultrasound device for ablation of prostate tissue.

Principal Product

Profound is focused on the commercialization of the TULSA-PRO™ system, its transurethral ultrasound device for ablation of prostate tissue. Profound has received IDE approval from the FDA to conduct a clinical trial of the TULSA-PRO™ system in a prostate cancer patient population. The most commonly offered standard of care for the prostate cancer patient population is radical prostatectomy and radiation therapy. Even though these treatment offers high survival rates, they can result in negative quality of life outcomes in a significant number of treatment cases. Potential negative outcomes can include urinary incontinence, erectile dysfunction and bowel complications. Profound's clinical trial is designed for a single arm study (i.e., no comparative data will be collected against standard of care procedure) which will collect data regarding quality of life. Profound believes its clinical trial will demonstrate that the use of the TULSA-PRO™ system in a prostate cancer patient population will have a well-tolerated safety profile with lower rates of procedure-related complications.

Product Description

The TULSA-PRO™ system is comprised of two categories of components: disposables and the capital equipment used in conjunction with a customer's magnetic resonance imager.

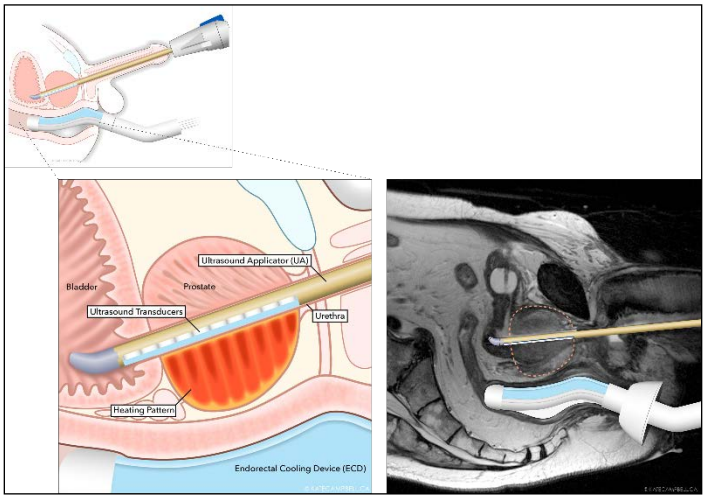
Magnetic Resonance Imager

Profound has designed the TULSA-PRO™ system to be capable of integration with most major MRIs currently deployed in hospitals and treatment facilities. That integration allows the TULSA-PRO™

system to display high resolution images of the prostate and surrounding anatomy. The integrated MRI is used for treatment planning but, more importantly, to provide real-time measurement of temperature in the prostate as the treatment is occurring to enable the physician/clinician to control and monitor tissue ablation. Profound has optimized its technology to work with particular models from two MRI vendors and is in the process of modifying the relevant technology used in the TULSA-PRO™ system to facilitate integration with models from other MRI vendors.

Ultrasound Applicator

The transurethral ultrasound applicator ("**UA**") is a sterile, single use, disposable component of the TULSA-PRO™ system. The UA produces parallel thermal ultrasound beams, through a linear array of 10 independent ultrasound transducers, each of which is independently computer controlled using real-time MRI feedback to deliver heat to the prescribed treatment boundary. The transducers that produce the thermal ultrasound beams are monitored with individual MRI "slices" of the prostate and execute a 360^0 sweep to effect treatment from the prostatic urethra to the prostate treatment boundary. The system monitors temperature of the prostate and surrounding tissue in real time throughout the entire procedure. The TULSA-PRO™ system is capable of adjusting automatically between higher or lower frequencies of ultrasonic beams to target different prostate shapes and sizes.



Source: Profound Medical Inc.

The UA is introduced into the patient via the urethra and is precisely located within the prostate using the system's robotic positioning, which is controlled by the system's software together with MRI feedback for guidance. The UA emits thermal energy from planar transducers with a precision of approximately ± 1 millimetre. There are ten planar transducers in the UA, but not all of these ultrasound elements have to be turned on. The physician/clinician can determine which elements to activate based on the size of the prostate gland. This precision is intended to enable the TULSA-PRO™ system to sculpt the ablated tissue volume to the shape of the patient's prostate, which may assist in avoiding damage to sensitive structures, including the bladder neck and urethral sphincter.

Source: Profound Medical Inc. TULSA-PRO™ System Components. The Ultrasound Applicator, Endorectal Cooling Device and Positioning System are inside the Scanning room on the MRI bed. The Treatment Delivery Console and System Electronics remain outside the Scanning room, in the Console and Equipment room, respectively.

Expected technical advantages of the TULSA-PRO™ system include:

- Proprietary algorithms and software intended to provide the physician/clinician with detailed 3D maps of the entire prostate in real-time and with immediate feedback as to the thermal ablation volume;

- Treatment planning software designed to allow the physician/clinician to plan the 3D target treatment volume tailored to the unique anatomy and pathology of each patient, prior to the start of therapy, on high resolution prostate MR;

- The software of the TULSA-PRO™ system is designed to measure and display the temperature of the prostate tissues throughout the procedure, allowing the treating physician/clinician to monitor the treatment in real-time;

- The control algorithm of the TULSA-PRO™ system is designed to track the temperature distribution during the delivery of heat and to dynamically adapt the delivery system though computer controlled feedback. This active process is intended to allow the system to compensate for changes in blood flow and tissue properties that occur during thermal therapy, and adapt to each patient's unique anatomy;

- The UA is inserted into the urethra to the center of the prostate, which is designed to facilitate ablation from the inside-out. This minimizes the distance between the TULSA-PRO™ system and the prostate, which is intended to maximize the opportunity for improved control and accuracy;

- The procedure is intended to occur at a precise temperature to ensure the ablation of targeted prostate tissue while preserving surrounding structures;

- Fluid circulating in the UA cools the urethra, which is designed to provide additional protection to the inner-most layer of the urethra in contact with the UA;

- The endo-rectal cooling device is intended to protect the rectal wall adjacent to the prostate;

- Energy delivery is designed to be completed quickly, typically in less than one hour (on average, to date, within 40 minutes). This may minimize potential inaccuracies due to swelling and motion of the prostate during the treatment, which may become significant sources of error in other ablation treatments that have longer procedure times;

- Dual frequency capability is intended to provide faster treatment and tighter control, particularly in the region where the greatest care is required, near the urethral apex and rectum;

- Robotic positioning system combined with MRI guidance is intended to provide fine control of the initial positioning of the UA, to within ±1 millimetre from the urethral apex, which may help limit damage that could result in urinary incontinence;

- Post-treatment verification using contrast-enhanced MRI techniques is designed to allow visualization of the region of thermal coagulation in the prostate, which allows the outcome of the treatment to be evaluated immediately upon completion.

Operations

Profound operates from its head office located at 2400 Skymark Avenue, Unit 6, Mississauga, Ontario, Canada, which Profound leases from its landlord. Profound does not own any real property.

Profound's product 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, fluid circuits, treatment delivery console and an MRI compatible robotic positioning system. Printed circuit boards and assemblies and custom mechanical parts are outsourced to approved local suppliers. Capital equipment is assembled and tested in-house.

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

Profound intends to, at least initially, rely on a single source for the manufacture of the UA and associated accessories. In the future, Profound may seek to add a second source for the manufacture of the UA. Profound's finished goods manufacturing processes, and those of some of its contract manufacturers, must comply with the medical device regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of its devices.

As a medical device manufacturer, Profound is subject to regulatory inspections. Profound and its critical suppliers/manufacturers must comply with applicable medical device 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 files.

Employees

As of the date of this AIF, Profound has 48 full-time employees, none of whom are unionized. Profound believes that its relations with its employees are excellent. The Company will be adding staff and consulting resources in order to support product development, market access, field support and additional clinical trials. Profound expects to increase its staffing to approximately 60 full and part-time employees by 2018.

Market Opportunity

European Market

According to iData Research Inc., Europe had, in 2011, a population of 378 million, including nearly 46 million men over the age of 50. There were 414,000 prostate cancer procedures and 105,000 men died of prostate cancer that year. By 2018 the number of men over 50 in Europe is expected to reach 53 million, an annual growth rate of 2.2%.

Profound believes that Germany represents the most important market in the European Union. It has the largest population in the region, an above average number of prostate cancer treatment procedures and the highest pricing for urological devices. Profound established its first European Union clinical trial site in Germany, providing German physicians/clinicians with the first exposure to the technology. According to iData Research Inc., in 2011, there were 11.3 million men over 50 years of age and 96,000 prostate cancer treatment procedures performed in Germany.

European Prostate Cancer Procedures by Country

Region	Millions of men over 50 years old (2011)	Total Prostate Cancer Procedures (2011)	Total Prostate Cancer Procedures Projected CAGR (2008-2018)
Germany	11.3	96,000	2.5%
France	5.5	66,000	2.8%
United Kingdom	7.7	62,000	2.3%
Italy	8.0	69,000	2.8%
Spain	7.4	46,000	2.0%
Benelux	3.4	34,000	3.4%
Scandinavia	3.0	29,000	3.2%
Switzerland	0.9	9,500	3.9%

Sources: iData Research Inc.; indexmundi.com

European Market Launch

Profound was granted CE mark approval in April 2016 for the commercial sale of the TULSA-PRO™ system in the European Union and in other CE Mark jurisdictions (i.e., Norway, Lichtenstein, Iceland and Switzerland). The CE Mark permits the marketing of the TULSA-PRO™ system in those jurisdictions for the ablation of malignant and benign prostate tissue. Profound has established a direct sales force in Germany and has commenced commercialization and marketing activities. Profound has established strategic partnerships with each of Royal Philips and Siemens.

Profound is also exploring the establishment of strategically placed clinical centers of excellence to accommodate the training needs of international physicians/clinicians on the TULSA-PRO™ system.

Canadian Market

According to the Canadian Cancer Society, it is estimated that 24,000 men have been diagnosed with prostate cancer in Canada in 2015, representing 24% of all new cancer cases in men in the year. It is also estimated that 4,100 men will die from prostate cancer, representing 10% of all cancer deaths in men in 2015. The incidence rate has increased since 1980; Profound believes that this increase is largely due to the more widespread use of early detection methods.

Canadian Market Launch

Profound submitted an application to Health Canada in May 2016 for a Class III Medical Device License so that it could market and sell the TULSA-PRO™ system in Canada for ablation of malignant and benign prostate tissue, and currently anticipates that such a license will be issued by the fourth quarter of 2016 from Health Canada. The Company 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. Knight intends to work to initiate market adoption into the Canadian healthcare system on a province by province basis.

In addition to working towards ultimate adoption of the TULSA-PRO™ system by the provincial healthcare systems, Profound is also exploring the establishment of strategically placed clinical centers of excellence to accommodate the training needs of international physicians/clinicians on the TULSA-PRO™ system, as well the needs of potential patients from other jurisdictions.

United States Market

In the United States prostate cancer is, according to iData Research, the most common cancer among men, aside from skin cancer. Every year more than 160,000 new prostate cancer diagnosis are made in the US, with nearly 30,000 men dying from this disease (iData Research).

The number of patients undergoing procedures to treat prostate cancer in the United States in 2016 is set out in the table below. Using data obtained from iData Research, Profound has estimated the number of patients undergoing Radiation Therapy (under what Profound believes to be a conservative assumption of 40 procedure sessions per patient). The number of patients undergoing other forms of treatment set out below is as published by iData Research.

Prostate Cancer # of Patients Treated in 2012						
Year	**Watchful Waiting**	**Prostatectomy**	**Ablation**	**Radiation Therapy**	**Total Patients**	**Growth (%)**
2012	66,680	159,964	31,425	158,747	416,816	
2013	63,675	149,140	27,938	159,092	399,845	-0.10%
2014	64,481	139,930	26,667	159,466	390,544	0.10%
2015	65,365	138,525	25,774	160,717	390,381	0.70%
2016	66,201	138,265	25,269	161,605	391,340	0.50%
2017	67,028	139,473	24,946	162,308	393,755	0.40%
2018	67,846	141,606	24,743	162,828	397,023	0.40%

Source: iData Research.

Profound believes that growth in prostate cancer procedures is being driven by the aging population, increased attention to early diagnosis and recurrence after initial treatment. Further, current diagnostic pathology methods employed in the United States do not yet enable physicians to make a confident prognosis that distinguishes slow-growing indolent tumors from dangerous aggressive tumors. This uncertainty has led many patients in the United States to choose treatment over watchful waiting/active surveillance in order to reduce the risk of cancer spread.

Profound believes that, in the future, a minimally invasive procedure with well-tolerable safety profile and quality of life results could create an alternative procedure to the treatments identified above.

United States Market Launch

Profound must successfully complete the Pivotal Trial and then obtain regulatory clearance or approval of the TULSA-PRO™ system for ablation of prostate tissue from the FDA in order to introduce its product to the United States market. On May 19, 2016, Profound announced that the FDA had granted IDE approval with respect to the multicenter Pivotal Trial. The objective of this trial is to evaluate the efficacy of the TULSA-PRO™ system in ablating prostate tissue in patients with localized prostate cancer.

