

**PROFOUND MEDICAL CORP**

**ANNUAL INFORMATION FORM**

**FOR THE YEAR ENDED DECEMBER 31, 2016**

**March 28, 2017**

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## 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 as issued by the International Accounting Standards Board (“IFRS”) 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. The information contained herein is dated as of December 31, 2016 (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 this 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](http://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.

<b>3D</b>	means three-dimensional.
<b>ablation</b>	means to remove or destroy tissue.
<b>ADT</b>	means androgen deprivation therapy.
<b>BDC</b>	means BDC Capital Inc.
<b>BPH</b>	means benign prostatic hyperplasia, a condition where the prostate gland is enlarged and not cancerous.
<b>brachytherapy</b>	means the precise placement of short-range radiation-sources (radioisotopes) directly at the site of the cancerous tumour.
<b>CE Mark</b>	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.
<b>CMDCAS</b>	means Canadian Medical Devices Conformity Assessment System.
<b>Common Shares</b>	means the common shares in the capital of Profound.
<b>company</b>	unless specifically indicated otherwise, means a corporation, incorporated association or organization, body corporate, partnership, trust, association or other entity other than an individual.
<b>cryotherapy</b>	means a therapy that uses extreme temperature to destroy benign and malignant tissue by crystallizing.
<b>de novo submission</b>	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 <i>United States Federal Food, Drug and Cosmetic Act</i> .

<b>EBRT</b>	means External Beam Radiation Therapy.
<b>European Union</b>	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.
<b>FDA</b>	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.
<b>Genesys</b>	means Genesys Ventures II LP.
<b>Gleason score</b>	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.
<b>HDR</b>	means High Dose Radiation.
<b>HIFU</b>	means High Intensity Focus Ultrasound.
<b>HMO</b>	means Health Maintenance Organizations.
<b>IFRS</b>	means the International Financial Reporting Standards issued by the International Accounting Standards Board.
<b>IDE</b>	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.
<b>Knight</b>	means Knight Therapeutics Inc.
<b>Knight Loan Agreement</b>	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.
<b>MCO</b>	means Managed Care Organizations.
<b>Medical Device License</b>	means the license for marketing approval of a medical device in Canada.
<b>Mira</b>	means Mira IV Acquisition Corp., a corporation incorporated under the OBCA.
<b>Mira Subco</b>	means Mira IV Subco Inc., a wholly-owned subsidiary of Mira incorporated under the OBCA.

<b>MR</b>	means magnetic resonance.
<b>MRI</b>	means magnetic resonance imaging.
<b>OBCA</b>	means the <i>Business Corporations Act</i> (Ontario), as amended, together with all regulations promulgated pursuant thereto.
<b>Options</b>	means options issued under the Share Option Plan.
<b>QSR</b>	means Quality System Regulations.
<b>Person</b>	means a company or individual.
<b>Pivotal Trial</b>	means a clinical trial or study intended to provide evidence and reasonable assurance of safety and efficacy for a device marketing approval.
<b>PMA</b>	means the Pre-Market Approval application process for marketing approval in the United States.
<b>PMI</b>	means Profound Medical Inc.
<b>Private Placement</b>	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.
<b>Promoter</b>	means a promoter as prescribed by applicable Securities Laws.
<b>Qualifying Transaction</b>	has the meaning given under the heading “ <i>Corporate Structure – Name, Address and Incorporation</i> ”.
<b>radical prostatectomy</b>	means a surgical procedure that involves the removal of the whole prostate gland.
<b>Securities Laws</b>	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.
<b>Share Option Plan</b>	means the share option plan of Profound dated June 4, 2015, as amended.
<b>Shareholder</b>	means a holder of a Common Share.
<b>Subscription Receipts</b>	means the subscription receipts issued by Profound in connection with the Private Placement, with each such subscription receipt being exchangeable for one Common Share.
<b>Sunnybrook</b>	means the Sunnybrook Health Sciences Centre.
<b>Sunnybrook License</b>	has the meaning given under the heading “ <i>Proprietary Protection</i> ”.
<b>TSX-V</b>	means the TSX Venture Exchange.
<b>TULSA</b>	means Transurethral ULtraSound Ablation.
<b>TULSA-PRO</b>	means the Transurethral ULtraSound Ablation device.

