



PROFOUND MEDICAL CORP.

**ANNUAL INFORMATION FORM
FOR THE YEAR ENDED DECEMBER 31, 2018**

March 7, 2019

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SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

In this annual information form (the “AIF”), unless otherwise noted or the context indicates otherwise, the “Company”, “Profound”, “we”, “us” and “our” refer to Profound Medical Corp. and, as the context requires, our principal subsidiaries Profound Medical Inc., Profound Medical (U.S.) Inc., Profound Medical Oy 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, 2018 (the last day of Profound’s most recently completed financial year), unless otherwise stated.

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. 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 data from the American Cancer Society, International Agency for Research on Cancer and the Agency for Health Care Research and Quality. 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.

TRADEMARKS AND TRADE NAMES

This AIF includes references to certain trademarks, such as “TULSA-PRO” and “SONALLEVE”, which are protected under applicable intellectual property laws in Canada and are Profound’s property. Solely for convenience, Profound’s trademarks and trade names may appear in this AIF without the ® or ™ symbol, but such references are not intended to indicate, in any way, that Profound will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

GLOSSARY

The following terms have the meanings set out below.

2018 Bought Deal Offering	has the meaning given under the heading “ <i>General Development of the Business – Three-Year History – Recent Highlights</i> ”.
3D	means three-dimensional.
ablation	means to remove or destroy tissue.
ACA	means the 2010 Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010.
ADT	means androgen deprivation therapy.
AIF	means this annual information form.
Audit Committee	has the meaning given under the heading “ <i>Audit Committee Information</i> ”.
BDC	means BDC Capital Inc.
BPH	means benign prostatic hyperplasia, a condition where the prostate gland is enlarged and not cancerous.
brachytherapy	means the precise placement of short-range radiation-sources (radioisotopes) directly at the site of the cancerous tumour.
CE Mark	means “Conformité Européenne” and is affixed to a medical device in the European Union by its manufacturer to declare that the medical device complies with applicable EU regulatory requirements and that the appropriate related conformity assessment procedure has been conducted.
CIBC	means Canadian Imperial Bank of Commerce.
CIBC Loan Agreement	means the loan agreement entered into on July 30, 2018 between PMI, as borrower; Profound, Profound Medical (U.S.) Inc and Profound Medical GmbH, as guarantors; and CIBC, as lender.

Common Shares	means the common shares in the capital of Profound.
Company	means Profound Medical Corp. and, as the context requires, its principal subsidiaries Profound Medical Inc., Profound Medical Oy and Profound Medical GmbH.
Confidentiality Agreement	has the meaning given under the heading “ <i>Material Contracts</i> ”.
cryoablation	means a therapy that uses extreme cold temperature to destroy benign and malignant tissue by crystallizing it.
DC&P	means disclosure controls and procedures.
de novo classification	means the submission of a petition to the FDA to reclassify a novel non-predicated Class III device as a Class I or II device pursuant to Section 513(f)(2) of the United States Federal Food, Drug and Cosmetic Act.
DTC	means a Depository Trust Company.
EBRT	means external beam radiation therapy.
Essential Requirements	has the meaning given under the heading “ <i>Narrative Description of the Business – Regulatory – Overview – European Union Regulation</i> ”.
European Union or EU	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.
FCPA	means the Foreign Corrupt Practices Act of 1977.
FDA	means the United States Food and Drug Administration, the regulatory authority in the United States that regulates companies that manufacture, repack, relabel, distribute and/or import food, drugs and/or devices sold in the United States.
FFDCA	means the Federal Food, Drug and Cosmetic Act.
FSCAs	means Field Safety Corrective Actions.
Genesys	means Genesys Ventures II LP.
Gleason Score	means the histological assessment of prostate tissue using a tumour grading system which describes how aggressive a prostate cancer is on a scale from 1 (least aggressive) to 5 (most aggressive). The Gleason score is a combination of the two most common growth patterns observed in a biopsy specimen.
Gn-RH	means gonadotrophin-releasing hormone.
HDR	means high dose radiation.
HIFU	means high intensity focus ultrasound.
HIPAA	means Health Insurance Portability and Accountability Act of 1996.
ICFR	means internal control over financial reporting.

IDE	means investigational device exemption; an approved IDE means that the Institutional Review Board of a clinical site and the FDA have approved the sponsor's clinical study application.
IFRS	means the International Financial Reporting Standards issued by the International Accounting Standards Board.
IP Assignment	has the meaning given under the heading " <i>Material Contracts</i> ."
IRB	means an institutional review board.
Knight	means Knight Therapeutics Inc.
Knight Loan Agreement	means the loan agreement entered into on April 30, 2015 between PMI 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 PMI granted to Knight a 0.5% royalty on net sales of PMI for the duration of such loan.
License Agreement	has the meaning given under the heading " <i>Material Contracts</i> ".
Laborie	has the meaning given under the heading " <i>Director Biographies</i> ".
MDB	means Medical Devices Bureau.
MDR	means the Medical Devices Regulations.
Medical Device Directive	means the Council Directive 93/42/EEC concerning medical devices.
Medical Device License	means the license for marketing approval of a medical device in Canada.
Mira	means Mira IV Acquisition Corp., a corporation incorporated under the OBCA.
Mira Subco	means Mira IV Subco Inc., a wholly-owned subsidiary of Mira incorporated under the OBCA.
MR	means magnetic resonance.
MR-HIFU	means magnetic resonance guided high intensity focused ultrasound.
MRI	means magnetic resonance imaging.
New Agreement	has the meaning given under the heading " <i>Alliances and Partnerships – Siemens</i> ."
New MDR	has the meaning given under the heading " <i>Narrative Description of the Business – Regulatory – Overview – European Union Regulation</i> ."
NI 52-109	means National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings.
OBCA	means the <i>Business Corporations Act</i> (Ontario), as amended, together with all regulations promulgated pursuant thereto.
Options	means options issued under the Share Option Plan.
Philips	means Koninklijke Philips N.V.
Philips Agreement	has the meaning given under the heading " <i>Narrative Description of the Business – Alliances and Partnerships – Philips</i> ."
Philips Medical	has the meaning given under the heading " <i>Material Contracts</i> ."

Pivotal Trial	means a clinical trial or study intended to provide evidence and reasonable assurance of safety and efficacy for marketing approval of a device.
PMA	means the Pre-Market Approval application process for marketing approval in the United States.
PMI	means Profound Medical Inc.
Profound	means Profound Medical Corp. and, as the context requires, our principal subsidiaries Profound Medical Inc., Profound Medical Oy and Profound Medical GmbH.
Promoter	means a promoter as prescribed by applicable Securities Laws.
PSA	means prostate specific antigen.
QMS	means a registered quality management system.
QSR	means Quality System Regulations.
Qualifying Transaction	has the meaning given under the heading “ <i>Corporate Structure – Name, Address and Incorporation.</i> ”
radical prostatectomy	means a surgical procedure that involves the removal of the whole prostate gland.
Resale Purchasing Agreement	has the meaning given under the heading “ <i>Material Contracts.</i> ”
Securities Laws	means securities legislation, securities regulation and securities rules, as amended, and the policies, notices, instruments and blanket orders in force from time to time that are applicable to an issuer.
Share Acquisition Agreement	has the meaning given under the heading “ <i>Material Contracts.</i> ”
Share Option Plan	means the share option plan of Profound dated June 4, 2015, as amended and restated on December 8, 2016 and as further amended.
Siemens	means Siemens Healthcare GmbH.
SONALLEVE MR-HIFU Transaction	has the meaning given under the heading “ <i>Narrative Description of the Business – Alliances and Partnership – Philips.</i> ”
Sunnybrook	means the Sunnybrook Health Sciences Centre.
Sunnybrook License	has the meaning given under the heading “ <i>Material Contracts.</i> ”
Supply Agreement	has the meaning given under the heading “ <i>Material Contracts.</i> ”
TACT	means the TULSA-PRO Ablation Clinical Trial.
TPD	means Health Canada’s Therapeutic Products Directorate.
Transitional Services Agreement	has the meaning given under the heading “ <i>Material Contracts.</i> ”
TSX	means Toronto Stock Exchange.
TSX-V	means the TSX Venture Exchange.
TULSA	means Transurethral ULtraSound Ablation.
TULSA-PRO	means the Transurethral ULtraSound Ablation device.

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

ITEM 1. CORPORATE STRUCTURE

1.1 Name, Address and Incorporation

Profound Medical Corp. is the company resulting from a “three-cornered” amalgamation involving Mira, Mira 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 a reverse takeover of Mira by the shareholders of PMI on June 4, 2015 (the “Qualifying Transaction”). On July 13, 2018, the Company graduated from the TSX-V and commenced trading on the TSX.