Profound is working towards TULSA-PRO™ system clearance with the FDA via the 510(k) pathway. Profound may, at a future date, seek additional clinical data and regulatory clearances or approvals to expand labeling claims for prostate cancer treatment. After completion of the Pivotal Study, Profound may assess whether or when to engage the FDA to discuss an appropriate regulatory path for any such claims.

Profound's market entry and sustained growth in the United States will be predicated on achieving the following:

- Demonstrating safety and effectiveness for ablation in the Pivotal Trial;
- Obtaining regulatory clearance of the device from the FDA;
- Scaling up manufacturing to support commercial launch; and
- Obtaining satisfactory reimbursement, ultimately through a CPT Code.

Profound currently believes that the clinical trial sites in the Pivotal Trial would be the most likely early commercial adopters of the technology for the initial indication to ablate prostate tissue. In the course of working with these sites, Profound will gain a broader understanding of clinic workflow and scheduling dynamics associated with the relevant MRI suite, which will enable the Company to develop a marketing strategy that incorporates facilitation of access to MRIs for its customers.

Government Regulation

A summary of the United States, Canadian and European Union regulatory pathways is as follows:

	United States	Canada	European Union
Regulatory Body	FDA	Health Canada	Notified Body
Pre-Market Clearance or Approval Path	510(k) submission for ablation of prostate tissue	Medical Device License for ablation of malignant and benign prostate tissue	CE Mark for ablation of malignant and benign prostate tissue
Phase I Trial	Completed	Completed	Completed

	United States	Canada	European Union
Regulatory Body	FDA	Health Canada	Notified Body
Pivotal Trial	Expected August 2016 commencement	N/A	
Clinical Study Population for the market clearance	110 patients	Phase I data sufficient for market approval	

Profound may at a future date seek collection of additional clinical data and regulatory approvals in order to market the product with prostate cancer treatment labeling claims. Any such strategy would require further consultation with the FDA for cancer specific device indication and clinical trial design.

Overview – U.S. Regulation

The FDA strictly regulates medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FFDCA, and the regulations promulgated under the FFDCA. The FFDCA and the implementing regulations govern, among other things, the following activities relating to Profound's medical device: preclinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, postmarket adverse event reporting, recalls, and advertising and promotion.

The TULSA-PRO™ system, and any future medical devices that Profound may develop, will be classified by the FDA under the statutory framework described in the FFDCA. This framework is a risk-based system that classifies medical devices into three classes from lowest risk (Class I) to highest risk (Class III). In general, Class I devices are subject to only general controls (e.g., labeling, medical devices reporting and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements. Class II devices generally require 510(k) premarket notification clearance before they may be commercially marketed in the United States. Class II devices also may be subject to special controls such as performance standards and FDA guidelines that are not applied to Class I devices. Class III devices require FDA approval of a premarket application, or PMA, prior to commercial distribution. Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device. Rather than requiring PMA for novel, low-risk devices, FDA may allow *de novo* classification to class II. Both premarket clearance and PMA applications are subject to the payment of user fees paid at the time of submission for FDA review.

The 510(k) Clearance Process. In the 510(k) process, the FDA reviews a premarket notification and determines whether or not a proposed device is "substantially equivalent" to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of premarket approval applications, referred to as a "predicate device." In making this determination, the FDA compares the proposed device to the predicate device. If the new device is substantially equivalent in intended use and safety and effectiveness to the predicate device, the new device may be cleared for marketing. The FDA's 510(k) clearance pathway usually takes from four to 12 months, but it can last longer and clearance is never guaranteed. In reviewing a premarket notification, the FDA may request additional information, including clinical data. Moreover, the FDA is making changes to its 510(k) clearance pathway that will likely require the submission of more clinical and pre-clinical data than has previously been required to obtain clearance for medical devices. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the agency can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified

device until 510(k) clearance or PMA approval is obtained. Also, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Reclassification. If there is no known predicate for a device (*i.e.*, a legally marketed Class I or II device with comparable indications for use and technological characteristics), a company can request a *de novo* reclassification of the product. *De novo* reclassification generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. FDA's *de novo* reclassification process has been streamlined to allow a company to request that a new product classification be established based on information provided by the requesting company. This "direct" *de novo* process must be discussed and agreed upon by FDA prior to submission. The "direct" *de novo* process allows a company to submit a reclassification petition which includes information that would be included in a 510(k) notice for the subject device in addition to providing FDA with a risk-benefit analysis demonstrating that the device presents a moderate risk thereby not requiring a PMA. The submitter also must provide draft Special Control(s) for the product. The Special Controls specify the recommendations for submission of subsequent devices for the same intended use. If a product is classified as Class II through the "direct" *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications. The "direct" *de novo* process can take a year or more for FDA to reach a decision on a "direct" *de novo* petition and issue a new product code. Should FDA fail to approve a "direct" *de novo* petition, or establish a new product code, PMA approval may be required.

The PMA Approval Process. A PMA must be submitted if the device cannot be cleared through the 510(k) process. The PMA process is generally more costly and time consuming than the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application", although, generally, review of the application can take between one and three years and it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Typically, the FDA will convene an advisory panel meeting to seek review of the data presented in the PMA for novel devices. The panel's recommendation is given great weight, but is not dispositive of the agency's decision. Prior to approving the PMA, the FDA will conduct an inspection of the manufacturing facilities and a number of the clinical sites where the supporting study was conducted. The facility inspection evaluates the company's compliance with the Quality System Regulation, or QSR, which impose elaborate testing, control, documentation and other quality assurance procedures in the manufacturing process. The FDA may approve the PMA with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to that information needed to support the proposed change from the product covered by the original PMA.

Clinical Trials. Clinical trials are generally required to support a PMA application or *de novo* petition and are sometimes required for 510(k) clearance. Such trials, if conducted in the United States, generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed an nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or 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. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device 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, either a 510(k) premarket notification or a PMA. Even if a study is completed and submitted to the FDA, the results of Profound's clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain approval of Profound's product.

Pervasive and Continuing Regulation. After a device is placed on the market, numerous regulatory requirements apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indications;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of cleared devices;
- approval of product modifications that affect the safety or effectiveness of approved devices;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the United States federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. Accordingly, once cleared or approved, Profound may not market or promote its product for any off-label use. Nonetheless, physicians may use its devices off-label for other indications within their practice of medicine. 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 or 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 its products would be impaired.

Furthermore, Profound's products could be subject to voluntary recall if Profound or the FDA determine, for any reason, that Profound's products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that Profound's device would cause serious adverse health consequences or death.

Once cleared, the Medical Device Reporting regulation (21 CFR 803), or the MDR regulation, requires device manufacturers to report to the FDA whenever they receive or become aware of information that reasonably suggests that a device marketed by the manufacturer "may have caused or contributed to a death or serious injury" or has malfunctioned and, if the malfunction were to recur, likely would cause or contribute to a death or serious injury. Adverse event reporting, under the MDR regulation, is subject to two different time frames and report types, depending on the nature of the event. Once reportable events have been identified, Profound would have to decide which individual adverse event report to file: a five-day report or a 30-day report. For events involving deaths, serious injuries or malfunctions that require remedial action to prevent an unreasonable risk of substantial harm to the public health, a five-day report must be filed. If remedial action is not necessary, a 30-day report must be filed. MDRs are disclosed to the public via the Manufacturer and User Facility Device Experience (MAUDE) database, which is maintained by the FDA.

The FDA has broad post-market and regulatory enforcement powers. Profound is subject to unannounced inspections by the FDA to determine its compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of its subcontractors. If the FDA were to find that Profound was not operating in compliance with applicable regulations, Profound could be subject to FDA enforcement action including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, 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 on PMA approvals that have already been granted;
- refusal to grant export approval or issue export documentation for Profound's products; or
- criminal prosecution.

In addition, later discovery of previously unknown problems with Profound's product, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, or observations found during a future inspection, could result in enforcement action by the FDA or other regulatory authorities.

Overview – European Union Regulation

In the European Union, legal manufacturers of medical devices, such as the TULSA-PRO™ system, are required to comply with the Essential Requirements laid down in Annex I to the Council

Directive 93/42/EEC concerning medical devices, known as the Medical Devices Directive. Compliance with these requirements entitles us to affix the CE mark to our medical devices, without which they cannot be commercialized in the European Union. To demonstrate compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive and obtain the right to affix the CE mark to our medical devices, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may prepare an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements laid down in the Medical Devices Directive, a conformity assessment procedure requires the intervention of a notified body. A notified body is an organization designated by the competent authorities of a European Union Member State to conduct conformity assessments. The notified body typically audits and examines products' Technical File and the quality system for the manufacture, design and final inspection of our devices before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements laid down in Annex I to the Medical Devices Directive. Following these audits, Profound's Notified Body issues CE Certificates of Conformity. These permit us to draw up an EC Declaration of Conformity and affix the CE mark to the products covered by this CE Certificate of Conformity and the EC Declaration of Conformity.

Additionally, as part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant Essential Requirements of the Medical Device Directive covering safety and performance. A clinical evaluation is defined as a "methodologically sound ongoing procedure to collect, appraise and analyze clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's Instructions for Use". A clinical evaluation must address:

- the intended purpose described in the information materials supplied by the manufacturer (including for all medical indications);

- the clinical performance and benefits described in the information materials supplied by the manufacturer (including, for example, any claims on product performance and safety);

- measures for risk avoidance and risk mitigation described in the information materials supplied by the manufacturer (including, for example the declaration of the residual risks, contraindications, precautions, warnings, instructions for managing foreseeable unwanted situations);

- the usability of the device for the intended users and the suitability of the information materials supplied by the manufacturer for the intended users (including, if applicable, for lay or disabled persons); and

- instructions for target population groups (including, for example, pregnant women, paediatric populations).

This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature. As part of the conformity assessment procedure, depending on the type of devices, the notified body will review the manufacturer's clinical evaluation for the medical device. The conduct of clinical studies to obtain

clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming.

After the product has been CE marked and placed on the market in the European Union, Profound must comply with a number of regulatory requirements relating to:

- registration of medical devices in individual European Union Member States;
- negotiation of pricing and reimbursement of medical devices;
- establishment of post-marketing surveillance and adverse event reporting procedures;
- Field Safety Corrective Actions, including product recalls and withdrawals; and
- interactions with physicians.

In the European Union, Profound must comply with the Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the European Union Member States. 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. FSCAs must be communicated by the manufacturer or its European Authorized Representative to its customers and/or to the end users of the device through Field Safety Notices.

The advertising and promotion of Profound’s products in the European Union is subject to the provisions of the Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation in the individual European Union Member States governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of Profound’s products to the general public and may impose limitations on Profound’s promotional activities with healthcare professionals.

Overview – Canadian Regulation

Health Canada's Therapeutic Products Directorate (TPD) is the Canadian authority that regulates medical devices. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and the Medical Devices Regulations (MDR).

The TPD applies the MDR through a combination of pre-market review, post-approval surveillance and quality systems in the manufacturing process. A Medical Device Licence is a pre-market requirement for a device previously authorized for sale for investigational testing now to be offered for general sale. Medical devices are classified into one of four classes, where Class I represents the lowest risk and Class IV represents the highest risk. Class II, III and IV medical devices must be licensed prior to importation or sale in Canada. A Medical Device Licence is issued to the device manufacturer, provided the requirements of the MDR are met.

The CMDCAS is a system designed to implement the MDR requirements that medical devices be designed and manufactured under a registered quality management system (QMS). The MDR requires that medical

devices be manufactured under a certified QMS that meets the criteria of the international standard, ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. Profound is manufacturing the TULSA-PRO™ system under a certified ISO 13485 Quality Management System.

Regulatory Update

The TULSA-PRO™ system has received CE mark in the European Union; however, it is an investigational device in the United States and Canada. Outside of the European Union, the device will require country-specific pre-market clearance or approval prior to launch. Profound's initial regulatory strategy for its clinical trials involves two phases: a safety and feasibility study (which is completed) and a Pivotal Trial.

In March 2014, Profound completed enrollment and treatment of 30 patients in the Phase I TULSA multi-jurisdictional safety and feasibility study. The procedure was delivered using our TULSA-PRO™ system, with the objective of determining its clinical safety and feasibility for prostate ablation in the primary treatment setting of patients with localized prostate cancer.

In October 2015, the results of Profound's safety and feasibility study were accepted for publication in *European Urology*, the official journal of the European Association of Urology. Profound presented the successful 12-month Phase I clinical trial outcomes at the European Symposium on Focused Ultrasound Therapy. Thirty (30) patients with low/intermediate risk, organ confined prostate cancer were enrolled in this multi-jurisdictional trial. The 12-month data show:

- No serious treatment related adverse events;
- Accurate and precise thermal ablation of the prostate; and
- Promising quality of life outcomes.

The 12-month data indicate that the TULSA-PRO™ system is a precise method to ablate prostate tissue, both malignant and benign, while providing a favourable safely profile and a low rate of erectile dysfunction. Upon completion of the study, the clinical data was also submitted to European regulatory authorities for regulatory clearance in Europe. On April 11, 2016, Profound announced that it was granted CE Mark approval for the commercial sale of the TULSA-PRO™ system in Europe and in other CE Mark jurisdictions. Profound completed its first commercial sale of the TULSA-PRO™ system in the same month. The TULSA-PRO™ system has been authorized for investigational testing in Canada by the TPD (in Canada). Profound submitted an application to the TPD for a Class III Medical Device Licence in May 2016 and anticipates that a license for the TULSA-PRO™ system will be issued sometime in the fourth quarter of 2016, although there can be no assurance in this regard.