<b>TURP</b>	means a transurethral resection of the prostate, a surgical procedure that removes portions of the prostate gland through the penis.
<b>UA</b>	means ultrasound applicator.
<b>U.S. PTO</b>	means the United States Patent and Trademark Office.
<b>urinary rectal fistula</b>	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**

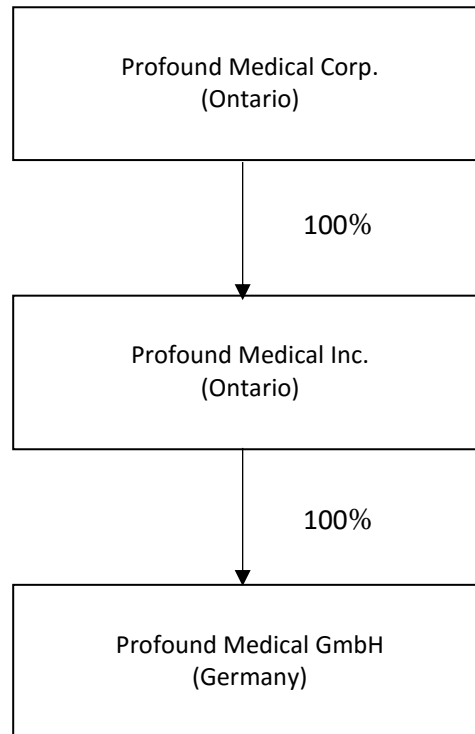
Profound operates its business through its wholly-owned principal subsidiaries, Profound Medical Inc. and Profound Medical GmbH.

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:

#### 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.

## 2016

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<sup>®</sup> 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<sup>®</sup> system.

On April 11, 2016, Profound announced that it has affixed the CE mark to the TULSA-PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system in ablating tissue in patients with localized prostate cancer.

On June 20, 2016, Profound announced the first sale of the TULSA-PRO<sup>®</sup> 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<sup>®</sup> system in Germany to University Hospital of Cologne, also resulting from the collaboration with Royal Philips.

On August 15, 2016, Profound announced the appointment of Arun Menawat, Ph.D. as its new Chief Executive Officer, the transition of its former Chief Executive Officer, Steven Plymale, to President and Chief Operating Officer of Profound and the promotion of Rashed Dewan from Corporate Controller to Vice President, Finance.

On September 22, 2016, the Company announced that the first patient had been treated in the TULSA-PRO<sup>®</sup> Ablation Clinical Trial (the "**TACT Pivotal Trial**"), designed to further evaluate the safety and efficacy of TULSA-PRO<sup>®</sup> to ablate prostate tissue in patients with localized, organ-confined prostate cancer, at Vanderbilt University Medical Center in Nashville, TN.

On October 5, 2016, the Company announced that it had received Frost & Sullivan's 2016 European Prostate Ablation System New Product Innovation Award for its TULSA-PRO<sup>®</sup> system.

On October 17, 2016, Profound announced that it had entered into an agreement with a syndicate of underwriters led by GMP Securities L.P., pursuant to which the underwriters have agreed to purchase, on a bought deal basis, 15,820,000 Common Shares of Profound at a price of \$1.10 per Common Share for aggregate gross proceeds to Profound of \$17,402,000 (the "**Bought Deal**"). The Bought Deal closed on November 14, 2016.

### Recent Developments

On January 17, 2017, Profound announced the appointment of Kenneth Galbraith to the board of directors of Profound and the resignation as director of Steven Plymale, however Steven Plymale remained as President and Chief Operating Officer.

On January 26, 2017, Profound announced the approval at a special meeting of shareholders of Profound, of the Amended and Restated Share Option Plan and the option grant to Arun Menawat of an option to purchase 1,417,583 Common Shares for an exercise price of \$1.10 per share.

On March 3, 2017, Profound announced the resignation of Jonathan Goodman and the appointment of Samira Sakhia, to the board of directors of Profound.

On March 9, 2017, Profound announced that its Common Shares will be eligible for trading on the OTCQX<sup>®</sup> Best Market under the ticker symbol "PRFMF" as of March 13, 2017.

On March 24, 2017, Profound announced the resignation of Steven Plymale as President and Chief Operating Officer.

### **Significant Acquisitions**

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<sup>®</sup> system, its transurethral ultrasound device for ablation of prostate tissue.

### Principal Product

Profound is focused on the commercialization of the TULSA-PRO<sup>®</sup> system, its transurethral ultrasound device for ablation of prostate tissue. Profound has received IDE approval from the FDA to conduct the TACT pivotal clinical trial of the TULSA-PRO<sup>®</sup> 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 TACT Pivotal 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<sup>®</sup> system in a prostate cancer patient population will have a well-tolerated safety profile with lower rates of procedure-related complications.