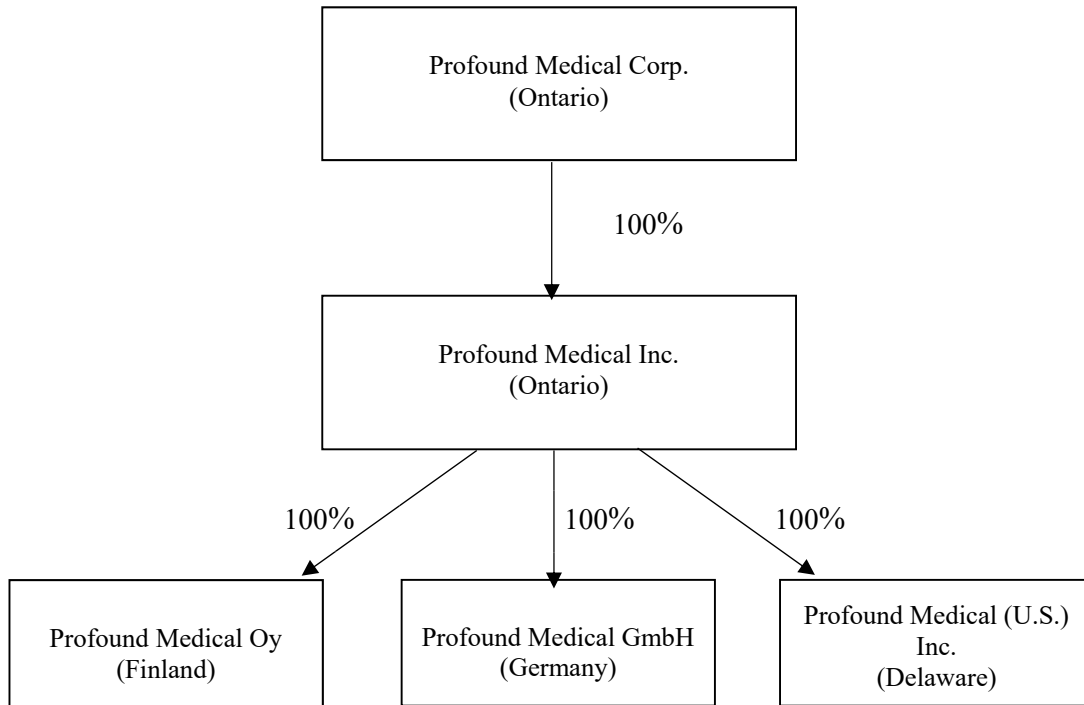
The Company’s head and registered office is located at 2400 Skymark Avenue, Unit 6, Mississauga, Ontario, L4W 5K5.

1.2 Inter-Corporate Relationships

Profound operates its business through its wholly-owned principal subsidiaries, Profound Medical Inc., Profound Medical Oy, Profound Medical GmbH and Profound Medical (U.S.) Inc.

Profound Medical Inc. was incorporated under the OBCA on June 13, 2008, and amalgamated with Mira Subco 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. Profound Medical Oy was established in Finland on July 31, 2017, as a wholly-owned direct subsidiary of PMI. Profound Medical (U.S.) Inc. was established under the laws of the state of Delaware on January 4, 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 as of the date of this AIF.



ITEM 2. GENERAL DEVELOPMENT OF THE BUSINESS

2.1 Overview

Profound (TSX: PRN; OTCQX: PRFMF) develops, manufactures and markets a therapeutic platform that provides the precision of real-time MR imaging combined with the safety and accuracy of directional and focused ultrasound technology for incision and radiation free ablation of diseased tissue. Profound's TULSA-PRO is a robotically controlled catheter based transurethral thermal ultrasound system that combines real time temperature monitoring by way of a continuous closed feedback loop via MRI guidance and the Company's process control software for customizable inside-out ablation of diseased prostate tissue; minimizing healthy tissue damage and the occurrence of disabling side effects. Additionally, the Company acquired the SONALLEVE focused ultrasound system in 2017 from Philips to create a MR-guided therapeutic ultrasound platform that can offer ablative therapies for use in the treatment of other multiple disease conditions, broadening the scope of the Company's long-term product offerings.

The Company's TULSA-PRO technology is designed to provide a minimally invasive and precise ablation of the prostate while simultaneously reducing the risk of harming the critical surrounding anatomy from potential side effects. TULSA-PRO provides physicians with the flexibility to customize the treatment to the patient's specific anatomy and pathology thus enabling prostate ablation for patients with localized prostate cancer in a whole gland to targeted (focal) approach, as well as ablative therapies for the treatment of BPH. In the Phase I clinical trial results published in 2016, TULSA-PRO demonstrated accurate and precise ablation of targeted prostate tissue, while providing a well-tolerated favourable safety profile with minor impact on urinary, erectile and bowel function at 12 months. TACT, Profound's Pivotal Trial, is a prospective, open-label, single-arm pivotal clinical study, of 115 prostate cancer patients across 13 research sites in the United States, Canada and Europe. The TACT Pivotal Trial completed patient enrolment in February 2018, and if successful, it is expected to support Profound's application to the FDA for clearance to market this technology in the United States. TULSA-PRO is CE marked for ablation of targeted benign and malignant prostate tissue. The TULSA-PRO system received CE Certificate of Conformity from its notified body in the European Union in April 2016 and the Company initiated a limited commercial launch within the jurisdiction in Q4 2016.

The Company continues to invest in additional research and development, clinical studies, and potentially acquisitions in order to expand the applications of its platform technologies and sales.

In 2017, Profound acquired SONALLEVE from Philips. SONALLEVE is a therapeutic platform that combines real-time MR imaging and thermometry with thermal ultrasound to enable precise and incision-free ablation of diseased tissue. There are approximately 200 publications detailing the clinical value of SONALLEVE in more than five disease conditions. The latest version of SONALLEVE received CE Mark certification for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone in March 2014. Profound markets SONALLEVE in countries that accept the CE Mark regulatory certification and is in the early stages of exploring additional potential markets where the technology has been shown to have clinical value. On May 9, 2018, the Company received regulatory approval in China from the China Food and Drug Administration for the use of SONALLEVE to treat uterine fibroids and initiated a limited launch in September 2018.

Profound is focused on commercialization of its products in jurisdictions with regulatory approval. The Company also continues to invest in additional research and development, clinical studies, and potential acquisitions in order to expand the applications of its platform technologies and sales.

2.2 Three-Year History

Fiscal 2018 Highlights

On December 14, 2018, Profound announces changes to the commercial organization; Ian Heynen resigned from his position as Senior Vice-President of Sales and Marketing.

On September 19, 2018, Profound filed a final base shelf prospectus with the securities commissions in each of the province of Canada, other than Quebec.

On September 18, 2018, Profound press released 3-year clinical outcomes in prostate patients and a BPH subgroup analysis of Profound's Phase I Clinical Trial which was included in a presentation at the Deutschen Gesellschaft für Urologie (DGU) 2018 conference.

On July 30, 2018, Profound entered into the CIBC Loan Agreement, which provides up to \$18.75 million of available borrowing capacity. The first tranche of \$12.5 million was funded upon execution of the agreement, with the option of a second tranche of up to an additional \$6.25 million available through December 31, 2019, subject to the satisfaction of certain financing and product development milestones.

On July 11, 2018, Profound received final approval for listing of its Common Shares on the TSX. The Common Shares continue to trade under the symbol "PRN".

On June 14, 2018, Profound disclosed at the annual meeting of their shareholders, voting results and welcomed two industry veterans, Dr. Arthur Rosenthal and Brian Ellacott, as independent directors to its board of directors.

On May 21, 2018, Profound presented the initial data from the TACT Clinical Trial at the American Urological Association 2018 conference.

On May 9, 2018, Profound obtained Chinese Food and Drug Administration approval for Sonalleve® for the non-invasive treatment of uterine fibroids.

On May 1, 2018, Profound further strengthened the management team with the appointment of Aaron Davidson as Chief Financial Officer and Senior Vice-President of Corporate Development.

On April 23, 2018, Profound hired Ian Heynen, Senior Vice-President Sales & Marketing, to lead Profound Medical's sales and marketing function.

On March 20, 2018, Profound completed a bought deal financing pursuant to a short form prospectus, for total gross proceeds of \$34.5 million ("2018 Bought Deal Offering"). The offering was conducted by a syndicate of underwriters led by Canaccord Genuity Corp. and including Paradigm Capital Inc., CIBC World Markets Inc., Beacon Securities Ltd., Echelon Wealth Partners Inc., and Mackie Research Capital Corporation.

On February 28, 2018, Profound announced the upsizing of the \$20,000,000 bought deal offering to \$30,000,000. The Company agreed to grant the Underwriters an over-allotment option to purchase up to an additional \$4.5 million units at the offering price, exercisable in whole or in part, at any time and from time to time on or prior to the date that was 30 days following the closing of the offering.

On January 31, 2018, Profound announced the completion of patient enrollment in the TACT Pivotal Trial designed to further evaluate the safety and efficacy of TULSA-PRO to ablate prostate tissue in patients with localized, organ-confined prostate cancer.

Fiscal 2017 Highlights

On November 6, 2017, Profound announced the expanded clinical use of TULSA-PRO in prostate care to include BPH. BPH is a common non-cancerous enlargement of the prostate gland due to an overgrowth of prostate cells and treatments for this condition were now being conducted in Germany utilizing TULSA-PRO.

On September 20, 2017, Profound closed a bought deal financing pursuant to a short form prospectus, for total gross proceeds of \$10 million. The offering was completed through a syndicate of underwriters led by Echelon Wealth Partners Inc. and including CIBC World Markets Inc.

On July 31, 2017, Profound completed the acquisition of Philips' SONALLEVE MR-HIFU business. SONALLEVE MR-HIFU is a therapeutic platform that combines real-time MR imaging and thermometry with high intensity focused ultrasound to enable precise and incision-free ablation of diseased tissue. SONALLEVE is CE marked for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone. Philips continues to distribute Profound's TULSA-PRO system. In addition, Philips and Profound announced that they expanded this non-exclusive strategic sales relationship to include distribution of SONALLEVE MR-HIFU.

On April 18, 2017, Profound announced that it had secured Depository Trust Company ("DTC") eligibility for its common shares listed on the OTCQX. Securities that are eligible to be electronically cleared and settled through the DTC are considered "DTC eligible".

On March 27, 2017, Profound announced that the first TULSA-PRO patient paid procedure was conducted at the ALTA Klinik in Bielefeld, Germany under the supervision of Dr. Agron Lumiani.

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

On March 20, 2017, Profound completed the first sale of a TULSA-PRO system in Finland to Turku University Hospital. The deal was completed in collaboration with Philips, who is working in partnership with Profound to commercialize TULSA-PRO.

On March 9, 2017, Profound announced that its Common Shares were eligible for trading on the OTCQX Best Market under the ticker symbol "PRFMF" as of March 13, 2017.

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

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. Steven Plymale remained as President and Chief Operating Officer.