Profound has obtained IDE approval from the FDA for the Pivotal Trial for use of the device in ablation of prostate tissue. All clinical sites have been identified for the Pivotal Trial, which is expected to commence in August 2016. The Pivotal Trial is designed to support a 510(k) premarket notification submission in the United States. This submission will seek clearance of the TULSA-PRO™ system for use in the ablation of prostate tissue.

Approval of an IDE by the FDA and completion of the Pivotal Trial does not guarantee that the FDA will clear a 510(k) premarket notification, even if the study is successful. Profound will maintain ongoing communication with the FDA to mitigate risks related to the data collection during the Pivotal Trial, working to ensure that the data will support a successful regulatory outcome.

Trends

According to iData Research Inc., there are approximately 500,000 new cases of prostate cancer diagnosed with an estimated 850,000 treatment procedures per year worldwide, representing a potential US$40 billion market. The American Cancer Society (2016 statistics) estimates that, other than skin cancer, prostate cancer is the most common cancer found in American men and is the second leading cause of cancer deaths in men in the United States. Prostate cancer is estimated to affect approximately 1 in 7 men in the United States in 2016, with over 180,890 new cases diagnosed each year. The probability of dying of prostate cancer is, on average, 1 in 39 for American men. According to the Canadian Cancer Society (2015 statistics), 66 Canadian men are diagnosed with prostate cancer every day, 24% of all new cancer cases in Canada are prostate cancer, and the probability of dying of prostate cancer is, on average, 1 in 27 for Canadian men. In Europe (EUCAN 2012 statistics), there were 399,964 prostate cancer cases and 92,247 men died of prostate cancer.

Clinicians diagnosing prostate cancer use a number of methods to diagnose and stage the disease. These methods include a digital rectal exam, imaging, PSA blood tests, biopsy, bone scan and fine needle aspiration. The resulting information is used in several scoring and staging systems. These scores can be combined to determine whether the patient is at low, intermediate or high risk of disease progression and death, and are useful in considering the choices for treatment. One key measure is the degree to which the cancer has spread: cancer may be confined to the prostate gland (i.e. localized prostate cancer), or to the gland and immediate surrounding tissues, or may have spread to distant tissues. Another measure (the Gleason score) is the degree of abnormality of the cancer cells; this is typically determined by a pathologist from biopsies.

Patients with localized prostate cancer and higher Gleason scores are candidates for intervention. Treating prostate cancer while it is still localized can produce effective long term outcomes.

Several drivers are influencing the prostate cancer treatment market:

1. *Earlier detection*. Digital rectal exams are now common for men over the age of 50 visiting their physician for a general health check-up. Additionally, PSA testing has become a standard screening paradigm.

2. *Men between 55–75 years old are an increasingly large proportion of the overall population*. Not only are more men being screened, there are simply more men in the age range where incidence is anticipated. Developed countries are experiencing a substantial demographic shift as baby-boomers move into retirement, with a larger percentage of the population being greater than 60 years old. As this trend is set to intensify through the next 20 years, it indicates accelerated growth of the addressable market.

3. *Greater emphasis on reducing the risk of post-procedure complications*. Growing acceptance of robotic prostatectomy, a procedure to remove the prostate, is part of a general trend toward a greater emphasis on reducing the risk of post-procedure complications.

4. *Increasing cost-consciousness of healthcare payers*. With healthcare reform in the European Union and United States, cost-awareness is spreading to providers as well.

Profound believes that the TULSA-PRO™ system performance will continue to demonstrate post-procedure complications similar to those shown in the 30 patient Phase I Clinical Trial and that the device will eventually stand to benefit from each of these four drivers for the prostate cancer treatment market, on the basis that an increasing emphasis towards minimally invasive procedures and the increasing cost-consciousness of healthcare payers may provide Profound an advantage over other current treatment

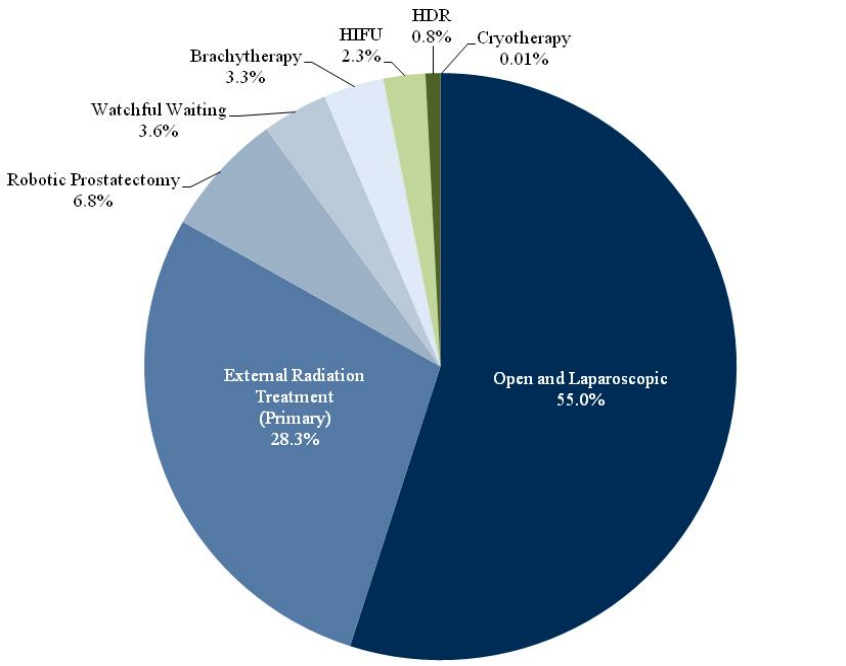
methods. The focus on attempting to minimize post-procedure complications without compromising efficacy is a key feature of TULSA technology.

Competitive Conditions

Profound believes that its TULSA-PRO™ system (subject to additional data requirements) will ultimately represent an improvement over the alternative procedures that are currently most commonly used to treat prostate cancer and that treatment outcomes from the TULSA-PRO™ system may be comparable to those of commonly used procedures. Profound believes that the TULSA-PRO™ system will be eventually capable of use as a tool to treat the whole prostate with greater speed, accuracy and precision than any of the current commonly used procedures. Profound believes that it will likely be able to generate clinical data on safety without compromising efficacy.

The most widely used treatment options for prostate cancer are currently: (1) Radical Prostatectomy (includes open, laparoscopic and robotic procedures) (2) External Beam Radiation Therapy ("**EBRT**"); (3) Brachytherapy and High Dose Radiation ("**HDR**"); (4) cryoablation; (5) trans-rectal High Intensity Focused Ultrasound ("**HIFU**"); and (6) Watchful Waiting/Active Surveillance. In addition to these widely used treatment options, certain adjunct or less common treatments are used or are under development, such as Androgen Deprivation Therapy and Proton Beam Therapy.

Prostate Cancer Treatment Procedure by Type, Europe, 2011



Source: iData Research Inc.

Radical Prostatectomy

Radical Prostatectomy, an open surgical removal of the entire prostate gland and some surrounding tissues, represents a current standard of care, practiced by urologists in North America and Europe, which procedure involves the removal of the localized cancerous tissue. However, the conventional open surgical technique has high post-surgery incidences of impotence and incontinence and long recovery time.

Recently, robotic surgery systems have entered the market. Cited benefits of the robotic technique include improved precision and range of motion. Risks specific to the robotic technique include longer operation time, the possible need to convert the procedure to a non-robotic approach, and the need for additional or larger incision sites. Converting the procedure could mean a longer operation time, resulting in a longer time under anesthesia.

External Beam Radiation Therapy

EBRT requires multiple weekly clinic visits over a period of six to eight weeks. The procedure directs a beam of radiation from outside the body to cancerous tissue inside the body. Although such procedures are relatively costly with studies showing significant risk of collateral damage and lengthy recovery times, Profound believes that the non-invasive nature of the procedure makes it attractive to patients. It can also be used to irradiate cancer that has spread to other areas.

Brachytherapy and High Dose Radiation

With Brachytherapy, radioactive seeds are implanted in the prostate to irradiate the cancerous tissue. The seeds irradiate the prostate over time and decay in place to background levels; they remain implanted and inert afterwards. The ability to target the radiation to the prostate versus surrounding tissues is limited, and Profound is aware of clinical observations that the radioactive seeds can and do migrate to other parts of the body, and can damage structures surrounding the prostate. An alternative is HDR, in which highly radioactive seeds are temporarily inserted, then removed during the same procedure, leaving nothing implanted afterward. HDR has the ability to target tissue, but requires hospital stays and usually is accompanied by adjunct EBRT over several weeks.

Cryoablation

Cryoablation freezes cells to death by introducing cooled liquids and gases to an area of cancerous tissue. Studies show cyroablation offers poor precision and has delivered impotence rates that are almost as high as those for conventional radical prostatectomy. The procedure also carries a risk of potential damage to the tissue between the urethra and rectum, potentially resulting in a urinary rectal fistula.

Trans-rectal High Intensity Focused Ultrasound

Trans-rectal HIFU is used increasingly in the European Union, United States and Canada. This technique utilises focused ultrasound that is delivered through the rectal wall to treat the prostate. Image guidance is generally provided by ultrasound. At FDA urology panel meetings in 2014, the panel indicated that HIFU can lead to complications such as rectal fistulae and rectal incontinence. Due to the focused treatment zone, this treatment requires approximately three hours to complete. One limitation of HIFU is prostate size; the procedure is limited to patients with prostate volume smaller than 40 cubic centimetres (i.e. the average size of a prostate). Patients with larger prostates need a separate surgical procedure, such as transurethral resection of the prostate ("**TURP**") or androgen deprivation therapy ("**ADT**"), both described below, to de-bulk or reduce the size of the prostate prior to HIFU. This additional procedure increases costs and the risk of complications. Recent studies have indicated positive survival outcomes and thermal ultrasound appears to be gaining traction in certain settings.

Watchful Waiting; Active Surveillance

Watchful waiting means no treatment until there is an indication that the cancer has spread**.** Active surveillance is monitoring of the prostate cancer closely with PSA tests and digital rectal exams every three to six months, and ultrasounds annually to see if the cancer is growing. Prostate biopsies may also be done to see if the cancer is becoming more aggressive. Test results will indicate whether a more aggressive treatment option should be considered.

Adjunct and Emerging Therapies

- ADT uses hormones to suppress testosterone production and alleviate symptoms, but with the primary side-effect of reduced sexual interest and activity. Although historically used as a last line of defence for the disease (and typically in a palliative setting), it is increasingly used as a first line treatment or in combination with other treatments.

- TURP is a surgical procedure that removes portions of the prostate gland through the penis. This procedure is used to relieve moderate to severe urinary symptoms caused by an enlarged prostate, a condition known as BPH. This procedure is also used in adjunct to a HIFU procedure when a prostate gland is larger than 40 cubic centimetres (i.e. the average size of a prostate).

- Proton beam therapy is a way to deliver radiation to tumors using tiny, sub-atomic particles (protons) instead of the photons used in conventional radiation treatment. Proton beam therapy uses new technology to accelerate atoms to approximately 93,000 miles per second, separating the protons from the atom. While moving at this high speed, the particles are "fired" at the patient's tumor. These charged particles deliver a very high dose of radiation to the cancer but release very little radiation to the normal tissue in their path. In theory, this approach minimizes damage to healthy organs and structures surrounding the cancer. The radiation beams must pass through the skin, the bladder and the rectum on the way to the prostate gland, and once they reach the gland, they encounter normal prostate cells and the nerves that control penile erections. Damage to these tissues can lead to complications, including bladder problems, rectal leakage or bleeding, and erectile dysfunction.

The following chart briefly summarizes the advantages and limitations/risks of each of the above-summarized treatments.