### Product Description

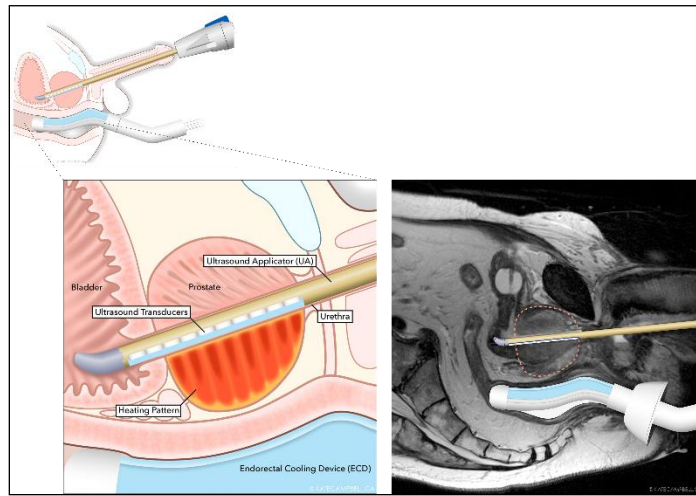
The TULSA-PRO<sup>®</sup> system is comprised of two categories of components: disposables and the capital equipment used in conjunction with a customer's magnetic resonance imaging (MRI) scanner.

#### *MRI Scanner*

Profound has designed the TULSA-PRO<sup>®</sup> system to be capable of integration with many major MRI scanners currently deployed in hospitals and treatment facilities. That integration allows the TULSA-PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system. The UA produces directional 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<sup>0</sup> 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<sup>®</sup> system is capable of adjusting automatically between higher or lower frequencies of ultrasonic beams to target different prostate shapes and sizes.



*Source: Profound Medical Corp.*

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  $\pm 1$  millimetre. There are ten planar transducers in the UA, but not all of these ultrasound elements have to be turned on. The system can determine which elements to activate based on the size of the prostate gland. This precision is intended to enable the TULSA-PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 through 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 cool and 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  $\pm 1$  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<sup>®</sup> 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 one of 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 the application is currently subject to ongoing review by 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 TACT 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 TACT 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. The first patient treatment in the TACT Pivotal Trial was completed on September 22, 2016.

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 Trial, 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 TACT 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 TACT 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
<b>Regulatory Body</b>	FDA	Health Canada	Notified Body
<b>Pre-Market Clearance or Approval Path</b>	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
<b>Phase I Trial</b>	Completed	Completed	Completed
<b>TACT Pivotal Trial</b>	Trial commenced September 2016	N/A	
<b>Clinical Study Population for the market clearance</b>	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<sup>®</sup> 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 a 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;
- 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;
- 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, pediatric 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 License 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 License is issued to the device manufacturer, provided the requirements of the MDR are met.

The Canadian Medical Device Conformity Assessment System (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<sup>®</sup> system under a certified ISO 13485 Quality Management System.

#### *Regulatory Update*

The TULSA-PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system is a precise method to ablate prostate tissue, both malignant and benign, while providing a favourable safety 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<sup>®</sup> system in Europe and in other CE Mark jurisdictions. Profound completed its first commercial sale of the TULSA-PRO<sup>®</sup> system in the same month. The TULSA-PRO<sup>®</sup> 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<sup>®</sup> system will be issued sometime in the second quarter of 2017, although there can be no assurance in this regard.

Profound has obtained IDE approval from the FDA for the TACT Pivotal Trial for use of the device in ablation of prostate tissue. All clinical sites have been identified for the TACT Pivotal Trial, which is expected to commence in August 2016. The TACT 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<sup>®</sup> system for use in the ablation of prostate tissue.

Approval of an IDE by the FDA and completion of the TACT 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 TACT 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, Canada and United States, cost-awareness is spreading to providers as well.