Fiscal 2016 Highlights

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 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.

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 system.

On September 22, 2016, the Company announced that the first patient had been treated in TACT, designed to further evaluate the safety and efficacy of TULSA-PRO to ablate prostate tissue in patients with localized, organ-confined prostate cancer, at Vanderbilt University Medical Center in Nashville, TN.

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

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

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

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

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

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

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

On 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.

ITEM 3. NARRATIVE DESCRIPTION OF THE BUSINESS

3.1 General

Profound develops, manufactures and markets therapeutic platforms that combine real-time MR imaging with directional (inside-out) and focused (outside-in) ultrasound technology for incision-free ablation of diseased tissue. These platforms offer clinicians and patients incision-free alternatives to current standards of care which could include traditional surgery or radiation therapy.

3.2 Products

TULSA-PRO

Profound’s novel technology TULSA-PRO combines MRI guidance and ultrasound energy to provide thermal ablative therapy to the prostate gland delivered through the urethra.

Prostate cancer is one of the most common types of cancer affecting men, with an annual incidence of newly diagnosed cases reaching 343,000 in the European Union¹ and 175,000 in the United States². It is estimated that there are currently 5.8 million men living with prostate cancer in these two geographies. Although ten-year survival outcomes for prostate cancer remain favourable, it is still one of most common causes of cancer deaths among men.

Currently men with localized prostate cancer are risk classified into low-risk, intermediate-risk, and high-risk categories, based on prostate specific antigen (“PSA”) levels, clinical stage and Gleason Score. There are a number of available treatments for localized prostate cancer with the most commonly utilized approaches being active surveillance, radical prostatectomy, and radiation therapy.

Active surveillance, utilized primarily for low-risk patients does not involve active patient treatment, as it is rather a postponement of treatment with regular patient assessment and testing. The rationale for active surveillance is that delayed treatment will also delay the high risk of side-effects associated with current treatment options. For intermediate-risk and high-risk patients, surgical radical prostatectomy and radiation therapy are most commonly utilized treatment options. Even though these treatments offer 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.

The current treatment paradigm consist mostly of either delaying therapy through Active Surveillance, removing the whole gland or radiation which requires several sessions. These options have created an unmet

¹ Source: International Agency for Research on Cancer (2018, April 18). Retrieved from <http://eco.iarc.fr/eucan/CancerOne.aspx?Cancer=29&Gender=1>.

² Source: American Cancer Society (2019, January 8). Retrieved from <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>.

need for a treatment option that could better enable the Clinician with a flexible and customizable treatment option of whole gland or disease targeted ablation that takes into account the need of each patient including consideration of the stage of the disease, aggressiveness and spatial spread of the disease and the need to minimize side effects.

The TULSA-PRO system is comprised of two categories of components: disposables and the capital equipment used in conjunction with a customer's MRI scanner. Profound has designed the TULSA-PRO system to be capable of integration with many major MRI scanners currently deployed in hospitals and treatment facilities. That integration allows the TULSA-PRO system to display high resolution images of the prostate and surrounding anatomy. The integrated MRI is used for treatment planning but, more importantly, to provide real-time measurement of temperature in the prostate as the treatment is occurring to enable the physician/clinician to control and monitor tissue ablation. Profound has optimized its technology to work with particular MRI scanners sold by Siemens and Philips and intends to increase compatibility of the TULSA-PRO system with models from other MRI vendors over time.

The ultrasound applicator (the "UA") is a sterile, single use, disposable component of the TULSA-PRO 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 out to the prescribed treatment boundary. 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 real time measurement of the temperature from the MR and the precision of transurethral ultrasound is intended to enable the TULSA-PRO system to sculpt the ablated tissue volume to the shape of the patient's prostate, which may assist in avoiding damage to sensitive structures, including the bladder neck and urethral sphincter.

There are a number of expected clinical advantages of TULSA procedure. The technology has demonstrated accurate and precise ablation of targeted prostate tissue, while providing a well-tolerated favourable safety profile with minor impact on urinary, erectile and bowel function at 12 months. TACT, Profound's Pivotal Trial conducted by Profound, is a prospective whole gland ablation, open-label, single-arm pivotal clinical study, of 115 prostate cancer patients across 13 research sites in the United States, Canada and Europe. Profound believes its clinical trial may demonstrate that the use of the TULSA-PRO system in a prostate cancer patient population will have a well-tolerated safety profile with lower rates of procedure-related complications. TACT completed patient enrolment in January 2018 with an additional 5 year patient follow up period to be completed, and if successful it is expected to support Profound's application to the FDA for clearance to market the technology in the United States.

SONALLEVE

In 2017, Profound acquired SONALLEVE from Philips. SONALLEVE is a therapeutic platform that combines real-time MR imaging and thermometry with thermal ultrasound to enable precise and incision-free ablation of diseased tissue. SONALLEVE is CE marked for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone. The Company is also in the early stages of exploring additional markets for SONALLEVE, where the technology has been shown to have clinical application.

The SONALLEVE uterine fibroid application is indicated for the ablation of symptomatic uterine fibroids or adenomyotic tissue in pre- or peri-menopausal women who desire a uterine sparing treatment. Uterine fibroids are the most common non-cancerous tumors in women of childbearing age. It is estimated that they occur in 70-80% of the female population, but only approximately one third of these cases will require treatment. In the United States, an estimated 26 million women between the ages of 15 and 50 have uterine

fibroids. More than 15 million of them will experience associated symptoms or health concerns³. Uterine fibroids cause a variety of symptoms that can significantly reduce the quality of life for a woman, which can include bleeding, pain, pressure and reproductive challenges including infertility, multiple miscarriages, and premature labor. Treatment options differ in fundamental aspects such as cost, invasiveness, recovery time, risks, likelihood of long-term resolution of symptoms, need for future care for fibroids, and influence on future childbearing potential.

The SONALLEVE procedure consists of imaging the uterus in an MR scanner and heating the fibroid or adenomyosis with high-intensity focussed ultrasound energy until the tissue reaches the temperature that causes necrosis. The MR scanner monitors the progress of the treatment. For the patient, the technique can be much more convenient and comfortable than traditional surgical procedures, such as hysterectomy or myomectomy. These require hospital admission on an in-patient basis and sometimes weeks of recovery. In contrast, with SONALLEVE fibroid therapy, patients can be treated on an outpatient basis without the need for anesthesia, discharged the same day and almost fully recovered within a few days.

The SONALLEVE bone pain relief application is indicated for palliative treatments to relieve pain associated with bone metastasis. In the later stages of their disease, many cancer patients develop bone metastases. Bone changes and malformations irritate nerve endings, which can cause severe and debilitating pain and become unbearable for many patients. Conventional treatment with strong medication or radiation therapy can result in unpleasant side effects. SONALLEVE provides an alternative option to alleviate this pain. Pain relief can be expected in as quickly as 2-3 days as compared to radiation therapy which could take up to three weeks.

The ultrasound energy utilized in the SONALLEVE system is High Intensity Focused Ultrasound (“HIFU”) or MR-HIFU. MR-HIFU therapy uses a focused transducer to bundle ultrasound energy into a small volume at the target locations inside the body under MR imaging and visualization. During treatment, the ultrasound energy beam passes through the intact skin and soft tissue, causing localized high temperatures in the focus area. The skin and intermediate tissue are left unharmed. Within a few seconds this produces a well-defined region of coagulative necrosis.

The SONALLEVE system is capable of integration with Philips MRI scanners and the Company intends to expand this compatibility to additional MRI scanner brands in time. MRI can measure temperature changes within the human body non-invasively. 3D MR images provide the anatomical reference data for treatment planning, while real-time temperature sensitive images are acquired during ablation to provide real-time information about treatment progress and monitor critical anatomical structures.

There are over 200 publications from leading institutions globally on SONALLEVE technology. There are also over 60 luminary institutions from around the globe that make up the installed base of the SONALLEVE system.

3.3 Business Strategy

Historically treatment of conditions such as localized prostate cancer and uterine fibroids have included surgical intervention. Over time, surgery has evolved from an ‘open’ to a ‘laparoscopic’ technique to laparoscopic robotic surgery. The surgeon’s motivation behind this evolution has been to create procedures that reduce invasiveness, with improved clinical outcomes, while reducing recovering times. Profound is now taking this concept to the next level by enabling incision-free, precise and customized procedures that are real-time MR-guided ultrasound ablations performed with the TULSA-PRO and SONALLEVE systems. These incision-free flexible procedures offer physicians the option of providing precise and

³ Source: Agency for Healthcare Research and Quality. Management of Uterine Fibroids Evidence Summary. AHRQ Pub. No. 17(18)-EHC028-1-EF. December 2017.

customized procedures that further reduce invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

TULSA-PRO revenue may include the sale of the capital equipment, procedure related sales of disposable single use components of the system, and service revenue for ongoing maintenance of the systems. Profound is currently pursuing a limited commercial launch of TULSA-PRO in CE marked jurisdictions. The key customer segments targeted by Profound include academic/university/clinical leadership hospitals as well as private clinics with access to MRI scanners. Profound collaborates with its strategic partners Philips and Siemens for lead generation and distribution of the capital equipment. Profound is establishing its own direct sales and marketing teams for sales of the capital and disposable components of TULSA-PRO and SONALLEVE systems. The primary focus of the direct sales team is to cultivate adoption of the TULSA-PRO technology, support clinical customers with the TULSA-PRO procedures and increase the utilization of the systems and disposable components. Recurring revenues are expected to be generated from the sale of disposables and service.

Sales of SONALLEVE currently are primarily a one-time capital sale with limited recurring service revenue. Given that it is currently only compatible with Philips MRI scanners, Profound relies primarily on its strategic partnership with Philips for lead generation and sale of the capital units. With regulatory approval for sale in certain jurisdictions, the 2019 focus will be primarily on Asia. In May 2018, the Chinese Food and Drug Administration approved SONALLEVE for the non-invasive treatment of uterine fibroids.