Procedure	Advantages	Limitations / Risks
Radical Prostatectomy (includes robot-assist)	☐ Certainty of removing whole gland ☐ Good outcomes data	☐ Invasive ☐ Hospital stay required ☐ Potential for post-surgical complications ☐ High cost
EBRT	☐ Non-invasive	☐ Collateral tissue damage ☐ Multiple visits required ☐ Recurrence ☐ High cost
Brachytherapy and High Dose Radiation	☐ Minimally invasive ☐ Low cost ☐ Image-guided	☐ Seed migration ☐ Collateral damage ☐ Potential for complications ☐ Recurrence
Cryotherapy	☐ Minimally invasive ☐ Image-guided	☐ High rates of collateral tissue damage ☐ Potential for complications
HIFU	☐ Minimally invasive ☐ Image-guided ☐ Good outcomes data	☐ Trans-rectal delivery can result in complications ☐ Prostate volume must be less than 40 cubic centimetres

Procedure	Advantages	Limitations / Risks
		☐ Significant capital equipment cost ☐ Potential for issues arising out of overheating of tissue
Watchful Waiting (includes active surveillance)	☐ Low cost ☐ Non-invasive	☐ Multiple visits required ☐ Treatment delay resulting in more aggressive treatment
Proton Beam Therapy	☐ Adjustable energy deposition depth	☐ Very costly equipment ☐ Limited data to support claims

Profound believes that use of the TULSA-PRO™ system as a tool to ablate prostate tissue can provide a clinician and his or her patients with the following clinical advantages:

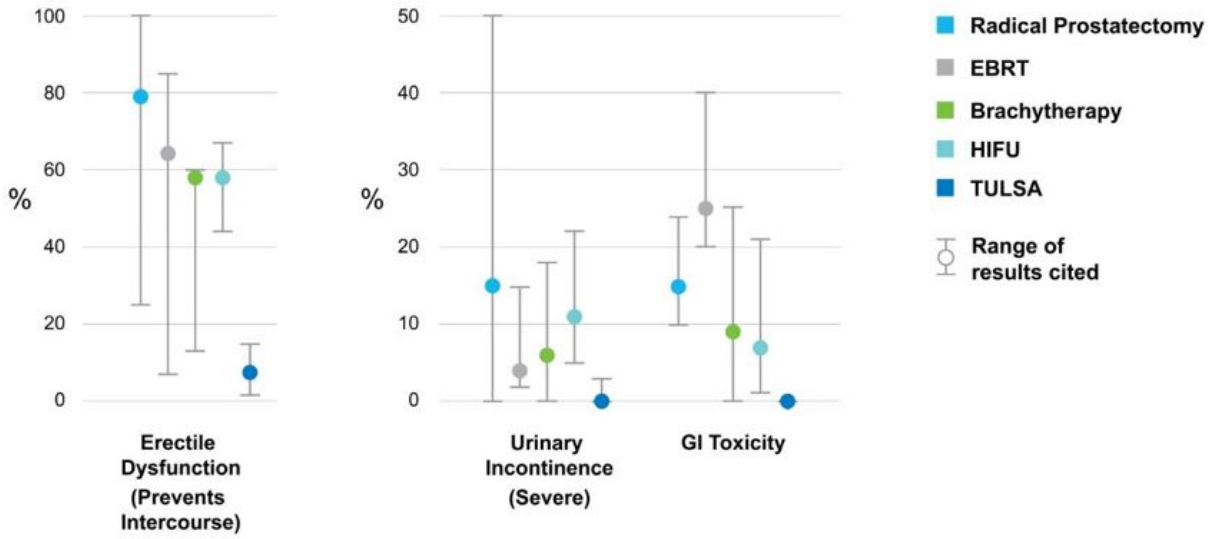
- Designed to be fast and accurate;
- Millimetre accuracy designed to ablate prostate tissue while sparing nearby critical structures;
- Potential outpatient procedure with single treatment and rapid recovery time;
- Minimally-invasive (transurethral) approach using thermal ablation designed to heat the prostate from the inside-out;
- Guided by real-time MRI with temperature (thermometry) feedback; and
- Designed to be compatible with leading MRI platforms.

Profound believes that the TULSA-PRO™ system may eventually provide a superior treatment time to the current long-term standard of care procedures. Typically, one or several of the surrounding critical structures, such as the urethra, urethral apex, bladder, seminal vesicles, bone and rectum can be compromised during the surgical procedure. Additionally, the neurovascular bundles that are critical for sexual potency are often compromised as a result of such surgical procedures, which can leave patients impotent.

Profound believes that the TULSA-PRO™ system may overcome certain limitations of HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. As noted above, Profound believes that a transurethral (inside out) ablation approach with millimetre accuracy has advantages over HIFU in treating the whole gland safely.

The graph below, prepared by Profound, displays complication rates for certain prostate cancer treatments from a study published in *The Journal of Urology*, together with data that Profound gathered from its 12-month 30 patient Phase I clinical trial.

Compilation of Multiple Studies Showing Complication Rates, and Compared to the TULSA-PRO™ System



Source: ***Complication rate data from Radical Prostatectomy, EBRT, Brachytherapy, and HIFU obtained from Thompson (Chair) et al for AUA Prostate Cancer Clinical Guideline Update Panel (2007) Guideline for the management of clinically localized prostate cancer: 2007 update. The Journal of Urology 177(6): 2106-31. Complication rate data from TULSA obtained from Profound's 12-month 30 patient Phase I clinical trial.***

Proprietary Protection

On May 16, 2011, Profound entered into an amended and restated technology license agreement (the "**Sunnybrook License**") with Sunnybrook pursuant to which Sunnybrook licenses to Profound certain intellectual property on the terms and conditions set forth therein. Pursuant to the Sunnybrook License, Sunnybrook has granted to Profound an exclusive worldwide and royalty-free right to use certain defined Sunnybrook technology in connection with, among other things, making products such as the TULSA-PRO™ system, in the field of MRI-guided transurethral ultrasound therapy. Under the license, Profound is subject to various obligations, including a milestone payment of $250,000 upon clearance by the FDA of Profound's first product for sale for human use and payment of legal costs associated with patent application preparation, filing and maintenance. If either party to the Sunnybrook License breaches or fails to perform a material obligation and fails to cure such breach or perform such obligations within a 30 day cure period, the non-breaching party may terminate the agreement. Material obligations include Profound agreeing not to use the technology or intellectual property outside of the license scope, not to use the technology or intellectual property outside the field of MRI-guided transurethral ultrasound therapy (or permitting Profound's customers to do so) and not to breach confidentiality obligations. The Sunnybrook License further provides Profound with an option to acquire an outright assignment of the licensed technology and intellectual property upon achievement of certain milestones. Profound has met two of the three relevant milestones and, if it is able to obtain PMA approval or FDA 510(k) clearance prior to December 31, 2018, can exercise such buyout option for payment of an additional fee of $200,000. Loss of any of the rights provided therein could result in a material adverse effect to Profound's financial condition and operating results. Profound has also agreed to indemnify Sunnybrook from and against any damages it may suffer from the license or the development or sale of products (such as the TULSA-PRO™ system) except for any damages caused by Sunnybrook's own gross negligence or wilful misconduct.

Research scientists working with Sunnybrook and Profound have produced a powerful portfolio of intellectual property that is in the name of, or has been exclusively licensed to, Profound pursuant to the

Sunnybrook License. Profound has continued to develop the technology and file new patent applications. Below is a list of patents and applications licensed to or assigned to Profound:

- Technique and apparatus for ultrasound therapy; Rajiv Chopra, Michael Bronskill: US6589174 (issued patent), WO2002032506 (filed patent application).

- Treatment of diseased tissue using controlled ultrasonic heating; Rajiv Chopra, Michael Bronskill, Mathieu Burtnyk: US7771418 (issued patent).

- Method and apparatus for obtaining quantitative temperature measurements in prostate and other tissues undergoing thermal therapy treatment; Rajiv Chopra, Michael Bronskill, Kee Tang: US8801701 (issued patent).

- System for treatment of diseased tissue using controlled ultrasonic heating; Rajiv Chopra, Michael Bronskill, Mathieu Burtnyk: US 8,989,838 (issued patent)

- Apparatus and Method for Cooling a Tissue Volume During Thermal Therapy Treatment; Michael J. Bronskill, Rajiv Chopra: US20110319748, CA2826761, EP2585012, WO2012005996 (filed patent applications).

- Fluid circuits for temperature control in a thermal therapy system; Cameron Mahon, Sean Donaldson: US20110230753, WO2011112251 (filed patent applications).

- Radio frequency power controller for ultrasound therapy system; Cameron Mahon, Nicolas Yak, Rajiv Chopra, Mathew Asselin, Michael Bronskill: US20110270366, WO2011112249A1 (filed patent applications).

- Ultrasonic therapy applicator; Rajiv Chopra, Michael Bronskill, Sean Donaldson, Cameron Mahon: US20110295161, CA2800238, EP2544767, WO2011112250 (filed patent applications).

- System and Method for Control and Monitoring of Conformal Thermal Therapy; Cameron Mahon, Mathieu Burtnyk: US 8,998,889, US 9,205,282, (issued patents), CA2849106, EP2760545, WO2013049108 (filed patent applications).

- Treatment Planning and Delivery Using Temperature Uncertainty Maps; Kee Tang, Ron Kurtz, Mathieu Burtnyk: US20150038883, CA 2,881,596, EP 14814725.9 (filed patent applications).

- Endocavity Temperature Control Device; Michael Wybenga, Owen Moffitt: US 14/988,056, PCT/US16/12149 (filed patent applications).

In the course of its research and development of the TULSA-PRO™ system, Profound may continue to develop intellectual property with respect to improvements on the above patents and application.

RISK FACTORS

Due to the nature of Profound's business, the legal and economic climate in which it operates and its present stage of development, Profound is subject to significant risks. Profound's future development and operating results may be very different from those expected as at the date of this AIF. Readers should carefully consider all such risks.

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

Risk Factors Relating to Profound's Business

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

Profound's business requires substantial capital investment in order to conduct the research and development and to fund the clinical and regulatory activities necessary to bring Profound's product to market and to establish commercial manufacturing, marketing and sales capabilities. As of December 31, 2015, Profound had a cash and short-term investment balance of $20.5 million. Profound will need additional capital to fund its current business activities and expectations and to fund any significant expansion of operations. In order to secure financing, if available, it is likely that Profound would need to sell additional common shares or financial instruments that are exchangeable for or convertible into common shares and/or enter into development, distribution and/or licensing relationships, to fund all or a part of particular programs. Any future equity financing may also be dilutive to existing shareholders. Any future debt financing arrangements Profound enters into would likely contain restrictive covenants that would impose significant operating and, if any, financial restrictions on it. The availability of equity or debt financing will be affected by, among other things, the results of its research and development, its ability to obtain regulatory approvals, the market acceptance of Profound's product, the state of the capital markets generally, strategic alliance agreements, and other relevant commercial considerations. Any additional financing may not be obtained on favourable terms, if at all.

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

Profound's cash outflows are expected to consist primarily of internal and external research and development expenditures to advance Profound's product pipeline in addition to selling, general and administrative expenditures to support its corporate infrastructure. If Profound does not obtain additional capital, there may be substantial doubt about its ability to continue as a going concern and realize assets and pay liabilities as they become due. Depending upon the results of Profound's research and development programs and the availability of financial resources, Profound could decide to accelerate, terminate or reduce certain projects, or commence new ones. Any failure on Profound's part to raise additional funds on terms favourable to it or at all, may require it to significantly change or curtail current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in Profound not taking advantage of business opportunities, in the termination or delay of clinical trials for one or more of its product candidates, in curtailment of its product development programs designed to identify new product candidates, in the sale or assignment of rights to Profound's technologies, product or product candidates and/or Profound's inability to file application for market clearance in the United States at all.

Profound has a limited operating history

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

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

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

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

Recent and anticipated future losses

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

Development-stage company in an uncertain industry

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

Debt Financing Risk

Profound's Health Technology Exchange loan and Federal Economic Development Agency loan and the Knight Loan Agreement contain financial and non-financial covenants, such as requirements that Profound comply with one or more financial ratios and change of control provisions. Complying with such covenants may at times necessitate that Profound must forego other favourable business opportunities, such as acquisitions. Moreover, Profound's failure to comply with any of these covenants would likely constitute a default under such facilities and agreements and could give rise to an acceleration of some, if not all, of

Profound's then outstanding indebtedness, which would have a material adverse effect on its business. Profound's indebtedness may grow as Profound's business grows and/or Profound makes new acquisitions. If Profound's income from operations underperforms, Profound may have to utilize cash flow or capital resources to fund its debt service payments. If Profound's cash flow and capital resources are insufficient to service amounts owed under Profound's current or any future indebtedness, as applicable, Profound may be forced to reduce or delay capital expenditures, dispose of assets, issue equity or incur additional debt to obtain necessary funds, or restructure its debt, any or all of which could have a material adverse effect on Profound's business, financial condition and results of operations. In addition, Profound cannot guarantee that it would be able to take any of these actions on terms acceptable to it, or at all; that these actions would enable Profound to continue to satisfy its capital requirements; or that these actions would be permitted under the terms of Profound's various debt agreements. The Knight Loan Agreement contains covenants with respect to capital expenditures and other indebtedness, maintaining minimum cash balances at all times and certain financial covenants in relation to the twelve month period ending on June 30, 2019 and for periods thereafter, in addition to covenants with respect to permitted distributions. Profound has granted a security interest over all assets (including the shares of PMI). 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 PMI.

Profound operates in a strict regulatory environment

Numerous statutes and regulations govern human testing and the manufacture and sale of medical devices in the United States, Canada and the European Union and other countries where Profound intends to market its product. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities including advertising and labelling.

There can be no assurances that Profound can scale-up or manufacture sufficient quantities with acceptable specifications for the regulatory agencies to grant approval or not require additional changes or that additional trials be performed. Regulatory agencies may also require additional trials be run in order to provide additional information regarding the safety or efficacy of Profound's device. Similar restrictions are imposed in foreign markets other than the United States, Canada and the European Union. Investors should be aware of the risks, problems, delays, expenses and difficulties which may be encountered by Profound in light of the extensive regulatory environment in which Profound's business operates. Even if Profound's device is cleared or approved by the FDA or any other regulatory authority, Profound may not obtain clearance or approval for an indication whose market is large enough to recoup its investment in the device or there may be limitations on the intended use. Profound may never obtain the required regulatory clearances or approvals for its device.