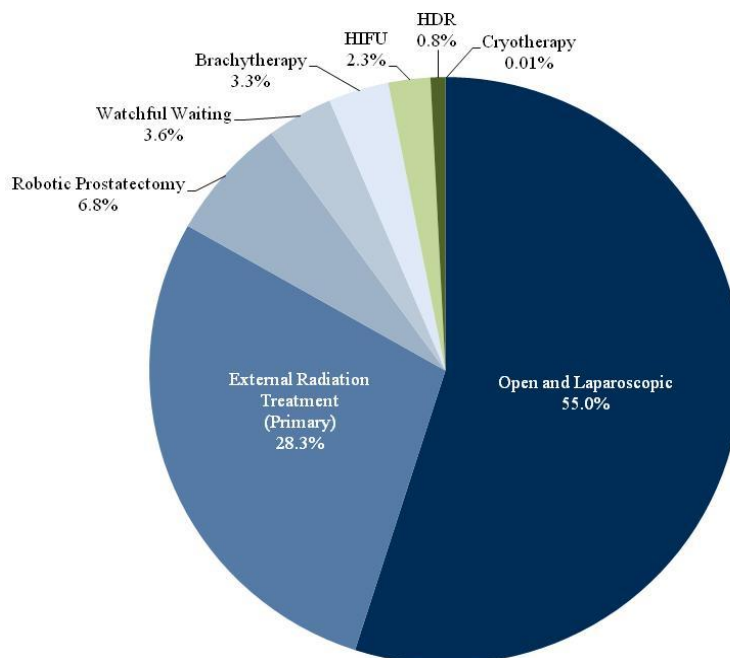
Profound believes that the TULSA-PRO<sup>®</sup> system performance will continue to demonstrate post-procedure complications similar to those shown in the 30 patient Phase I Clinical Trial and that the device will eventually stand to benefit from each of these four drivers for the prostate cancer treatment 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<sup>®</sup> 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<sup>®</sup> system may be comparable to those of commonly used procedures. Profound believes that the TULSA-PRO<sup>®</sup> 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
<b>Radical Prostatectomy (includes robot-assist)</b>	<input type="checkbox"/> Certainty of removing whole gland <input type="checkbox"/> Good outcomes data	<input type="checkbox"/> Invasive <input type="checkbox"/> Hospital stay required <input type="checkbox"/> Potential for post-surgical complications <input type="checkbox"/> High cost
<b>EBRT</b>	<input type="checkbox"/> Non-invasive	<input type="checkbox"/> Collateral tissue damage <input type="checkbox"/> Multiple visits required <input type="checkbox"/> Recurrence <input type="checkbox"/> High cost
<b>Brachytherapy and High Dose Radiation</b>	<input type="checkbox"/> Minimally invasive <input type="checkbox"/> Low cost <input type="checkbox"/> Image-guided	<input type="checkbox"/> Seed migration <input type="checkbox"/> Collateral damage <input type="checkbox"/> Potential for complications <input type="checkbox"/> Recurrence
<b>Cryotherapy</b>	<input type="checkbox"/> Minimally invasive <input type="checkbox"/> Image-guided	<input type="checkbox"/> High rates of collateral tissue damage <input type="checkbox"/> Potential for complications
<b>HIFU</b>	<input type="checkbox"/> Minimally invasive <input type="checkbox"/> Image-guided <input type="checkbox"/> Good outcomes data	<input type="checkbox"/> Trans-rectal delivery can result in complications <input type="checkbox"/> Prostate volume must be less than 40 cubic centimetres <input type="checkbox"/> Significant capital equipment cost <input type="checkbox"/> Potential for issues arising out of overheating of tissue
<b>Watchful Waiting (includes active surveillance)</b>	<input type="checkbox"/> Low cost <input type="checkbox"/> Non-invasive	<input type="checkbox"/> Multiple visits required <input type="checkbox"/> Treatment delay resulting in more aggressive treatment
<b>Proton Beam Therapy</b>	<input type="checkbox"/> Adjustable energy deposition depth	<input type="checkbox"/> Very costly equipment <input type="checkbox"/> Limited data to support claims

Profound believes that use of the TULSA-PRO<sup>®</sup> 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;