Profound continues to focus on further demonstrating the clinical and economic value of its products.

3.4 Manufacturing Operations

The Company operates from leased premises in three different locations. Profound does not own any real estate property.

Location	Area	Premise Use	Expiry Date
2400 Skymark Ave, Unit 6, Mississauga, ON, Canada	38,148 ft ²	Corporate offices and administration, Manufacturing, Research and Development	September 30, 2026
Äyritie 4B, 01510 Vantaa, Finland	6,372 ft ²	Manufacturing, Research and Development	December 31, 2021
Kehrwieder 9, 20457 Hamburg, Germany	162 ft ²	Sales and Marketing	month to month

Profound manufactures TULSA-PRO and SONALLEVE systems at dedicated manufacturing facilities located in Canada and Finland which are ISO 13485 certified. The Profound manufacturing model consists primarily of outsourcing sub-assemblies where it is most cost effective to do so, while assembling and quality testing the final products in-house. Additionally, single use products are assembled entirely in the Mississauga facility within a class 300 clean room which became operational in August 2017. Profound's manufacturing facilities have sufficient capacity to meet its manufacturing needs through the foreseeable future.

Profound has in place supply agreements with manufacturers of key technologies and components. Profound and strategically located service partners handle equipment installation and field service globally.

3.5 Competition

TULSA-PRO

The most widely used treatment options for prostate cancer currently are: (1) watchful waiting/active surveillance; (2) radical prostatectomy (includes open, laparoscopic and robotic procedures); (3) radiation therapies including, external beam radiation therapy (“EBRT”), brachytherapy and high dose radiation (“HDR”); (4) cryoablation and (5) trans-rectal HIFU. 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 (“ADT”) and proton beam therapy.

Active surveillance is generally recommended for patients who have been diagnosed with earlier stage, lower risk, disease where the possibility of side effects from intervention may outweigh the expected benefit of the chosen procedure. For clinicians and patients, the gap between active surveillance and the most commonly utilized treatment options of surgery or radiation therapy impose the possibility of substantial side effects, create an unmet need for treatment options that address treatment of the cancer with a more favourable side-effect profile.

Profound believes that its TULSA-PRO system could become a compelling option for clinicians in treating prostate cancer with a favorable side-effect profile, fulfilling the unmet clinical need. Profound believes that the flexibility of the TULSA-PRO system may allow Profound to demonstrate its use as a tool to treat either the whole prostate gland or a customized partial gland option with greater speed, accuracy, less side effects and greater precision than current treatment options. Profound believes that it may be able to generate clinical data to demonstrate a clear safety advantage without compromising efficacy.

Profound believes that the TULSA-PRO system may provide a treatment option that could fulfill an unmet clinical need by providing an ablation tool for prostate cancer while minimizing potential side effects. 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 or partial gland safely.

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. 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.

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. Relatively recently, robotic surgery systems have become more common in 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, it is non-invasive. 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. Side effects of brachytherapy are similar to those of EBRT in terms of urinary, bowel and erectile function. 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 cryoablation 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 fistulas.

Trans-rectal High Intensity Focused Ultrasound

Trans-rectal HIFU is used increasingly in the European Union, United States and Canada. This technique utilizes focused ultrasound that is delivered through the rectal wall to treat the prostate. Image guidance is generally provided by ultrasound. At an FDA urology panel meeting 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. Patients with larger prostates need a separate surgical procedure, such as transurethral resection of the prostate (“TURP”) or 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.

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.
- Proton beam therapy is a way to deliver radiation to tumors using tiny, sub-atomic particles (protons) instead of the photons used in conventional radiation treatment. Proton beam therapy uses new technology to accelerate atoms to approximately 93,000 miles per second, separating the protons from the atom. While moving at this high speed, the particles are “fired” at the patient’s tumor. These charged particles deliver a very high dose of

radiation to the cancer but release very little radiation to the normal tissue in their path. In theory, this approach minimizes damage to healthy organs and structures surrounding the cancer. The radiation beams must pass through the skin, the bladder and the rectum on the way to the prostate gland, and once they reach the gland, they encounter normal prostate cells and the nerves that control penile erections. Damage to these tissues can lead to complications, including bladder problems, rectal leakage or bleeding, and erectile dysfunction.

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

Procedure	Advantages	Limitations / Risks
Radical Prostatectomy (includes robot-assist)	Certainty of removing whole gland Good outcomes data	Invasive Hospital stay required Potential for post-surgical complications High cost
EBRT	Non-invasive	Collateral tissue damage Multiple visits required Recurrence High cost
Brachytherapy and High Dose Radiation	Minimally invasive Image-guided	Seed migration Collateral damage Potential for complications Recurrence
Cryoablation	Minimally invasive Image-guided	High rates of collateral tissue damage Potential for complications
HIFU	Minimally invasive Image-guided Good outcomes data	Trans-rectal delivery can result in complications Prostate volume must be less than 40 cubic centimetres Significant capital equipment cost Potential for issues arising out of overheating of tissue
Watchful Waiting (includes active surveillance)	Non-invasive	Multiple visits required Treatment delay
Proton Beam Therapy	Adjustable energy deposition depth	Very costly equipment Limited data to support claims

Profound believes that use of the TULSA-PRO system as a tool to ablate prostate tissue can provides clinician and their patients with the following clinical advantages:

- Clinically shown to have millimeter accuracy designed to ablate prostate tissue while sparing nearby critical structures. Real time MR thermometry also ensures precision in ablation temperature, minimizing side effects that can occur from overheating;
- Enables clinician to define the boundaries of the tissue to be ablated, whether the whole prostate or any of its subsections, to ensure customization of the needs of each patient;
- Transurethral approach allows for ablation of even the largest prostates that may be 120 cubic centimetres or larger in size;
- Potential to be a single treatment outpatient procedure with a rapid recovery time; and
- Designed to be compatible with leading MRI platforms and could become part of a continuum of care from MR imaging diagnosis, MR guided biopsy to MR guided treatment.

Profound believes that the TULSA-PRO system may provide a treatment option that could fulfill an unmet clinical need by providing an ablation tool for prostate cancer while minimizing potential side effects. 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.

SONALLEVE

The treatment choices for uterine fibroids usually depend on the symptoms of the patient, size of the fibroid, desire for future pregnancy, and preference of the treating gynecologist. Most common treatment options for uterine fibroids include: (1) hormonal medications including gonadotrophin-releasing hormone agonists (“Gn-RH”); (2) progesterone releasing intra-uterine devices; (3) surgical procedures such as hysterectomy and myomectomy; and (4) uterine artery embolization.

Profound believes that the SONALLEVE system may provide a treatment option that is more convenient and comfortable with less side effects than surgical procedures, such as hysterectomy or myomectomy.

Hormonal Medications

Fibroids can be treated with hormonal drugs, such as Gn-RH agonists. Gn-RH agonists can treat fibroids by blocking the production of estrogen and progesterone, putting women into a temporary postmenopausal state. As a result, menstruation stops, fibroids shrink and anemia is often alleviated. Other hormonal medications can also be utilized in patients with uterine fibroids. In many cases, however, medication may provide only temporary relief from the symptoms caused by fibroids. The symptoms often return when the patient stops taking the medication. Moreover, the side effects of some drugs may cause them to be unsuitable for some patients. Gn-RH agonists typically are used for no more than three to six months because long-term use can cause loss of bone.

Progesterone Releasing Intra-Uterine Devices

Progesterone releasing intra-uterine devices can relieve heavy bleeding caused by fibroids. However, these devices can only provide symptom relief and do not impact the fibroid itself.

Uterine Artery Embolization

Uterine artery embolization involves injection of embolic agents into the arteries that supply the uterus, thereby cutting off the blood supply to the fibroids. Many women require at least one day of hospitalization and heavy pain medication. The prolonged pain may slow down the recovery period. Complications may occur if the blood supply to the ovaries or other organs is compromised.

Surgery

Surgical options for the treatment of uterine fibroids include hysterectomy and myomectomy. Hysterectomy is a surgical procedure which involves the complete removal of uterus with or without removal of the cervix, ovaries and fallopian tubes. Hysterectomy can be performed abdominally in an open, laparoscopic, robotic-assisted or vaginal method. Surgical options are associated with blood loss, hospital stays, long recovery times, pain and scarring. Post-operative complications can include infections, urinary incontinence, vaginal prolapse, fistula formation and chronic pain. After a hysterectomy, a woman will enter menopause and is infertile. Myomectomy is a surgical procedure to remove uterine fibroids from the wall of the uterus. The procedure can be performed with an abdominal incision, laparoscopic, or hysteroscopic.

Profound believes that use of the SONALLEVE system as a tool to ablate uterine fibroids can provide a clinician and his or her patients with the following clinical advantages:

- Millimetre accuracy designed to ablate uterine fibroid while sparing nearby critical structures;
- Outpatient procedure with rapid recovery time, not requiring general anesthesia; and
- Non-invasive approach using thermal ablation designed to heat the uterine fibroid; and guided by real-time MRI with temperature (thermometry) feedback.

Profound believes that the SONALLEVE system may provide a treatment option that is more convenient and comfortable with less side effects than surgical procedures, such as hysterectomy or myomectomy.

3.6 Alliances and Partnerships

Philips

On July 31, 2017, Profound closed an asset and share purchase agreement (the “Philips Agreement”) with Philips in order to expand the existing collaboration and acquire Philip’s SONALLEVE MR-HIFU business (the “SONALLEVE MR-HIFU Transaction”).

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

“Net Sales” include the revenues (less any royalties) received by Profound or its affiliates or others on their behalf in respect of the sale or transfer of the SONALLEVE MR-HIFU, any subsequent, successor or next-generation treatment technology of which is primarily based on SONALLEVE MR-HIFU and which utilizes intellectual property rights acquired under the Philips Agreement or any future product that combines the technologies of SONALLEVE MR-HIFU and TULSA-PRO and any amounts received by

Profound with respect to service agreements, but does not include any revenues with respect to consumables.