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

Before obtaining regulatory clearances or approvals for the commercial sale of the TULSA-PRO™ system, Profound must demonstrate through clinical trials that the device is safe and effective for its intended use or, to receive 510(k) clearance in the United States, that the device is substantially equivalent to an existing predicate device for its intended use. Obtaining product clearance or approval and conducting the requisite clinical trials is a long, expensive and uncertain process and is subject to delays and failures at

any stage. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Profound will be required to demonstrate through well-controlled clinical trials that its device is sufficiently safe and effective for its intended use in a diverse population before it can seek regulatory clearances or approvals for commercial sale. Data obtained from a clinical trial can be insufficient to demonstrate to the regulatory authority that the TULSA-PRO™ system is sufficiently safe and effective for its intended use or that it is substantially equivalent to a predicate device. The data from a clinical trial may be inadequate to support clearance or approval of an application to the regulatory authorities for numerous reasons including, but not limited to:

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

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

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

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

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

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

Clinical trials recruitment

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

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

Profound's products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities and notified bodies. Profound's device has not received regulatory clearance or approval for commercial sale in the Unites States or Canada. The process of obtaining FDA clearances or approvals, or equivalent third country approvals to market a medical device can be costly and time consuming, and Profound may not be able to obtain these clearances or approvals on a timely basis, if at all. Profound expects to eventually generate a significant portion of its revenues from sales of the TULSA-PRO™ system, but may be unable to do so if the TULSA-PRO™ system does not prove to be safe and effective for its intended use in clinical trials to the satisfaction of the relevant

regulatory authorities in the United States, Canada or other countries. No assurance can be given that Profound's device will prove to be safe and effective in clinical trials or that it will receive the regulatory approval. Furthermore, no assurance can be given that current regulations relating to regulatory approval will not change or become more stringent.

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

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

Third-party reimbursement

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

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

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

- safety, efficacy, convenience and cost-effectiveness of Profound's device as a method of ablation of prostate tissue, or ultimately (pending the relevant approvals) treatment for localized prostate cancer, compared to products of Profound's competitors or other forms of treatment;

- scope of approved uses and marketing approval or clearance;

- timing of market approvals and market entry;

- difficulty in, or excessive costs to, manufacture;

- infringement or alleged infringement of the patents or intellectual property rights of others;

- availability of alternative products from Profound's competitors;

- acceptance of the price of Profound's product relative to those of its competitors;

- acceptance and adoption of its product by physicians/clinicians and the medical community;

- ability to market Profound's product effectively at the patient, physician/clinician and medical community level; and

- acceptance of Profound's product by government and third-party payers for adequate reimbursement.

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

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

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

Any product for which Profound obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, Profound and its suppliers are required to comply with the FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations

for the manufacture of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which Profound obtains clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. Profound and its contract manufacturers have been, and anticipate in the future being, subject to such inspections. The failure by Profound of one of its suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

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

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

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

In addition, Profound may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of its products, and Profound must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to its products. Later

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

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

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

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

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

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

- contract manufacturers or suppliers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the efficacy or safety of Profound's products or cause delays in shipments of products;

- Profound or its contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, Profound's suppliers may have excess or inadequate inventory of materials and components;

- Profound or its contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;

- Profound or its contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of Profound's products;

- Profound may experience delays in delivery by our contract manufacturers and suppliers due to changes in demand from Profound or their other customers;

- fluctuations in demand for products that Profound's contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components in a timely manner;

- suppliers or contract manufacturers may wish to discontinue supplying components or services for risk management reasons;

- Profound may not be able to find new or alternative components or reconfigure its system and manufacturing processes in a timely manner if the necessary components become unavailable; and

- contract manufacturers and suppliers may encounter financial hardships unrelated to Profound's demand, which could inhibit their ability to fulfill orders and meet Profound's requirements.

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

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

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

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

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

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

Profound currently intends to partner with one or more companies to commercialize products manufactured by QSR compliant and FDA registered contract manufacturers and, in connection therewith, Profound will likely be required to enter into manufacturing, licensing and distribution arrangements with third parties. These arrangements will likely reduce our product profit margins. In addition, the identification of new product candidates for development may require the entering into licensing or other collaborative agreements with others, including medical device and pharmaceutical companies and research institutions. These collaborative agreements may require the payment of license fees, milestone payments or royalties or granting rights, including marketing rights, to one or more parties. Any such arrangement will reduce Profound's profits. Moreover, these arrangements may contain covenants restricting product development or business efforts in the future.

Scaling issue due to growth

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

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

- the possibility that one or more suppliers or assemblers that do not have supply agreements with Profound could terminate their services at any time without penalty;
- natural disasters that impact suppliers;
- the potential obsolescence of, and/or inability of suppliers to obtain, required components;
- the potential delays and expenses of seeking alternate sources of supply or manufacturing services;
- the inability to qualify alternate sources without impacting performance claims of products;

- reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and

- increases in prices of raw materials and key components.

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

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

Profound may rely on third parties to provide distribution, clinical trial planning and execution, regulatory and sales and marketing services for its device in certain geographic regions. In connection with the Knight Loan Agreement, Profound has entered into a product sales, marketing and distribution agreement with Knight pursuant to which Knight will act as exclusive distributor of the Company's TULSA-PRO™ system in Canada for an initial 10 year term, renewable for successive 10 year terms by either party. Profound may be unable to find suitable partners, external consultants or service providers to provide such services outside of Canada or such arrangements may not be available on commercially reasonable terms. There can be no assurances that Profound will be able to enter into manufacturing or other collaborative arrangements with third parties on acceptable terms, if at all. Further, Profound may engage third parties that may cease to be able to provide these services, or may not provide these services in a timely or professional manner. Accordingly, Profound may not be able to successfully manage such services, execute clinical trials or generate revenues from its devices in such regions, which may result in decreases in sales. If Profound fails to establish such arrangements when, and as necessary, it could be required to undertake these activities at its own expense, which would significantly increase capital requirements and may delay the development, manufacturing and commercialization of Profound's product. If Profound is unable to address these capital requirements, it would likely be forced to sell or abandon its business. Additionally, any delay or interruption in the process or in payment could result in a delay delivering product to its customers, which could have a material adverse effect on Profound's business, financial condition and operating results.

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

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

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

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

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

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

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

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

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

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

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

Market not accepting of the product

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

Profound depends on key managerial personnel for its continued success

Profound is highly dependent upon qualified managerial personnel. Profound's anticipated growth will require additional expertise and the addition of new qualified personnel. There is intense competition

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

Profound currently maintains key-man insurance on its Chief Executive Officer, Steven Plymale, and its Vice-President of Engineering, Ron Kurtz, but not on its other executive officers or employees. The policies on Mr. Plymale and Mr. Kurtz are term policies, each with one million dollar benefits to Profound. Although it would not solve the potential problem of a loss of the services of any particular employee, Profound may seek key-man insurance on other key individuals to help in the case of such an event. The loss of the services of any of the executive officers identified in this AIF could have a material impact on Profound.

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

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

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

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

Research and development of products carries substantial technical risk

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

Achievement of development goals in time frames announced and expected

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

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

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

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

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

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

The government and regulatory authorities in the United States, Canada, the European Union and other markets in which Profound expects to sell its device may propose and adopt new legislation and regulatory requirements relating to medical product approval criteria, manufacturing and marketing requirements. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect Profound's business and products. It is impossible to predict whether

legislative changes will be enacted or FDA regulations, guidance or interpretations changed and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact Profound's operations and could have a material adverse effect on Profound's business, financial condition and results of operations.

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

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

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly. These pressures are particularly strong given the ongoing effects of the recent global economic and financial crisis, including the continuing debt crisis in certain countries in Europe, and the risk of a similar crisis in the United States. As a result, Profound's businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. In recent years, national, federal, provincial, state and local officials and legislators have proposed, or are reportedly considering proposing, a variety of price based reforms to the healthcare systems in the United States, the European Union and other countries. Some proposals include measures that would limit or eliminate payments for certain medical procedures and treatments or subject pricing to government control. Furthermore, in certain foreign markets, the pricing or profitability of healthcare products is subject to government controls and other measures that have been prepared by legislators and government officials. While Profound cannot predict whether any such legislative or regulatory proposals or reforms will be adopted, the adoption of any such proposals or reforms could adversely affect the commercial viability of Profound's existing and potential products.

In March 2010, the President of the United States, Barack Obama, signed into law the *Patient Protection and Affordable Care Act* and the *Health Care and Education Affordability Reconciliation Act of 2010*. Certain provisions of the law will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the law. The legislation imposes new taxes on medical device makers in the form of a 2.3% excise tax on all medical device sales in the United States.

Under the legislation, the total cost to the medical device industry is expected to be approximately US$20 billion over 10 years. The new tax could materially and adversely affect Profound's business, cash flows and results of operations. The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending beginning in 2014. Profound cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursement for Profound's products or reduce medical procedure volumes could adversely affect Profound's business and results of operations.

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

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

Rising insurance costs could negatively impact Profound's profitability

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

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

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

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

Profound's financial condition, results of operations and prevent or interfere with Profound's product commercialization efforts. In addition, any successful claim may prevent Profound from obtaining adequate product liability insurance in the future on commercially desirable terms. Even if a claim is not successful, defending such a claim may be time-consuming and expensive.

Use of product in unapproved circumstances could expose Profound to liabilities

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

Unexpected product safety or efficacy concerns may arise

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

Customer misuse could result in lack of adoption

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

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

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

Profound is also subject to various privacy and security regulations, including but not limited to the *Health Insurance Portability and Accountability Act of 1996* ("**HIPAA**") in the United States. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions (e.g. health care claims information and plan eligibility, referral certification and authorization, claims status, plan enrolment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health

information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states, provinces and other countries have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws could result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could have a material adverse effect on Profound's business, financial condition and operating results.

Foreign currency risk

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

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

Risk Factors Relating to Intellectual Property

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

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

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

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

Profound applies for patents covering its technologies as Profound deems appropriate. However, Profound may fail to apply for patents on important technologies in a timely fashion, or at all. Profound's existing patent applications and any future patents Profound may obtain may not be sufficiently broad to

prevent others from utilizing Profound's technologies or from developing competing products and technologies. In addition, Profound cannot guarantee that:

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

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

Protection afforded by United States patents may be adversely affected by recent or future changes to patent related statutes in the United States and to U.S. PTO rules. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of Profound's patent applications and the enforcement or defense of Profound's issued patents. On September 16, 2011, the *Leahy-Smith Act* was signed into law in the United States. The *Leahy-Smith Act* includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. PTO recently developed new regulations and procedures to govern administration of the *Leahy-Smith Act* and many of the substantive changes to patent law associated with the *Leahy-Smith Ac*t and, in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the *Leahy-Smith Act* will have on the operation of Profound's business. However, the *Leahy-Smith Act* and its implementation, as well as any future changes to patent law in the United States or otherwise, could increase the uncertainties and costs surrounding the prosecution of Profound's or its licensors' patent applications and the enforcement or defense of Profound's or its licensors' issued patents, all of which could have a material adverse effect on Profound's business, financial condition and operating results.

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

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

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

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

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

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

The patents for Profound's technologies have varying expiration dates and, when these patents expire, Profound may be subject to increased competition and may not be able to recover its development costs. In some of the larger economic territories, such as the United States and the European Union, patent term extension/restoration may be available to compensate for time taken during aspects of the product candidate's regulatory review. However, Profound cannot be certain that an extension will be granted or, if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. If Profound or its licensors are unable to obtain patent term extension/restoration or some

other exclusivity, Profound could be subject to increased competition and Profound's opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, Profound may not have sufficient time to recover Profound's development costs prior to the expiration of Profound's or its licensors' patents in the United States or elsewhere.

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

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

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

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

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

- patent infringement and other intellectual property claims, which would be costly and time consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from Profound's business;

- substantial damages for past infringement, including possible treble damages, which Profound may have to pay if a court determines that Profound's product candidates or technologies infringe a competitor's patent or other proprietary rights;

- a court prohibiting us from selling or licensing Profound's technologies unless the third party licenses Profound's patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and

- if a license is available from a third party, Profound may have to pay substantial royalties or lump sum payments or grant cross licenses to Profound's patents or other proprietary rights to obtain that license.

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

requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

Because some patent applications in the United States or other countries may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, Profound cannot be certain that others have not filed patent applications for technology covered by Profound's or its licensors' issued patents or Profound's pending applications or Profound's licensors' pending applications, or that Profound or its licensors were the first to invent the technology.

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

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

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

to Profound, if at all, which could have a material adverse effect on Profound's business, financial conditions and results of operations.

DIVIDENDS

Profound has not declared or paid any dividends since incorporation and has no present intention to declare or pay any dividends in the foreseeable future. Any decision to declare or pay dividends on the Common Shares will be made by the board of directors based upon Profound's earnings, financial requirements and other conditions existing at such future time.

DESCRIPTION OF CAPITAL STRUCTURE

The authorized capital of Profound consists of an unlimited number of Common Shares. As of the date of this AIF, 39,485,577 Common Shares were issued and outstanding. The holders of the Common Shares are entitled to one vote per share at all meetings of the shareholders of the Corporation.