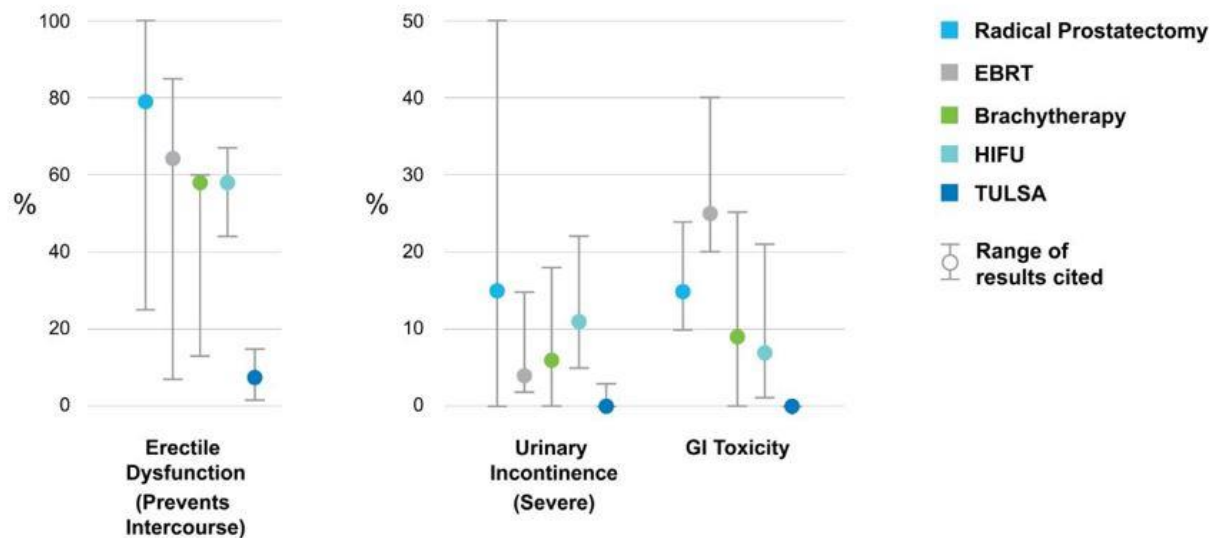
- Guided by real-time MRI with temperature (thermometry) feedback; and
- Designed to be compatible with leading MRI platforms.

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 several published studies, 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> system, Profound may continue to develop intellectual property with respect to improvements on the above patents and application.

## RISK FACTORS

See the “Risk Factors” section of Profound’s management discussion and analysis for the year ended December 31, 2016, which are incorporated herein by reference and available on SEDAR at [www.sedar.com](http://www.sedar.com).

## 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, 55,319,639 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) 6,087,422 Options under Profound’s Share Option Plan; and (ii) 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<sup>(1)</sup>:

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
January 2016	\$0.98	\$0.75	532,637
February 2016	\$1.44	\$0.91	336,807



Month	High	Low	Volume
March 2016	\$1.43	\$1.05	172,411
April 2016	\$1.59	\$1.09	1,117,638
May 2016	\$1.50	\$1.16	209,116

**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
May 4, 2016	\$1.46	30,000
July 9, 2016	\$1.35	50,000
August 22, 2016	\$1.46	934,055
September 15, 2016	\$1.35	82,500
November 24, 2016	\$1.10	554,141
December 21, 2016	\$1.10	<sup>1</sup> 1,417,583

**Note:**

- (1) The share options issued were conditional upon receiving shareholders' approval on January 26, 2017.

### Common Shares

The following table summarizes the issuance of Common Shares for the most recently completed financial year.

Date of Issuance	Price per Common Share (\$)	Number of Common Shares Issued
July 26, 2016	\$0.30	12,250
November 16, 2016	\$1.10	15,820,000

### 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 was originally adopted by the

board of directors of the Corporation on June 4, 2015, and then amended and restated on December 8, 2016. The text of the Share Option Plan is set out as Appendix “A” to the Management Information Circular of the Corporation dated December 21, 2016.

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 7,189,725 Common Shares. If Profound obtains a listing on the Toronto Stock Exchange for the Common Shares, the Share Option Plan will automatically become a “rolling” plan, such that the maximum number of Common Shares reserved for issuance under the Share Option Plan shall be equal to a number that is 13% of the issued and outstanding shares in the capital of the Company at the time of any Option grant.

The exercise price of Options shall not be less than 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 Options granted to any one person, within any one-year period, shall not exceed 5% of the issued and outstanding Common Shares. Subject to this limitation, the Share Option Plan does not limit the number of Options that may be granted to any insiders of the Corporation, from time to 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 10<sup>th</sup> 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.

Subject to the limitations set out in the Share Option Plan, and any further shareholder approvals required by the TSX-V, the board of directors of the Corporation may amend the Share Option Plan from time to time.

As of the date of this AIF, there are 6,093,672 issued and outstanding Options under the Share Option Plan with a weighted-average exercise price of \$1.06 and a weighted-average contractual life of 8.21 years.