As part of the SONALLEVE MR-HIFU Transaction, Philips and Profound expanded their non-exclusive strategic sales relationship for Profound's TULSA-PRO system to include distribution of SONALLEVE MR-HIFU.

Siemens

On February 29, 2016, Profound entered into a strategic collaboration agreement with Siemens, aimed at advancing the commercial launch of Profound's TULSA-PRO system. As of April 1, 2018, the TULSA-PRO is marketed by Siemens through its electronic catalog. Effective as of January 21, 2019, Profound entered into and replaced the original co-marketing and co-selling agreement with Siemens (the "New Agreement"). Under the New Agreement, all prior financial commitments and obligations owed to Siemens are released and replaced with a one-time fixed license fee of US\$100,000 and a per annum payment per device interfaced to Siemens MRI scanner.

3.7 Regulatory

Profound has identified primary regulatory pathways to market its products in the United States, and European Union. The Company's long-term goal is to expand its regulatory indications in Asia and other parts of the world where potential profitable business development opportunities warrant such investments.

Overview – United States Regulation

The FDA strictly regulates medical devices under the authority of the Federal Food, Drug and Cosmetic Act, or FFDC, and the regulations promulgated under the FFDC. The FFDC and the implementing regulations govern, among other things, the following activities related to our products: preclinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, record keeping, sales and distribution, post-market adverse event reporting, recalls, and advertising and promotion.

The TULSA-PRO system, and any future medical devices that Profound may develop, will be classified by the FDA under the statutory framework described in the FFDC. Medical devices are classified into three classes from lowest risk (Class I) to highest risk (Class III) and require FDA clearance or approval prior to commercial sale depending on the assigned risk class. In general, Class I devices are subject to only general controls and in some cases, to the 510(k) premarket clearance requirements. Class II devices generally require 510(k) premarket notification clearance. 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 approval for novel, low-risk devices, FDA may allow de novo classification to Class II. 510(k) premarket notifications, de novo classification requests, and PMA applications are subject to the payment of user fees paid at the time of submission for FDA review.

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance or de novo classification requests. 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 non-significant risk device eligible for more abbreviated IDE requirements or an exemption applies. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements as well as a requirement to submit information regarding certain clinical trials to a public database maintained by the National Institutes of Health. 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. 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, i.e., a 510(k) premarket notification, de novo classification request 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 market clearance or approval of Profound's product.

After a device is placed on the market, numerous regulatory requirements apply. These include: product listing and establishment registration, Quality System Regulation, or QSR, labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indications, medical device reporting regulations, post-approval restrictions or conditions, post-market surveillance regulations, recall regulations and corrections or removals regulations.

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 (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 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, 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. On the basis of these notified body CE Certificates of Conformity, the manufacturer is able to draw up an EC Declaration of Conformity and affix the CE Mark to the relevant device. The CE mark allows the device to be placed on the market throughout the EU.

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 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 of the device, clinical performance, benefits that outweighs associated risks and the usability of the device.

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.

In the European Union, Profound must establish a medical device vigilance system, including post-marketing surveillance and adverse event reporting procedures. Under this system, incidents occurring in

the EU that 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 must be reported to the relevant authorities of the European Union Member States. Manufacturers are required to take Field Safety Corrective Actions (“FSCAs”), including product recalls and withdrawals, 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. For class I devices and certain other devices, the manufacturer of the device or its authorized representative in the EU, must also register with the competent authority before placing the product on the market in the EU.

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 public and may impose limitations on Profound’s promotional activities with healthcare professionals.

In May 2017, the EU adopted a new Medical Devices Regulation (EU) 2017/745 (the “New MDR”), which will repeal and replace the Medical Device Directive effective May 26, 2020. The New MDR does not set out a substantially different regulatory system, but clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations as regards clinical data for devices and pre-market regulatory review of high-risk devices. The New MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional provisions, medical devices with notified body certificates issued under the Medical Devices Directive prior to 26 May 2020 may continue to be placed on the market for the remaining validity of the certificate, until 27 May 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the New MDR may be placed on the market in the EU.

Overview – Canadian Regulation

Health Canada’s Therapeutic Products Directorate (“TPD”) is the Canadian authority that regulates medical devices. In general, prior to being given market authorization to sell a medical device in Canada, 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 Medical Devices Bureau (“MDB”) of the TPD applies the MDR through a combination of pre-market review, post-approval surveillance and quality systems in the manufacturing process. Medical devices are classified into one of four classes, where Class I represents the lowest risk and Class IV represents the highest risk. In order to perform investigational testing in Canada for a Class II, III or IV medical device, authorization for the testing must be granted by the MDB. A Medical Device License is a pre-market requirement for a Class II, III and IV medical device previously authorized for sale for investigational testing now to be offered for general/commercial sale. 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 is a system designed to implement the MDR requirements that medical devices be designed and manufactured under a registered quality management system (“QMS”). The MDR requires that medical devices be manufactured under a certified QMS that meets the criteria of the international standard, ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. Profound is manufacturing the TULSA-PRO system under a certified ISO 13485 Quality Management System.

Regulatory Update

The TULSA-PRO system received CE Mark in April 2016 in the European Union; however, it is still an investigational device in the United States. Outside of the European Union, the device will require country-specific pre-market clearance or approval prior to launch.

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

In October 2015, the results of Profound's safety and feasibility study were accepted for publication in *European Urology*, the official journal of the European Association of Urology. Profound presented the successful 12-month Phase I clinical trial outcomes at the European Symposium on Focused Ultrasound Therapy. Upon completion of the study, the clinical data was also submitted to European regulatory authorities for regulatory clearance in Europe. On April 11, 2016, Profound announced that it was granted CE Mark approval for the commercial sale of the TULSA-PRO system in Europe and in other CE Mark jurisdictions. Profound completed its first commercial sale of the TULSA-PRO system in the same month.

In August 2016, Profound initiated the FDA approved IDE TACT Pivotal Trial. 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 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 based upon a successful trial.

The SONALLEVE system is available for sale in several jurisdictions. The SONALLEVE applications to treat uterine fibroids and bone metastasis are CE marked and available in the European Union and its member states. The uterine fibroids application is also available for sale in Canada. Philips Oy had registered SONALLEVE in several Middle East, North African, and South Asian countries. Profound is in a process of transferring existing regulatory registrations of SONALLEVE from Philips Oy to Profound. Profound is also in a process of assessing current clinical research network activities and the investigator lead studies in the United States to form regulatory strategies for several potential indications.

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

3.8 Reimbursement

The Company's ability to successfully commercialize products depends in large part on the extent to which coverage and reimbursement for such products and related treatments or procedures will be available from government health administration authorities, government and private health insurers, and other organizations or third-party payers. Pricing and reimbursement procedures and decisions vary from country to country. Many government health authorities and private payers condition payment on the cost-effectiveness of the product. Even if a device is CE marked or has received regulatory approval, there is no guarantee that third party payers will reimburse providers or patients for the cost of the device and related procedures. The availability of adequate coverage and reimbursement to hospitals and clinicians using our products therefore is critical to our ability to generate revenue.

In 2017, Profound made reimbursement progress in Germany for TULSA-PRO. TULSA received a dedicated procedure code in Germany, securing an initial Diagnosis-Related Group payment of €3,963 starting in January 1, 2018. The Company believes that this reimbursement will help to offset approximately 40%-60% of the cost of the procedure and is working closely with clinicians and reimbursement consultant experts to enhance the reimbursement levels.

SONALLEVE currently does not have significant reimbursement in the European markets.

The Company is also pursuing reimbursement activities for the United States market and other key European markets.

ITEM 4. RISK FACTORS

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

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

Risk Factors Relating to Profound's Business

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

Profound's business requires substantial capital investment in order to conduct the research and development and to fund the clinical and regulatory activities necessary to bring Profound's products to market and to establish commercial manufacturing, marketing and sales capabilities. As of December 31, 2018, Profound had a cash balance of \$30.8 million. Profound will need additional capital to fund its current business activities and expectations and to fund any significant expansion of operations. In order to secure financing, if available, it is likely that Profound would need to sell additional Common Shares or financial instruments that are exchangeable for or convertible into Common Shares and/or enter into development, distribution and/or licensing relationships, to fund all or a part of particular programs. Any future equity financing may also be dilutive to existing shareholders. Any future debt financing arrangements Profound enters into would likely contain restrictive covenants that would impose significant operating and, if any, financial restrictions on it. The availability of equity or debt financing will be affected by, among other things, the results of its research and development, its ability to obtain regulatory approvals, the market acceptance of Profound's products, the state of the capital markets generally, strategic alliance agreements, and other relevant commercial considerations.

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

Profound's cash outflows are expected to consist primarily of internal and external research and development expenditures to advance Profound's product pipeline in addition to selling, cost of sales, general and administrative expenditures to support its corporate infrastructure. If Profound does not obtain additional capital, there may be substantial doubt about its ability to continue as a going concern and realize assets and pay liabilities as they become due. Depending upon the results of Profound's research and development programs and the availability of financial resources, Profound could decide to accelerate, terminate or reduce certain projects, or commence new ones. Any failure on Profound's part to raise

additional funds on terms favourable to it or at all, may require it to significantly change or curtail current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in Profound not taking advantage of business opportunities, in the termination or delay of clinical trials for one or more of its product candidates, in curtailment of its product development programs designed to identify new product candidates, in the sale or assignment of rights to Profound's technologies, products or product candidates, and/or Profound's inability to file an application for market clearance in the United States at all or in time to competitively market Profound's products.

Profound has a limited operating history.

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

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

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

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

Profound has a history of losses and it may never achieve or maintain profitability.