In addition, as of the date of this AIF, Profound has outstanding (i) 3,164,143 Options under Profound's Share Option Plan; (ii) compensation options issued to the agents in connection with the initial public offering of Mira to purchase an additional 73,333 Common Shares, which expire on September 24, 2016; and (iii) compensation options issued to the agents in connection with the Qualifying Transaction to purchase an additional 576,235 Common Shares, which expire on June 4, 2017.

MARKET FOR SECURITIES

Profound's common shares are listed and posted for trading on the TSX-V under the trading symbol "PRN". The following table sets forth the price range per share and trading volume for the Common Shares on the TSX-V, for the period indicated[(1)]:

Month	High	Low	Volume
June 2015	1.69	1.31	1,542,352
July 2015	1.45	1.12	570,450
August 2015	1.28	0.74	193,150
September 2015	1.04	0.87	162,928
October 2015	1.10	0.84	90,415
November 2015	0.90	0.68	662,860
December 2015	0.99	0.67	2,038,177

Note:

(1) Trading of the common shares was halted by the TSX-V from November 5, 2014 through June 7, 2015 at the request of the Company in contemplation of the Qualifying Transaction.

PRIOR SALES

Stock Options

The following table summarizes the issuances of Options under Profound's Share Option Plan for the most recently completed financial year.

Date of Issuance	Exercise Price ($)	Number of Options Granted
September 8, 2015	$1.50	839,000
December 7, 2015	$1.50	80,000

Compensation Options

The following table summarizes the issuance of compensation options, issued to the agents in connection with the Qualifying Transaction, for the most recently completed financial year.

Date of Issuance	Exercise Price ($)	Number of Compensation Options Granted
June 4, 2015	$1.50	576,235

Share Option Plan

The Share Option Plan is administered by the board of directors of the Corporation which may, from time to time, delegate to a committee of the board of directors, all or any of the powers conferred to the board of directors under the Share Option Plan.

The Share Option Plan provides that the board of directors of the Corporation may from time to time, in its discretion, grant to directors, officers, employees, consultants and any other person or entity engaged to provide ongoing services to the Corporation non-transferable options to purchase Common Shares, provided that the maximum number of Common Shares reserved for issuance under the Share Option Plan shall not exceed 4,733,079 Common Shares. The exercise price of Options shall not be less than the lesser of: (i) the closing trading price of the Common Shares on the TSX-V on the date an option is granted; and (ii) the Market Price of the Common Shares on the date the Option is granted. For the purposes of the Share Option Plan, "**Market Price**" means the volume-weighted average price of the Common Shares on the stock exchange where the majority of trading volume and value of the Common Shares occurs, for the five trading days immediately preceding the relevant date on which the Market Price is to be determined. If the Common Shares are not listed for trading on a stock exchange, the Market Price shall be the fair market value of the Common Shares as determined by the board of directors of the Corporation.

The number of Common Shares reserved for issuance to any one person shall not exceed 5% and, to the insiders of the Corporation as a group, shall not exceed 10%, of the issued and outstanding Common Shares. Options granted under the Share Option Plan shall not result in the number of Common Shares issued to insiders of the Corporation as a group within any one-year period exceeding 10% of the issued and outstanding Common Shares, and issued to any one insider of the Corporation within any one-year period exceeding 5% of the issued and outstanding Common Shares. The Share Option Plan also includes an additional 'insider participation limit' which provides that the aggregate number of Common Shares issued to insiders of the Corporation within any 12-month period, or issuable to insiders of the Corporation at any time, under the Share Option Plan and any other security-based compensation arrangement of the Corporation, may not exceed 10% of the total number of issued and outstanding Common Shares of the Corporation at such time.

The Share Option Plan also provides that:

1. Common Shares that were the subject of options granted under the Share Option Plan that have been surrendered, lapsed, cancelled or terminated shall thereupon no longer be in reserve and may once again be subject to an option granted under the Share Option Plan;

2. the expiry date for an Option shall not in any circumstance be later than the lesser of the 10th anniversary of the date an Option is granted and the maximum period of time allowed by the TSX-V; and

3. subject to certain exceptions outlined in the Share Option Plan, all Options held by an officer or employee of the Corporation shall expire and terminate, and such employee optionee shall cease to be an eligible person, immediately upon the termination date of such optionee or the date of such optionee's death, disability or retirement.

The board of directors of Profound may amend the Share Option Plan from time to time without Shareholder approval, except for amendments relating to:

1. the maximum number of Common Shares reserved for issuance under the Share Option Plan;

2. a reduction in the exercise price for options held by insiders of the Corporation;

3. an extension to the term of any option held by insiders of the Corporation;

4. an increase in any limit on grants of options to insiders of the Corporation; and

5. any amendment that is not necessary or desirable to ensure continuing compliance with applicable laws or is not of a "housekeeping" nature.

As of the date of this AIF, there are 3,164,143 issued and outstanding Options under the Share Option Plan with a weighted-average exercise price of $0.95 and a weighted-average contractual life of 7.60 years.

Escrowed Securities

Pursuant to the TSX-V Corporate Finance Manual, certain of the Common Shares and Options were placed under escrow, and remain under escrow as set out in the table below. The escrow agent is TMX Equity Transfer Services. As a condition of the closing of the Private Placement, Genesys, BDC and each executive officer and director of Profound (each, a "**Significant Shareholder**") entered into lock-up agreements pursuant to which such parties agreed not to sell Common Shares or securities convertible or exchangeable into Common Shares (or announce any intention to do so) for a certain agreed period. Notwithstanding that some of the Common Shares and Options have been released from TSX-V escrow, holders of such securities may continue to be restricted from selling those securities in accordance with the terms of their respective lock-up agreements.

The following table summarizes the escrow conditions and contractual restrictions attaching to certain Common Shares and Options as of the filing of this AIF.

Designation of Class	Number of securities held in escrow or that are subject to a contractual restriction on transfer	Percentage of type of security
Common Shares subject to TSX escrow[(1)]	4,550,476	11.52%
Stock Options subject to TSX escrow[(2)]	521,036	16.47%
Common Shares subject to contractual restriction[(3)]	5,224,403	13.23%
Stock Options subject to contractual restriction[(4)]	694,714	21.96%

Notes:

(1) Certain Common Shares remain subject to escrow pursuant to the Corporate Finance Manual of the TSX-V. A total of 4,550,476 Common Shares will be released on the date that is 18 months following June 4, 2015, being December 4, 2016.

(2) Certain Options remain subject to escrow pursuant to pursuant to the Corporate Finance Manual of the TSX-V. A total of 521,036 Options will be released on the date that is 18 months following June 4, 2015, being December 4, 2016.

(3) Certain Common Shares remain subject to contractual restrictions under which certain persons will not sell Common Shares during an agreed period. A total of 5,224,403 Common Shares will be released on the date that is 18 months following June 4, 2015, being December 4, 2016.

(3) Certain Options remain subject to contractual restrictions under which certain persons will not sell Options during an agreed period. A total of 694,714 Options will be released on the date that is 18 months following June 4, 2015, being December 4, 2016.

DIRECTORS AND OFFICERS

Set out below is information with respect to the directors and officers of the Company as at the date hereof:

Name and Place of Residence	Positions with the Corporation and Date First Appointed to the Board (if applicable)	Principal Occupation for the Past 5 years
STEVEN PLYMALE Toronto, Ontario, Canada	Chief Executive Officer, Director June 4, 2015	Chief Executive Officer (since November 17, 2011) and Director (since January 23, 2009) of Profound Medical Inc.
DAMIAN LAMB[(1)(4)] Toronto, Ontario, Canada	Director June 4, 2015	Co-Founder of Genesys Capital (since April 2000)
JEAN-FRANÇOIS PARISEAU[(2)(4)(5)(6)(7)] Montreal, Quebec, Canada	Director June 4, 2015	Partner, BDC Capital Healthcare Fund (since July 2001)
WILLIAM CURRAN[(4)(5)(6)(7)] Rye, New York, USA	Director June 4, 2015	Director, Chairman of Audit Committee and member of Executive Committee of 3D Systems Corporation (since 2008); previously non-Executive Chairman and Director of Resonant Medical Inc.

Name and Place of Residence	Positions with the Corporation and Date First Appointed to the Board (if applicable)	Principal Occupation for the Past 5 years
ARUN MENAWAT[5][6][7] Oakville, Ontario, Canada	Director June 4, 2015	President and Chief Executive Officer of Novadaq Technologies Inc. (from April 2003 to July 2016)
JONATHAN ROSS GOODMAN[3][4][5] Montreal, Quebec, Canada	Director June 4, 2015	President and Chief Executive Officer of Knight (since Febraury 2014); Chief Executive Officer of Paladin Labs Inc. (since May 1995).
RASHED DEWAN Toronto, Ontario, Canada	Interim Chief Financial Officer November 17, 2015	Interim Chief Financial Officer of Profound Medical Inc. (since November 17, 2015); Corporate Controller of Profound Medical Inc. (since July 6, 2015).

Notes:
(1) The Common Shares are controlled and held by Genesys.
(2) The Common Shares are controlled and held by BDC.
(3) The Common Shares are controlled and held by Knight.
(4) Member of the Audit Committee.
(5) Member of the Compensation Committee.
(6) Member of the Corporate Governance and Nominating Committee.
(7) Member of the Executive Committee.

The term of each director of Profound will expire on the date of the next annual meeting of shareholders of Profound.

As of the date hereof, the directors and executive officers of Profound as a group beneficially own, directly or indirectly, or exercise control or direction, 21,972,651 of the issued and outstanding Common Shares, representing approximately 55.7% of the total votes attaching to all of the then outstanding voting securities of Profound before giving effect to the exercise of options held by such directors and executive officers (and assuming exercise of all options held by such individuals, 23,911,794 Common Shares representing approximately 57.7% of the total outstanding voting securities of Profound).

Director Biographies

Steven Plymale - Chief Executive Officer and Director - Mr. Plymale is a Director and the Chief Executive Officer of Profound and has over two decades of senior management experience in the medical device industry. Previously, he was the Vice President and General Manager of Excel-Tech Ltd., a division of Natus Medical Incorporated. Excel-Tech Ltd., formerly a public company, was acquired by Natus Medical Incorporated in November 2007 and designs, manufactures and sells a broad portfolio of diagnostic monitoring devices for neurology. Mr. Plymale led Excel-Tech Ltd. to profitability within 12 months of assuming the General Manager role as well as completing four acquisitions. Prior to this appointment, Mr. Plymale served in various senior management roles within several medical device companies such as ISG Technologies/Cedara Software, CryoCath Technology, Claron Technology and The Bluehaven Consulting group. He brings a unique blend of management skills and experience focusing on operations, quality and regulatory affairs and strategic planning.

Damian Lamb - Director - Mr. Lamb is co-Founder and Managing Director of Genesys Capital, a Canadian-based venture capital firm exclusively focused on the life sciences industry. He brings a unique experience base, blending skills in both the commercial and technical side of biotechnology. Since co-founding Genesys Capital in 2000, Mr. Lamb has been instrumental in raising over CDN$225 million in venture capital funds and has been involved in deploying over CDN$140 million across 28 investments. Other than Profound, he currently serves on the board of directors of Affinium Pharmaceuticals Inc. and the Centre for

Probe Development and Commercialization at McMaster University. He has served on the board of directors of Ionalytics Corporation (acquired by Thermo Electron Corp.), Millenium Biologix (acquired by Medtronic) and was Chairman of the board of directors of DELEX Therapeutics Inc. when it was sold to YM BioSciences. Mr. Lamb works closely with Genesys Capital investee companies to strategically position the companies to build value for shareholders. Prior to co-founding Genesys Capital, Mr. Lamb was an Investment Manager with MDS Capital Corp. He is a frequently invited speaker at biotechnology industry conferences. Mr. Lamb graduated from McMaster University, Faculty of Health Sciences, with an M.S. in Molecular Neurobiology and also holds a Master of Business Administration from Queen's University.

Jean-François Pariseau - Director - Mr. Pariseau joined BDC Capital in July 2001 and is a Partner in the Healthcare Fund. Prior to joining BDC, Mr. Pariseau was an investment manager with CDP Capital Technology Ventures. He brings over 20 years of transactional experience in private and in public companies, IPOs, M&A and has invested over $200m in biopharmaceutical and medical devices companies in North America. Mr. Pariseau holds a Bachelor of Science in Biotechnology from Université de Sherbrooke, a Master of Science in Biomedical Sciences from Université de Montréal, and an MBA from HEC Montréal. In addition to the Corporaiton, he currently sits on the Board of Directors of AngioChem Inc., Clementia Pharmaceuticals, Clearwater Clinical Inc. and Imagia Cybernetics Inc. He is also a board member of MedDev and an advisor to Hacking Health.

William Curran - Director - Mr. Curran has extensive experience in operations, finance and executive management. He was formerly President and Chief Executive Officer of Philips Electronics North America. He served in diverse functional and senior management positions during his career with Philips, including as Chief Financial Officer of Philips Medical Systems North America. Mr. Curran currently serves on the board of directors of 3D Systems, Inc., a provider of three-dimensional (3D) content-to-print solutions including 3D printers, print materials and on-demand custom parts services for professionals and consumers, and is Chairman of that company's Audit Committee and a member of the Executive Committee. He was non-executive Chairman and a Director of Resonant Medical before it was sold to Elekta A.B. in 2010. He has previously served as a director for companies in the medical, electronics, and software industries. Mr. Curran holds a Master of Business Administration from the Wharton School of the University of Pennsylvania.