## DIRECTORS AND OFFICERS

Set out below is information with respect to the directors and officers of the Company as of December 31, 2016:

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 <sup>(1)(4)</sup> Toronto, Ontario, Canada	Director June 4, 2015	Co-Founder of Genesys Capital (since April 2000)
JEAN-FRANÇOIS PARISEAU <sup>(2)(4)</sup> (5)(6)(7) Montreal, Quebec, Canada	Director June 4, 2015	Partner, BDC Capital Healthcare Fund (since July 2001)
WILLIAM CURRAN <sup>(4)(5)(6)(7)</sup> 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.
ARUN MENAWAT <sup>(5)(6)(7)</sup> 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 <sup>(3)(4)(5)</sup> Montreal, Quebec, Canada	Director June 4, 2015	President and Chief Executive Officer of Knight (since February 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 of this AIF, Jonathan Goodman has resigned as a director of Profound, Steven Plymale has resigned as a director and officer of Profound, and Kenneth Galbraith and Samira Sakhia have been appointed to the board of directors 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, 25,269,936 of the issued and outstanding Common Shares, representing approximately 45.7% 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, 31,363,608 Common Shares representing approximately 56.7% of the total outstanding voting securities of Profound).

### **Director Biographies**

*Arun Menawat* – Chief Executive Officer and Director – Mr. Menawat has an accomplished history of executive leadership success in the healthcare industry. Dr. Menawat served as the President and CEO 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.

*Steven Plymale* – President 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 Corporation, 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.

*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.

#### New Directors

*Samira Sakhia* – Director – Prior to Knight, Ms. Sakhia served as the CFO at Paladin from 2001 to 2015. At Paladin, Ms. Sakhia was responsible for the finance, operations, human resources and investor relations functions. During her employment with Paladin, Ms. Sakhia was instrumental in executing in-licensing and acquisition transactions of Canadian and international pharmaceutical products and businesses. In addition, Ms. Sakhia led several M&A and strategic lending transactions as well as equity rounds on the TSX and completed the sale of Paladin to Endo International for over \$3 billion. Ms. Sakhia holds an MBA and a Bachelors of Commerce degree from McGill University and is also a Chartered Professional Accountant.

*Kenneth Galbraith* – Director – Mr. Galbraith is an accomplished life sciences industry veteran with over 25 years of experience acting as an executive, director, investor and advisor to companies in the biotechnology, medical device, pharmaceutical and healthcare sectors. Mr. Galbraith joined Ventures West as a General Partner in 2007 and led the firm's biotechnology practice prior to founding Five Corners Capital in 2013 to continue management of the Ventures West investment portfolio. Previously, he served as the Chairman and Interim CEO of AnorMED until its sale to Genzyme Corp. in a cash transaction worth almost US\$600 million. Starting his career in the life sciences sector in 1987, Mr. Galbraith spent 13 years in senior management with QLT Inc., retiring in 2000 from his position as Executive VP and CFO when QLT's market capitalization exceeded US\$5 billion. He has served on the Board of Directors of several public and private companies, including Angiotech Pharmaceuticals, Arbutus Biopharma and Cardiome Pharma. Mr. Galbraith currently serves on the Board of Directors of MacroGenics and Prometic Life Sciences. Mr. Galbraith earned a Bachelor of Commerce (Honors) degree from the University of British Columbia in 1985 and was appointed a Fellow of the Chartered Accountants of BC in 2013.

#### **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, 2016. 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
SAMIRA SAKHIA	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 (excluding out of pocket expenses) by the Corporation's external auditor in the last two fiscal years as follows:

<b>Financial Year Ending</b>	<b>Audit Fees<sup>(1)</sup></b>	<b>Audit Related Fees<sup>(2)</sup></b>	<b>Tax Fees<sup>(3)</sup></b>	<b>All Other Fees<sup>(4)</sup></b>
December 31, 2016	\$228,500	\$97,200	\$82,200	\$0
December 31, 2015	\$162,500	\$192,807	\$74,550	\$0

**Notes:**

(1) Audit fees includes quarter reviews.

(2) Audit related fees includes fees related to the Qualifying Transaction and the Bought Deal.

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

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, 2016 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](http://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 January 26, 2017 special 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.**  
**AUDIT COMMITTEE CHARTER**

**PURPOSE**

The Audit Committee (the “**Committee**”) is a standing committee appointed by the board of directors (the “**Board**”) of the Profound Medical Corp. (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 (if any) 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 IFRS 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 IFRS.

## 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 (if any) 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 IFRS 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 IFRS;
  - (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 IFRS; 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.