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

Profound is a development-stage company that operates in an uncertain industry.

Profound is in the mid-stage of development. Clinical trial work and remaining validation work must still be completed before Profound's devices are ready for use within all of the markets Profound has identified. Profound may fail to obtain regulatory approvals or clearance, enter clinical trials or commercialize the

products. Profound does not know whether any of its potential product development efforts will prove to be effective, meet applicable regulatory standards, obtain the requisite regulatory approvals or be capable of being manufactured at a reasonable cost. If Profound's devices are approved for sale, there can be no assurance that the devices will gain market acceptance among patients, physicians/clinicians and others in the medical community. A failure to gain market acceptance may adversely affect Profound's revenues.

Profound has several loan agreements with financial and non-financial covenants. Failure to comply with any of the covenants could have a material adverse effect on its business.

Profound's CIBC Loan Agreement contains financial and non-financial covenants, such as requirements that Profound comply with one or more financial ratios and change of control provisions. Complying with such covenants may at times necessitate that Profound must forego other favourable business opportunities, such as acquisitions. Moreover, Profound's failure to comply with any of these covenants would likely constitute a default under such facilities and agreements and could give rise to an acceleration of some, if not all, of Profound's then outstanding indebtedness, which would have a material adverse effect on its business. Profound's indebtedness may grow as Profound's business grows and/or Profound makes new acquisitions. If Profound's income from operations underperforms, Profound may have to utilize cash flow or capital resources to fund its debt service payments. If Profound's cash flow and capital resources are insufficient to service amounts owed under Profound's current or any future indebtedness, as applicable, Profound may be forced to reduce or delay capital expenditures, dispose of assets, issue equity or incur additional debt to obtain necessary funds, or restructure its debt, any or all of which could have a material adverse effect on Profound's business, financial condition and results of operations. In addition, Profound cannot guarantee that it would be able to take any of these actions on terms acceptable to it, or at all; that these actions would enable Profound to continue to satisfy its capital requirements; or that these actions would be permitted under the terms of Profound's debt agreement. In particular, the CIBC Loan Agreement contains covenants with respect to capital expenditures and other indebtedness, maintaining minimum cash balances at all times and certain financial covenants. Profound has granted a security interest over all assets (including the shares owned by Profound). Events of default under the CIBC Loan Agreement include any covenant breach, failure to maintain minimum required net assets at all times, cross defaults to other agreements, a failure to comply with certain financial tests as to, a change of control of Profound. The enforcement by CIBC of its rights and remedies pursuant to the terms of the CIBC Loan Agreement and associated documentation could result in CIBC, its agent or any third party purchaser thereof owning all assets of Profound, including all share capital of Profound.

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

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

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

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

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

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

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

Clinical trials are generally required to support PMA approval and *de novo* classification and are sometimes required to support 510(k) clearance. Such trials, if conducted in the United States, generally require an IDE application to be approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements or the trials are exempted. As noted above, the FDA has granted IDE approval with respect to the Pivotal Trial. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, Profound must also obtain the patients' informed consent that complies with FDA requirements, state and federal privacy regulations and human subject protection regulations. Profound, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Additionally, Profound may decide at any time,

for business or other reasons, to terminate a study. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device for its intended use or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States. Following completion of a study, Profound would need to collect, analyze and present the data in an appropriate submission to the FDA. Even if a study is completed and submitted to the FDA, the results of clinical testing may not demonstrate the safety and efficacy of the device for its intended use, or may be equivocal or otherwise not be sufficient to obtain clearance or approval of Profound's product. In addition, the FDA may perform a biosearch monitoring inspection of a study and if it finds deficiencies, Profound will need to expend resources to correct those deficiencies, which may delay clearance or approval or the deficiencies may be so great that the FDA could refuse to accept all or part of the data or could trigger enforcement action.

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

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

Profound believes, based on non-binding discussions with the FDA, that there are suitable predicate devices for the TULSA-PRO system for use in the ablation of prostate tissue. As such, Profound intends to follow a 510(k) path for regulatory clearance of its device. Based on its discussions with the FDA, Profound has determined it will need to submit clinical data with its 510(k) premarket notification to support this indication. Profound will collect data from the 115 patient TACT Pivotal Trial designed to demonstrate substantial equivalence for the intended use of device. There is no guarantee that the FDA will clear a submission for 510(k) clearance for the device. Profound is also in discussion with the FDA regarding SONALLEVE and has submitted an application requesting designation of a regulatory pathway.

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

Even after regulatory approvals or clearance is obtained, successful commercialization will depend largely upon the cost of the device and the availability of coverage and reimbursement for the procedure and medical costs associated with the use of the device.

Even after regulatory approvals or clearances are obtained, successful commercialization of a device depends largely upon the cost of the device and the availability of coverage and reimbursement for the

device and medical procedure associated with its use from third-party payers, such as government healthcare programs, private health insurers and other organizations, such as health maintenance organizations and managed care organizations. Profound expects that its devices will be purchased by health-care providers, including clinics and hospitals, and that these providers will subsequently bill various third-party payers or will be responsible for covering the costs of the device through the provider's operating budget.

Third-party payers carefully review and increasingly challenge the prices charged for medical devices, procedures and services. Government healthcare programs in the United States and the European Union may reimburse certain providers at a pre-determined all-inclusive amount for all the costs associated with a particular procedure performed or course of treatment, based on such factors as the patient's principal diagnosis, age and severity or complexity. Similarly, the surgeon or physician may be reimbursed at a pre-determined amount based on the procedure performed, and without taking into consideration the actual costs incurred, including the actual cost of the specific devices used.

New products are being increasingly scrutinized with respect to whether or not they will be covered at all by the various health plans and at what level of reimbursement. In some instances, economic research studies are and will be required to demonstrate whether Profound's products and approach are superior from a long term cost containment standpoint. Third-party payers may determine that Profound's products are not medically necessary, not cost-effective, experimental, or primarily intended for non-approved indications. Such determinations could have a material adverse effect on Profound's business, results of operations and financial condition.

Further, healthcare reform measures may be adopted in the future that may impose more rigorous coverage and reimbursement standards. Profound is unable to predict what, if any, additional legislation or regulation impacting the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on Profound's business.

Profound relies on certain distributors for the sale and distribution of its products. If the distributors are unable or unwilling to promote and deliver the products to Profound's customers, the Company's financial condition and operating results could be materially impacted.

Profound distributes its products through distribution partnerships with multiple distributors, including Philips, Knight and Siemens. In the future, Profound expects to enter into distribution partnerships with additional distributors world-wide for the sale and distribution of its products. If the distributors are unable or unwilling to promote and deliver the products to Profound's customers, the Company's business, financial condition and operating results could be materially impacted. Additionally, if Profound decides to terminate any of its existing distribution partnership, there can be no assurance that the Company will be able to generate alternative distribution channels rapidly enough to prevent disruptions in sales generated in those markets or will be successful in managing the nuances of those markets to ensure the success of the Company's products in those markets.

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

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

- safety, efficacy, convenience and cost-effectiveness of Profound's devices as a method of ablation of prostate tissue, uterine fibroids, bone metastases or ultimately (pending the relevant approvals) treatment for localized prostate cancer, uterine fibroids and bone metastases, compared to products of Profound's competitors or other forms of treatment;
- scope of approved uses and marketing approval or clearance;
- timing of market approvals and market entry;
- difficulty in, or excessive costs to, manufacture;
- infringement or alleged infringement of the patents or intellectual property rights of others;
- availability of alternative products from Profound's competitors;
- acceptance of the price of Profound's products relative to those of its competitors;
- acceptance and adoption of its products by physicians/clinicians and the medical community;
- the availability of training necessary for proficient use of Profound's products, as well as willingness of physicians to participate in such training;
- the ability of Profound's sales force to sell enough units at the prices required to meet its revenue targets;
- the perceived risks generally associated with the use of new products and procedures;
- the placement of Profound's products in treatment guidelines published by leading medical organizations;
- the size and growth rate of the market for Profound's products in the major geographies in which it operates or intends to operate;
- ability to market Profound's products effectively at the patient, physician/clinician and medical community level; and
- acceptance of Profound's products by government and third-party payers for adequate coverage and reimbursement.

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

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

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

Any product for which Profound obtains clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, Profound and its suppliers are required to comply with the FDA's QSR and International Standards Organization regulations for the manufacture of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which Profound obtains clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. Profound and its contract manufacturers have been, and anticipate in the future being, subject to such inspections.

The failure by Profound or one of its suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

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

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

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

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

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

Profound may not be able to achieve the benefits of the SONALLEVE MR-HIFU Transaction.

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

Profound relies on third parties to manufacture components of its system and Profound cannot be certain that manufacturing sources will continue to be available or that Profound can continue to outsource the manufacturing of Profound's devices on reasonable or acceptable terms.

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

TULSA-PRO disposables consist of the UA, an endo-rectal cooling device and associated accessories. Due to sterility requirements used in connection with the TULSA-PRO system, the UA must be manufactured under clean conditions. Profound has developed proprietary automated manufacturing test equipment to improve quality and provide scalability as demand grows and is assembled and tested in-house. The endo-rectal cooling device, which does not require sterilization, is assembled and tested in-house.

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

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

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

- Profound or its contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, Profound's suppliers may have excess or inadequate inventory of materials and components;
- Profound or its contract manufacturers and suppliers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- Profound or its contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of Profound's products;
- Profound may experience delays in delivery by its contract manufacturers and suppliers due to changes in demand from Profound or their other customers;
- fluctuations in demand for products that Profound's contract manufacturers and suppliers manufacture for others may affect their ability or willingness to deliver components in a timely manner;
- suppliers or contract manufacturers may wish to discontinue supplying components or services for risk management reasons;
- Profound may not be able to find new or alternative components or reconfigure its system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- contract manufacturers and suppliers may encounter financial hardships unrelated to Profound's demand, which could inhibit their ability to fulfill orders and meet Profound's requirements.