Arun Menawat - Director - Mr. Menawat is the former President, Chief Executive Officer and Chairman of Novadaq Technologies Inc., a public company that develops and commercializes medical imaging and therapeutic devices for use in the operating room; he served in that role since April 2003. Previously, he held senior management positions at Cedara Software, Tenneco, Inc. and Hercules, Inc. His educational background includes a Bachelor of Science in Biology, University of District of Columbia, Washington, District of Columbia, and Ph.D. in Chemical Engineering, from the University of Maryland, College Park, MD, including graduate research in Biomedical Engineering from the National Institute of Health, Bethesda, MD. He also earned an Executive MBA from the J.L. Kellogg School of Management, Northwestern University, Evanston, Illinois.

Jonathan Ross Goodman - Director - Mr. Goodman is the co-founder of Knight Therapeutics Inc. Prior to his involvement with Knight, he was the co-founder, President and CEO of Paladin Labs Inc. which was acquired by Endo for $3.2 billion in 2014. Under his leadership, $1.50 invested in Paladin at its founding was worth $142, 19 years later. Prior to co-founding Paladin in 1995, Mr. Goodman was a consultant with Bain & Company and also worked in brand management for Procter & Gamble. Mr. Goodman holds a B.A. with Great Distinction from McGill University and the London School of Economics with 1st Class Honours. Additionally, Mr. Goodman holds an LL.B. and an M.B.A. from McGill University.

Corporate Cease Trade Orders or Bankruptcies

No director or executive officer of Profound is as at the date of this AIF, or has been, within the 10 years prior to the date hereof, a director, chief executive officer or chief financial officer of any company that:

(a) was the subject of a cease trade or similar order, or an order that denied such company access to any exemptions under applicable securities legislation for a period of more than 30 consecutive days that was issued while the proposed director was acting as director, chief executive officer or chief financial officer; or

(b) was the subject of a cease trade or similar order, or an order that denied such company access to any exemptions under applicable securities legislation for a period of more than 30 consecutive days that was issued after the proposed director ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

No director or executive officer of Profound is, or has been within the 10 years prior to the date of this AIF, a director or executive officer of any company that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold the assets of that person.

No director or executive officer of Profound is, or has been within the 10 years prior to the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold the assets of that person.

No director or executive officer of Profound or a shareholder holding a sufficient number of securities of Profound to affect materially the control of Profound has been subject to any penalties or sanctions imposed by a court relating to securities legislation or by any securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority or has been subject to any other penalties or sanctions imposed by a court or regulatory body that would be likely to be considered important to an investor in making an investment decision.

PROMOTER

There are no promoters of Profound.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

During the most recently completed fiscal year: (a) there were no legal proceedings to which Profound was a party, or by which any of its property was subject, which would be material to it and are not aware of any such proceedings being contemplated, (b) there were no penalties or sanctions imposed by a court relating to securities legislation, or other penalties or sanctions imposed by a court or regulatory body against it that would likely be considered important to a reasonable investor making an investment decision and (c) Profound has not entered into any settlement agreements before a court relating to securities legislation or with a securities regulatory authority.

INTEREST OF INFORMED PERSONS IN MATERIAL TRANSACTIONS

To the knowledge of management of the Corporation, other than in connection with the Qualified Transaction, there are no material interests, direct or indirect, by way of beneficial ownership of securities

or otherwise, of any informed persons of the Corporation, directors, proposed directors or officers of the Corporation, any shareholder who beneficially owns more than 10% of the common shares of the Corporation, or any associate or affiliate of these persons in any transaction since the commencement of the Corporation's last completed fiscal year or in any proposed transaction, which has materially affected or would materially affect the Corporation other than as disclosed herein or in the financial statements of the Corporation for the fiscal year ended December 31, 2015. Reference should be made to the notes to the audited financial statements for a more detailed description of any material transaction.

TRANSFER AGENT AND REGISTRAR

The Company's registrar and transfer agent is TMX Equity Transfer Services at its principal office in Toronto, Ontario.

MATERIAL CONTRACTS

Except for contracts entered into in the ordinary course of business, the following are the only material agreements of Profound:

- Sunnybrook License; and
- Knight Loan Agreement.

AUDIT COMMITTEE INFORMATION

Set out below is the information with respect to the audit committee of Profound's board of directors (the "**Audit Committee**"), including the composition of the Audit Committee, the text of the Audit Committee charter (attached hereto as **Schedule "A**"), and the fees paid to the external auditor.

The Audit Committee oversees the accounting and financial reporting practices and procedures of the Corporation's financial statements. The principal responsibilities of the Audit Committee include: (i) overseeing the quality and integrity of the internal controls and accounting procedures of the Corporation, including reviewing the Corporation's procedures for internal control with the Corporation's auditor and chief financial officer; (ii) reviewing and assessing the quality and integrity of the Corporation's annual and quarterly financial statements and related management discussion and analysis, as well as all other material continuous disclosure documents; (iii) monitoring compliance with legal and regulatory requirements related to financial reporting; (iv) reviewing and approving the engagement of the auditor of the Corporation and independent audit fees; (v) reviewing the qualifications, performance and independence of the auditor of the Corporation, considering the auditor's recommendations and managing the relationship with the auditor, including meeting with the auditor as required in connection with the audit services provided to the Corporation; (vi) assessing the Corporation's financial and accounting personnel; (vii) reviewing the Corporation's risk management procedures; (viii) reviewing any significant transactions outside of the Corporation's ordinary course of business and any pending litigation involving the Corporation; and (ix) examining improprieties or suspected improprieties with respect to accounting and other matters that affect financial reporting.

Composition of the Audit Committee

The following are the current members of the Audit Committee:

Name	Independence	Financial Literacy
DAMIAN LAMB	Independent	Financially Literate
WILLIAM CURRAN	Independent	Financially Literate
JEAN-FRANCOIS PARISEAU	Independent	Financially Literate
JONATHAN ROSS GOODMAN	Independent	Financially Literate

Relevant Education and Experience

The relevant education and experience of each member of the Audit Committee is provided above, under the heading "*Directors and Officers*". All of the Audit Committee members are independent of management of the Corporation as required by the TSX Venture Exchange and each member is financially literate in that each has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Corporation's financial statements.

Audit Committee Oversight

At no time since the commencement of the Corporation's most recently completed financial period was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the board of directors.

External Auditor Service Fees (By Category)

The aggregate fees billed by the Corporation's external auditor in the last two fiscal years as follows:

Financial Year Ending	Audit Fees[(1)]	Audit Related Fees[(2)]	Tax Fees[(3)]	All Other Fees[(4)]
December 31, 2015	$162,500	$10,122	$74,550	$192,807
December 31, 2014	$131,783	$6,223	$44,625	$145,079

Notes:

(1) Audit fees includes quarter reviews.

(2) Audit related fees includes out of pocket expenses.

(3) Tax fees includes fees related to annual tax returns and scientific research credit return along with tax advice.

(4) All other fees includes audit fees related to IFRS transition of prior periods and fees related to the qualified transaction.

The Corporation is relying on the exemption provided in Section 6.1 of NI 52-110 as the Corporation is a "venture issuer". As a result, the Corporation is exempt from the requirements of Part 3 (*Composition of Audit Committee*) and Part 5 (*Reporting Obligations*) of NI 52-110.

INTEREST OF EXPERTS

The consolidated financial statements of the Company for the fiscal year ended December 31, 2015 have been audited by PricewaterhouseCoopers LLP which is independent in accordance with the Rules of Professional Conduct as outlined by the CPA Ontario.

ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com. Additional information, including directors' and executive officers' remuneration and indebtedness and principal holders of the Company's securities is contained in the Company's management information circular for its June 21, 2016 annual meeting of shareholders. Additional financial information is available in the Company's financial statements and MD&A for its most recently completed financial year.

SCHEDULE "A"

PROFOUND MEDICAL CORP.

(THE "COMPANY")

AUDIT COMMITTEE CHARTER

PURPOSE

The Audit Committee (the "**Committee**") is a standing committee appointed by the Board of Directors (the "**Board**") of the Company. The Committee is established to assist the Board in fulfilling its oversight responsibilities with respect to the financial affairs of the Company, including responsibility to:

- oversee the integrity of the Company's financial statements and financial reporting process, audit process, internal accounting controls and procedures and compliance with related legal and accounting principles;
- oversee the qualifications and independence of the external auditor;
- oversee the work of the Company's financial management, internal audit function and external auditor in these areas; and
- provide an open avenue of communication between the external auditor, the internal auditors (if any), the Board and the Company's management.

In addition, the Committee shall prepare, if required, an audit committee report for inclusion in the proxy circular prepared in connection with the Company's annual meeting of shareholders, in accordance with applicable rules and regulations.

The function of the Committee is oversight. It is not the duty or responsibility of the Committee or its members (i) to plan or conduct audits, (ii) to determine that the Company's financial statements are complete and accurate and are in accordance with international financial reporting standards or (iii) to conduct other types of auditing or accounting reviews or similar procedures or investigations. The Committee members and its Chair are members of the Board, appointed to the Committee to provide broad oversight of the financial, risk and control-related activities of the Company, and are specifically not accountable or responsible for the day to day operation or performance of such activities. In particular, the member or members identified as audit committee financial experts, if any, shall not be accountable for giving professional opinions on the internal or external audit of the Company's financial information.

Management is responsible for the preparation, presentation and integrity of the Company's financial statements. Management is also responsible for ensuring that adequate systems of risk assessment and internal controls and procedures are designed and put in place in accordance with the accounting policies determined by the Committee to provide reasonable assurance that assets are safeguarded and transactions are properly authorized, recorded and reported and to assure the effectiveness and efficiency of operations, the reliability of financial reporting and compliance with accounting standards and with applicable laws and regulations. The internal auditor (if any) is responsible for monitoring and reporting on the adequacy and effectiveness of the system of internal controls. The external auditor is responsible for planning and carrying out an audit of the Company's annual financial statements in accordance with international financial reporting standards to provide reasonable assurance that, among other things, such financial statements are in accordance with international financial reporting standards.

PROCEDURES

1. Composition – The Committee shall be comprised of at least three members. None of the members of the Committee shall be an officer or employee of the Company or any of its subsidiaries and each member of the Committee shall be an "independent" director (as such term is defined from time to time under the requirements or guidelines for audit committee service under applicable securities laws and the rules of any stock exchange on which the Corporation's securities are listed for trading) and none of the members shall have participated in the preparation of the financial statements of the Company or any current subsidiaries of the Company at any time over the past three years.

   All members of the Committee must be "financially literate" (as that term is defined from time to time under the requirements or guidelines for audit committee service under securities laws and the rules of any stock exchange on which the Company's securities are listed for trading or, if it is not so defined, then as that term is interpreted by the Board of Directors in its business judgment) or must become financially literate within a reasonable period of time after their appointment to the Committee.

2. Appointment and Replacement of Committee Members – Any member of the Committee may be removed or replaced at any time by the Board and shall automatically cease to be a member of the Committee upon ceasing to be a director. The Board may fill vacancies on the Committee by appointing another director to the Committee. The Board shall fill any vacancy if the membership of the Committee is less than three directors or if the Committee does not have at least one member with accounting or related financial expertise. Whenever there is a vacancy on the Committee, the remaining members may exercise all its power as long as a quorum remains in office. Subject to the foregoing, the members of the Committee shall be appointed by the Board annually and each member of the Committee shall remain on the Committee until the next annual meeting of shareholders after his or her election or until his or her successor shall be duly elected and qualified.

3. Committee Chair – Unless a Chair of the Committee is designated by the full Board, the members of the Committee may designate a Chair by majority vote of the full Committee. The Chair of each Committee shall be responsible for leadership of the Committee, including preparing the agenda, presiding over the meetings, making committee assignments and reporting to the Board.

4. Conflicts of Interest – If a Committee member faces a potential or actual conflict of interest relating to a matter before the Committee, other than matters relating to the compensation of directors, that member shall be responsible for alerting the Committee Chair. If the Committee Chair faces a potential or actual conflict of interest, the Committee Chair shall advise the Chair of the Board. If the Committee Chair, or the Chair of the Board, as the case may be, concurs that a potential or actual conflict of interest exists, then the member faced with such conflict shall disclose to the Committee the member's interest and shall not participate in consideration of the matter and shall not vote on the matter.

5. Compensation of Committee Members – The members of the Committee shall be entitled to receive such remuneration for acting as members of the Committee as the Board may from time to time determine. No member of the Committee shall receive from the Company or any of its affiliates any compensation other than the fees to which he or she is entitled as a director or a member of the Committee of the Board or any of its affiliates.

6. Meetings of the Committee –

   (a) *Procedures for Meetings* – Subject to any applicable statutory or regulatory requirements, the articles and by-laws of the Company and the terms of this Charter, the time at which

and place where the meetings of the Committee shall be held and the calling of Committee meetings and the procedure in all things at such meetings shall be determined by the Committee, provided that it is understood that the Committee may meet in person and by telephone or electronic means that permit all persons participating in the meeting to communicate simultaneously and instantaneously and that the Committee may act by means of a written resolution signed by all members entitled to vote on the matter.