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

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

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

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

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

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

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

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

Profound may experience scaling issues due to growth.

As Profound expands its manufacturing capabilities in order to meet its growth objectives, it may not be able to produce sufficient quantities of products or maintain consistency between differing lots of consumables. If Profound encounters difficulties in scaling its manufacturing operations as a result of, among other things, quality control and quality assurance issues and availability of components and raw material supplies, it will likely experience reduced sales of its products, increased repair or re-engineering costs due to product returns, defects and increased expenses due to switching to alternate suppliers, and reputational damage, any of which would reduce revenues and gross margins. In addition, Profound's ability to operate such facilities successfully will greatly depend on its ability to hire, train and retain an adequate number of employees, in particular employees with the appropriate level of knowledge, background and skills. Profound will compete with several other medical device companies to hire these

skilled employees. Should Profound be unable to hire such employees, and an adequate number of them, its business and financial results could be negatively impacted.

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

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

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

If Profound's facilities are damaged or destroyed, it may experience delays that could negatively impact its revenues.

Profound's facilities may be affected by natural or man-made disasters. If Profound's facilities were affected by a disaster, it would be forced to rely on third party manufacturers or to set up production at another manufacturing facility. In such an event, Profound might not be able to find a suitable alternate manufacturer or might face significant delays in manufacturing which would prevent it from being able to sell its products. In addition, Profound's insurance may not be sufficient to cover all of the potential losses and may not continue to be available to it on acceptable terms, or at all.

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

Profound may rely on third parties to provide clinical trial planning and execution, regulatory and sales and marketing services for its device in certain geographic regions. Profound may be unable to find suitable partners, external consultants or service providers to provide such services outside of Canada or such arrangements may not be available on commercially reasonable terms. There can be no assurances that Profound will be able to enter into manufacturing or other collaborative arrangements with third parties on acceptable terms, if at all. Further, Profound may engage third parties that may cease to be able to provide these services, or may not provide these services in a timely or professional manner. Accordingly, Profound may not be able to successfully manage such services, execute clinical trials or generate revenues from its

devices in such regions, which may result in decreases in sales. If Profound fails to establish such arrangements when, and as necessary, it could be required to undertake these activities at its own expense, which would significantly increase capital requirements and may delay the development, manufacturing and commercialization of Profound's product. If Profound is unable to address these capital requirements, it would likely be forced to sell or abandon its business. Additionally, any delay or interruption in the process or in payment could result in a delay delivering product to its customers, which could have a material adverse effect on Profound's business, financial condition and operating results.

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

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

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

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

If Profound's products cause or contribute to a death or a serious injury, or malfunction in certain ways, they will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that reasonably suggests that one of their marketed devices may have caused or

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

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

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

Physicians/clinicians, however, in most jurisdictions, can use these products in ways or circumstances other than those strictly within the scope of the regulatory clearance or approval. Although the product training Profound will provide to physicians and other health care professionals will be limited to cleared/approved uses or for clinical trials, no assurance can be given that claims might not be asserted against Profound if its products are used in ways or for procedures that are not approved.

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

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

Further, this industry is also subject to changing industry standards, market trends and customer preferences and to competitive pressures which can, among other things, necessitate revisions in pricing strategies, price

reductions and reduced profit margins. The success of Profound will depend, in part, on its ability to secure technological superiority in its product and operations and maintain such superiority in the face of new technologies. No assurance can be given that further modification of product offerings of Profound will not be required in order to meet demands or to make changes necessitated by developments made by competitors that might render services and operations of Profound less competitive. The future success of Profound will be influenced by its ability to continue to adapt its device. Although Profound has committed resources to research and develop its device, there can be no assurance that these efforts will be successful.

Market may not accept Profound's products and may continue to use the incumbent products.

The market may not accept Profound's products and may continue to use the incumbent products. The TULSA-PRO and SONALLEVE systems may not be adopted as Profound expects and its treatment may not be considered an advantage by some or all physicians/clinicians, adversely affecting Profound's ability to see its products become profitable. Many of Profound's competitors have more resources and will be more effective at commercializing current and future products that compete with the TULSA-PRO and SONALLEVE systems.

Profound depends on key managerial personnel for its continued success.

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

Profound's good labour relations may not continue.

14 of Profound's employees in Vantaa, Finland are unionized. Currently, labour relations are good; however, the maintenance of a productive and efficient labour environment cannot be assured. If any of Profound's employees at its other manufacturing facilities unionize in the future, or if protracted and extensive work stoppages occur, labour disruptions such as strikes or lockouts could have a material adverse effect on Profound's business and financial results.

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

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

Research and development of products carries substantial technical risk and Profound may not be able to successfully commercialize its current and future products.

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

Profound may not achieve its development goals in time frames announced and expected.

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

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

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

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

With respect to any products for which Profound obtains regulatory clearance or approval, it will be subject to post-marketing regulatory obligations, including requirements by the FDA, EU competent authorities, Health Canada and similar agencies in other jurisdictions to maintain records regarding product safety and to report to regulatory authorities serious or unexpected adverse events. The occurrence of unanticipated serious adverse events or other safety problems could cause the governing agencies to impose significant restrictions on the indicated uses for which the product may be marketed, impose other restrictions on the distribution or sale of the product or require potentially costly post-approval studies. In addition, post-market discovery of previously unknown safety problems or increased severity or significance of a pre-

existing safety signal could result in withdrawal of the product from the market and product recalls. Compliance with extensive post-marketing record keeping and reporting requirements requires a significant commitment of time and funds, which may limit Profound's ability to successfully commercialize approved products.

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

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

In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. In 2016, Congress enacted the 21st Century Cures Act, which included a number of modifications to the medical device provisions of the FDCA, including a new priority review program for "breakthrough devices". Further, the FDA Reauthorization Act of 2017, amended certain pre- and post-market requirements for medical devices. For example, the legislation imposed a new user fee for de novo classification requests. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon Profound and delay Profound's ability to obtain new 510(k) clearances or PMA approvals or increase the costs of compliance. Any change in the laws or regulations that govern the clearance and approval processes relating to Profound's products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for Profound's products would have a material adverse effect on Profound's business, financial condition and operating results.

Another example can be found in the European Union. In May 2017, the EU adopted a new Regulation on medical devices and a new Regulation on in vitro diagnostic medical devices, which will take effect on May 26, 2020 and May 26, 2022, respectively. The Regulations do not set out a substantially different regulatory system, but clearly envisage, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations as regards clinical data for devices and pre-market regulatory review of high-risk devices. The new legislation may prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payers are under intense pressure to control healthcare spending even more tightly. As a result, Profound's businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. In recent years, national, federal, provincial, state and local officials and legislators have proposed, or are reportedly considering proposing, a variety of price-based reforms to the healthcare systems in the United States, the European Union and other countries. Some proposals include measures that would limit or eliminate payments for certain medical procedures and treatments or subject pricing to government control. Furthermore, in certain foreign markets, the pricing or profitability of healthcare products is subject to government controls and other measures that have been prepared by legislators and government officials. While Profound cannot predict

whether any such legislative or regulatory proposals or reforms will be adopted, the adoption of any such proposals or reforms could adversely affect the commercial viability of Profound's existing and potential products.

The 2010 Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "ACA") was intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The legislation imposes a number of changes to the U.S. healthcare market that are designed to reduce the number of uninsured individuals through, among other things, expansion of certain federal and state healthcare programs such as Medicaid, and establishment of health insurance exchanges. In addition, the legislation imposes changes directly affecting the device industry, specifically taxes on medical device makers in the form of a 2.3% excise tax on all medical device sales in the United States. President Obama signed into law a bill that included a two-year suspension of the medical device tax beginning in January 2016. Although that suspension expired on December 31, 2017, on January 22, 2018, President Trump signed legislation delaying implementation of the medical device excise tax for an additional two years. The tax will now go into effect on January 1, 2020, if the delay is not further extended or the medical tax is not permanently repealed. It is uncertain whether future legislation will suspend, modify or repeal this tax. The tax could materially and adversely affect Profound's business, cash flows and results of operations.

The ACA also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the law includes a productivity adjustment, or reduction in the annual rate of inflation for Medicare payments to a number of providers, including hospitals, that began in 2011. The United States President and certain members of the U.S. Congress have indicated their desire to repeal and replace all or portions of the ACA and to decrease fiscal burdens. Recent legislation has been passed addressing certain ACA measures and effectively repealing the individual mandate insurance requirement. In addition, in December 2018, a federal district court judge in Texas found the ACA to be unconstitutional, although the ruling was stayed while the case is appealed. It is unclear whether, when and how a repeal of, or a court order enjoining, the ACA repeal would be effectuated and what the effect on the healthcare sector would be.

Other measures by the current administration that address ACA provisions include regulatory changes to healthcare insurance exchange parameters. According to the administration's statements describing the changes, they are intended to increase flexibility, improve affordability, promote stability, and reduce unnecessary burdens. Profound cannot predict the full effect of these new measures, what other health care laws, and regulations and programs will be ultimately implemented at the federal or state level, or the effect of any future legislation, regulation or court order. However, any changes that lower reimbursement for Profound's products or reduce medical procedure volumes could adversely affect Profound's business and results of operations. Changes in the law or regulatory framework that reduce Profound's revenues or increase Profound's costs could also have a material adverse effect on its business, financial condition and results of operations and cash flows.

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

Existing and proposed changes in the laws and regulations affecting public companies may cause Profound to incur increased costs as it evaluates the implications of new rules and responds to new requirements. Failure to comply with the new rules and regulations could result in enforcement actions or the assessment of other penalties. The new laws and regulations could make it more difficult to obtain certain types of insurance, including directors' and officers' liability insurance, and Profound may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

The impact of these events could also make it more difficult for Profound to attract and retain qualified persons to serve on Profound's board of directors, or as executive officers. Profound may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause Profound's general and administrative costs to increase beyond what it currently has planned. Profound is presently evaluating and monitoring developments with respect to these rules, and it cannot predict or estimate the amount of the additional costs it may incur or the timing of such costs.