(b) *Calling of Meetings* – The Committee shall meet as often as it deems appropriate to discharge its responsibilities. Notice of the time and place of every meeting shall be given in writing, by any means of transmitted or recorded communication, including facsimile, telex, telegram or other electronic means that produces a written copy, to each member of the Committee at least 24 hours prior to the time fixed for such meeting. However, a member may in any manner waive a notice of a meeting. Attendance of a member at a meeting constitutes a waiver of notice of the meeting, except where a member attends a meeting for the express purpose of objecting to the transaction of any business on the grounds that the meeting is not lawfully called. Whenever practicable, the agenda for the meeting and the meeting materials shall be provided to members before the Committee meeting in sufficient time to provide adequate opportunity for their review.

(c) *Quorum* – A majority of the members of the Committee constitute a quorum for the transaction of Committee business.

(d) *Chair of Meetings* – If the Chair of the Committee is not present at any meeting of the Committee, one of the other members of the Committee who is present shall be chosen by the Committee to preside at the meeting.

(e) *Secretary of Meeting* – The Chair of each Committee shall designate a person who need not be a member of the Committee to act as secretary or, if the Chair of the Committee fails to designate such a person, the secretary of the Company shall be secretary of the Committee. The agenda of each Committee meeting will be prepared by the secretary of the Committee and, whenever reasonably practicable, circulated to each member prior to each meeting.

(f) *Separate Executive Meetings* – The Committee shall meet at least once every year, and more often as warranted, with the Chief Executive Officer and such other officers of the Company as the Committee may determine to discuss any matters that the Committee or such individuals believes should be discussed privately.

(g) *Minutes* – Minutes of the proceedings of each Committee meeting shall be kept in minute books provided for that purpose. The minutes of Committee meetings shall accurately record the discussions of and decisions made by the Committee, including all recommendations to be made by the Committee to the Board and shall be distributed to all Committee members.

AUDIT RESPONSIBILITIES OF THE COMMITTEE

Fundamental Powers

7. Subject to any applicable statutory or regulatory requirements, the articles and by-laws of the Corporation and the terms of this Charter, the Committee shall have the following fundamental powers in addition to any powers set out in this Charter or otherwise specified by the Board from time to time:

(a) *Access* – The Committee is entitled to full access to all books, records, facilities, and personnel of the Company and its subsidiaries. The Committee may require such officers, directors and employees of the Company and its subsidiaries and others as it may see fit from time to time to provide any information about the Company and its subsidiaries it may deem appropriate and to attend and assist at meetings of the Committee.

(b) *Delegation* – The Committee may delegate from time to time to any person or committee of persons any of the Committee's responsibilities that lawfully may be delegated.

(c) *Adoption of Policies and Procedures* – The Committee may adopt policies and procedures for carrying out its responsibilities.

Selection and Oversight of the External Auditor

8. The external auditor is ultimately accountable to the Committee and the Board as the representatives of the shareholders of the Company and shall report directly to the Committee and the Committee shall so instruct the external auditor. The Committee shall evaluate the performance of the external auditor and make recommendations to the Board on the appointment, reappointment or replacement of the external auditor of the Company to be proposed in the Company's proxy circular for shareholder approval and shall have authority to terminate the external auditor. If a change in external auditor is proposed, the Committee shall review the reasons for the change and any other significant issues related to the change, including the response of the incumbent auditors, and enquire as to the qualifications of the proposed auditors before making its recommendation to the Board.

9. The Committee shall approve in advance the terms of engagement and the compensation to be paid by the Company to the external auditor with respect to the conduct of the annual audit. The Committee may approve policies and procedures for the pre-approval of services to be rendered by the external auditor, which policies and procedures shall include reasonable detail with respect to the services covered. All non-audit services to be provided to the Company or any of its affiliates by the external auditor or any of its affiliates which are not covered by pre-approval policies and procedures approved by the Committee shall be subject to pre-approval by the Committee.

10. The Committee shall review the independence of the external auditor and shall make recommendations to the Board on appropriate actions to be taken which the Committee deems necessary to protect and enhance the independence of the external auditor. In connection with such review, the Committee shall:

(a) actively engage in a dialogue with the external auditor about all relationships or services that may impact the objectivity and independence of the external auditor;

(b) require that the external auditor submit to it on a periodic basis and, at least annually, a formal written statement delineating all relationships between the Company and its subsidiaries, on the one hand, and the external auditor and its affiliates, on the other hand;

(c) consider whether there should be a regular rotation of the audit partners responsible for performing the audit and/or of the external audit firm itself; and

(d) consider the auditor independence standards promulgated by applicable auditing regulatory and professional bodies.

11. The Committee shall consider whether to prohibit the external auditor and its affiliates from providing certain non-audit services to the Company and its affiliates.

12. The Committee shall establish and monitor clear policies for the hiring by the Company of employees or former employees of the external auditor.

13. The Committee shall require the external auditor to provide to the Committee, and the Committee shall review and discuss with the external auditor, all reports which the external auditor is required to provide to the Committee or the Board under rules, policies or practices of professional or regulatory bodies applicable to the external auditor, and any other reports which the Committee may require.

14. The Committee is responsible for resolving disagreements between management and the external auditor regarding financial reporting.

Appointment and Oversight of Internal Auditors (If Any)

15. The appointment, authority, budget, replacement or dismissal of the internal auditors, if any, shall be subject to prior review and approval by the Committee. When any such internal audit function is performed by employees of the Company or its subsidiaries, the Committee may delegate responsibility for approving the employment, term of employment, compensation and termination of employees engaged in such function other than the head of the Company's internal audit function.

16. The Committee shall obtain from the internal auditors (if any), and shall review, summaries of the significant reports to management prepared by any such internal auditors (or the actual reports if requested by the Committee) and management's responses to such reports.

17. The Committee shall, as it deems necessary, communicate with the internal auditors (if any) with respect to their reports and recommendations, the extent to which prior recommendations have been implemented and any other matters that such internal auditors bring to the attention of the Committee. The head of the internal audit function (if one exists) shall have unrestricted access to the Committee.

18. The Committee shall, annually or more frequently as it deems necessary, evaluate the internal auditors (if any), including their activities, organizational structure and qualifications and effectiveness.

Oversight and Monitoring of Audits

19. The Committee shall review with the external auditor, the internal auditors (if any) and management the audit function generally, the objectives, staffing, locations, co-ordination, reliance upon management and internal audit and general audit approach and scope of proposed audits of the financial statements of the Company and its subsidiaries, the overall audit plans, the responsibilities of management, the internal auditors (if any) and the external auditor, the audit procedures to be used and the timing and estimated budgets of the audits.

20. The Committee shall meet periodically as it deems necessary with the internal auditor (if any) to discuss the progress of their activities and any significant findings stemming from internal audits and any difficulties or disputes that arise with management and the adequacy of management's responses in correcting audit-related deficiencies.

21. The Committee shall discuss with the external auditor any difficulties or disputes that arose with management or the internal auditors (if any) during the course of the audit, any restrictions on the scope of activities or access to requested information and the adequacy of management's responses in correcting audit-related deficiencies.

22. The Committee shall review with management the results of internal (if any) and external audits.

23. The Committee shall take such other reasonable steps as it may deem necessary to satisfy itself that the audit was conducted in a manner consistent with all applicable legal requirements and auditing standards of applicable professional or regulatory bodies.

Oversight and Review of Accounting Principles and Practices

24. The Committee shall, as it deems necessary, oversee, review and discuss with management, the external auditor and the internal auditors (if any):

    (a) the quality, appropriateness and acceptability of the Company's accounting principles and practices and that of its subsidiaries used in its financial reporting, changes in the Company's accounting principles or practices and that of its subsidiaries and the application of particular accounting principles and disclosure practices by management to new transactions or events;

    (b) all significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including the effects of alternative methods within international financial reporting standards on the financial statements and any "second opinions" sought by management from any other auditor firm or advisor with respect to the accounting treatment of a particular item;

    (c) disagreements between management and the external auditor or the internal auditors (if any) regarding the application of any accounting principles or practices;

    (d) any material change to the Company's auditing and accounting principles and practices or that of its subsidiaries as recommended by management, the external auditor or the internal auditors (if any) or which may result from proposed changes to applicable international financial reporting standards;

    (e) the effect of regulatory and accounting initiatives on the Company's financial statements and other financial disclosures;

    (f) any reserves, accruals, provisions, estimates or management programs and policies, including factors that affect asset and liability carrying values and the timing of revenue and expense recognition, that may have a material effect upon the financial statements of the Company;

    (g) the use of special purpose entities and the business purpose and economic effect of off-balance sheet transactions, arrangements, obligations, guarantees and other relationships of the Company or its subsidiaries and their impact on the financial results of the Company;

    (h) any legal matter, claim or contingency that could have a significant impact on the financial statements, the Company's compliance policies and that of its subsidiaries and any material reports, inquiries or other correspondence received from regulators or governmental agencies and the manner in which any such legal matter, claim or contingency has been disclosed in the Company's financial statements;

    (i) the treatment for financial reporting purposes of any significant transactions which are not a normal part of the Company's operations or those of its subsidiaries;

    (j) the use of any "pro forma" or "adjusted" information not in accordance with generally accepted accounting principles; and

(k) management's determination of goodwill impairment, if any, as required by applicable accounting standards.

25. The Committee will review and resolve disagreements between management and the external auditor regarding financial reporting or the application of any accounting principles or practices.

Oversight and Monitoring of Internal Controls

26. The Committee shall, as it deems necessary, exercise oversight of, review and discuss with management, the external auditor and the internal auditors (if any):

(a) the adequacy and effectiveness of the Company's internal accounting and financial controls and also of its subsidiaries and the recommendations of management, the external auditor and the internal auditors (if any) for the improvement of accounting practices and internal controls;

(b) any significant deficiencies or material weaknesses in the internal control environment, including with respect to computerized information system controls and security;

(c) any fraud that involves personnel who have a significant role in the Company's internal control over financial reporting or that of its subsidiaries; and

(d) management's compliance with the Company's processes, procedures and internal controls.

Communications with Others

27. The Committee shall establish and monitor procedures for the receipt and treatment of complaints received by the Company and its subsidiaries regarding accounting, internal accounting controls or audit matters and the anonymous submission by employees of concerns regarding questionable accounting or auditing matters and shall review periodically with management and the internal auditors (if any) these procedures and any significant complaints received.

Oversight and Monitoring of the Company's Financial Disclosures

28. The Committee shall:

(a) review with the external auditor and with management and shall recommend to the Board for approval the financial statements and the notes and Management's Discussion and Analysis (if any) accompanying such financial statements, the Company's annual report and any financial information of the Company contained in any prospectus or information circular of the Company; and

(b) review, as necessary, with the external auditor and with management each set of interim financial statements and the notes and Management's Discussion and Analysis (if any) accompanying such financial statements and any other disclosure documents or regulatory filings of the Company containing or accompanying financial information of the Company.

Such reviews shall be conducted prior to the release of any summary of the financial results or the filing of such reports with applicable regulators.

29. The Committee shall review the disclosure with respect to its pre-approval of audit and non-audit services provided by the external auditor.

Oversight of Finance and Financial Risk Matters

30. Appointments of the key financial executives involved in the financial reporting process of the Company, including the Chief Financial Officer, shall require the prior review of the Committee.

31. The Committee shall receive and review:

    (a) periodic reports on compliance with requirements regarding statutory deductions and remittances and, in the event of any non-compliance, the nature and extent of the non-compliance, the reasons therefor and management's plan and timetable to correct any deficiencies;

    (b) material policies and practices of the Company and its subsidiaries respecting cash management and material financing strategies or policies or proposed financing arrangements and objectives of the Company and its subsidiaries; and

    (c) material tax policies and tax planning initiatives, tax payments and reporting and any pending tax audits or assessments.

32. The Committee shall meet periodically with management to review and discuss the Company's major financial risk exposures and the policy steps that management has taken to monitor and control such exposures, including the use of financial derivatives and hedging activities and the Company's insurance programs.

33. The Committee shall receive and review the financial statements and other financial information of material subsidiaries of the Company and any auditor recommendations concerning such subsidiaries.

34. The Committee shall meet with management to review the process and systems in place for ensuring the reliability of public disclosure documents that contain audited and unaudited financial information and their effectiveness.

Additional Responsibilities

35. The Committee shall review and make recommendations to the Board concerning the financial structure, condition and strategy of the Company and its subsidiaries, including with respect to annual budgets, long-term financial plans, corporate borrowings, investments, capital expenditures, long term commitments and the issuance and/or repurchase of shares.

36. The Committee shall review and/or approve any other matter specifically delegated to the Committee by the Board and undertake on behalf of the Board such other activities as may be necessary or desirable to assist the Board in fulfilling its oversight responsibilities with respect to financial reporting and the Company's financial obligations.

THE CHARTER

The Committee shall review and reassess the adequacy of this Charter periodically as it deems appropriate and recommend changes to the Board. The performance of the Committee shall be evaluated with reference to this Charter annually or otherwise periodically as deemed appropriate by the Board.