Rising insurance costs could negatively impact Profound's profitability.

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

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

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

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

Unexpected product safety or efficacy concerns may arise leading to product recalls, withdrawals or declining sales, as well as product liability, consumer fraud and/or other claims.

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

Physicians/clinicians misuse could result in negative publications, negative sentiment or adverse events, thereby limiting future sales of the products.

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

Even after Profound's products receive regulatory approval, modifications to Profound's products may require new regulatory clearances or approvals or may require Profound to recall or cease marketing its products until clearances or approvals are obtained.

Modifications to Profound's products may require the submission of new 510(k) notifications, PMA applications, or other regulatory agency approval applications or documents. If a modification is implemented to address a safety concern, Profound may also need to initiate a recall or cease distribution of the affected device. In addition, if the modified devices require the submission of a 510(k) or PMA and Profound distributes such modified devices without a new 510(k) clearance or PMA approval, Profound may be required to recall or cease distributing the devices. The FDA can review a manufacturer's decision not to submit a modification and may disagree. The FDA may also on its own initiative determine that clearance of a new 510(k) or approval of a new PMA submission is required. Profound may make additional modifications to its products in the future that it believes do not or will not require clearance of a new 510(k) or approval of a new PMA. If Profound begins manufacture and distribution of the modified devices and the FDA later disagrees with its determination and requires the submission of a new 510(k) or PMA for the modifications, it may also be required to recall the distributed modified devices and to stop distribution of the modified devices, which could have an adverse effect on its business. If the FDA does not clear or approve the modified devices, Profound may need to redesign the devices, which could also harm its business. When a device is marketed without a required clearance or approval, the FDA has the authority to bring an enforcement action, including injunction, seizure and criminal prosecution. The FDA considers such additional actions generally when there is a serious risk to public health or safety and the company's corrective and preventive actions are inadequate to address the FDA's concerns.

Where Profound determines that modifications to its products require clearance of a new 510(k) or approval of a new PMA or PMA supplement, Profound may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Economic Area, Profound must notify a notified body, if significant changes are made to the products or if there are substantial changes to its quality assurance systems affecting those products. Delays in obtaining required future clearances or approvals would adversely affect Profound's ability to introduce new or enhanced products in a timely manner, which in turn would harm its future growth.

Profound is subject to "fraud and abuse" laws, anti-bribery laws, environmental laws and privacy and security regulations. Any violation by Profound's employees or other agents could expose Profound to severe penalties and other consequences that may have a material adverse effect on its business, financial condition and results of operations.

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

Profound's operations may be directly or indirectly affected by various broad United States or foreign healthcare fraud and abuse laws. In particular, the United States federal healthcare program Anti-Kickback Statute prohibits any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in return for or to induce the referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of an item or service, for which payment may be made under United States federal healthcare programs, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between device manufacturers on one

hand and prescribers and purchasers on the other. For example, the United States government has sought to apply the Anti-Kickback Statute to device manufacturers' financial relationships with physician consultants. Among other theories, the United States government has alleged that such relationships are payments to induce the consultants to arrange for or recommend the ordering, purchasing or leasing of the manufacturers' products by the hospitals, medical institutions and other entities with whom they are affiliated. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and arrangements that involve remuneration that could induce prescribing, purchases, or recommendations may be subject to government scrutiny if they do not qualify for an exemption or a safe harbor.

Also, the U.S. False Claims Act prohibits persons from knowingly submitting, or causing to be submitted, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act can be brought by the United States government or they can be brought by an individual on behalf of the United States government, as "qui tam" actions, and such individuals, commonly known as "whistleblowers," may share in any damages paid by the entity to the United States government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the United States government, plus civil penalties of up to \$11,000 for each separate false claim. Various states have also enacted laws modeled after the False Claims Act.

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

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject Profound to significant liability.

Profound may use hazardous materials in its research and development and manufacturing processes. Profound is subject to various regulations governing use, storage, handling and disposal of these materials and associated waste products. Profound will need one or more licenses to handle such materials, but there can be no assurance that it will be able to retain these licenses in the future or obtain licenses under new regulations if and when they are required by governing authorities. Profound cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and it may incur liability as a result of any such contamination or injury. In the event of an accident, Profound could be held liable for damages or penalized with fines, and the liability could exceed our resources and any applicable insurance. Profound will also incur expenses related to compliance with environmental laws. Such future expenses or liability could have a significant negative impact on its business, financial condition and results of operations. Further, Profound cannot assure that the cost of compliance with these laws and regulations will not materially increase in the future. Profound may also incur expenses related to ensuring that its operations comply with environmental laws related to its operations, and those of prior owners or operators of any properties it may own, at manufacturing sites where operations have previously resulted in spills, discharges or other releases of hazardous substances into the environment. Profound could be held strictly liable under

environmental laws for contamination of property that it occupies without regard to fault or whether its actions were in compliance with law at the time. Profound's liability could also increase if other responsible parties, including prior owners or operators of its facilities, fail to complete their clean-up obligations or satisfy indemnification obligations to Profound. Similarly, if Profound fails to ensure compliance with applicable environmental laws in foreign jurisdictions in which it operates, Profound may not be able to offer its products and may be subject to civil or criminal liabilities.

Profound is exposed to foreign currency risk and currently Profound has not hedged against risk associated with foreign exchange rate exposure.

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

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

General national and worldwide economic conditions may materially and adversely affect Profound's financial performance and results of operations.

Profound's operations and performance depend significantly on national and worldwide economic conditions and the resulting impact on purchasing decisions and the level of spending on its products by customers in the geographic markets in which Profound's products will be sold or distributed. These economic conditions remain challenging in many countries and regions, including without limitation the United States, Europe and Asia. If Profound's customers do not obtain or do not have access to the necessary capital to operate their businesses, or are otherwise adversely affected by a deterioration in national or worldwide economic conditions, this could result in reductions in the sales of Profound's products, longer sales cycles and slower adoption of new technologies by its customers, which would materially and adversely affect Profound's business. In addition, Profound's customers', and suppliers' liquidity, capital resources and credit may be adversely affected by their relative ability or inability to obtain capital and credit, which could adversely affect Profound's ability to collect on its outstanding invoices or lengthen its collection cycles, distribute its products or limit its timely access to important sources of raw materials and components necessary for the manufacture of its products.

Profound's reported or future financial results could be adversely affected by the application of existing or future accounting standards.

Generally accepted accounting principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Profound's ability to properly interpret these principles and implement internal controls may result in errors in its reported financial results. As well, changes in these rules or their interpretation, the adoption of new guidance or the application of existing guidance to changes in Profound's business could have a significant adverse effect on its financial results. Profound cannot predict if or when any such change could be made, and any such change could have an adverse impact on its reported or future financial results, and the results that such change would have on its access to capital.

Profound is increasingly dependent on sophisticated information technology systems to operate its business and if Profound fails to properly maintain the integrity of its data, if its products do not operate as intended

or it experiences a cyber-attack or other breach of these systems, Profound's business could be adversely affected.

Profound is increasingly dependent on sophisticated information technology for its development activities, products and infrastructure. Profound relies on information technology systems to process, transmit and store electronic information in its day-to-day operations. The complexity of Profound's information technology systems makes the Company vulnerable to increasingly sophisticated cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Profound's products and its information systems require an ongoing commitment of resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, and changing customer patterns.

In addition, third parties may attempt to hack into Profound's products or systems and may obtain data relating to patients, its products or the Company's proprietary information. If Profound fails to maintain or protect its information systems and data integrity effectively, it could lose existing customers, have difficulty attracting new customers, have problems in determining product cost estimates and establishing appropriate pricing, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, physicians, and other health care professionals, become subject to litigation, have regulatory sanctions or penalties imposed, experience increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach, or suffer other adverse consequences.

Risk Factors Relating to Intellectual Property

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

Profound licenses certain development and commercialization rights for certain offerings, and expects to enter into similar licenses in the future. For instance, Profound licenses exclusive rights from Sunnybrook that enable it to use, manufacture, distribute and sell the TULSA-PRO device. Under this license, Profound is subject to various obligations, including a milestone payment of \$250,000 upon obtaining FDA clearance, and legal costs associated with patent application preparation, filing and maintenance. If Profound breaches any of the agreements under which Profound licenses rights to its technology from third parties, Profound could lose license rights that are important to its business. Certain of Profound's license agreements may not provide an adequate remedy for their breach by the licensor.

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

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

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

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

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

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

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

in non-litigation settings. The costs of patent enforcement or invalidity proceedings could be substantial, result in adverse determinations, and divert management attention from Profound's business.

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

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

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

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

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

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

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

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

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

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

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

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

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

Patent laws in the United States as well as the laws of certain other jurisdictions provide for provisional rights in published patent applications beginning on the date of publication, including the right to obtain reasonable royalties, if a patent is subsequently issued and certain other conditions are met. While Profound believes that there may be multiple grounds on which to challenge the validity of United States patents and the counterparts filed in other jurisdictions possibly relevant to Profound's business, Profound cannot predict the outcome of any invalidity challenge. Alternatively, it is possible that Profound may determine

it is prudent to seek a license from a patent holder to avoid potential litigation and other potential disputes. Profound cannot be sure that a license would be available to it on acceptable terms, or at all.

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

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

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

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

Risk Factors Relating to Ownership of Profound's Common Shares

Future sales or the issuances of Profound's securities may cause the market price of Profound's equity securities to decline.

The market price of Profound's equity securities could decline as a result of issuances of securities by Profound or sales by its existing shareholders of Common Shares in the market, or the perception that these sales could occur, during the currency of this AIF. Sales of Common Shares by shareholders may make it more difficult for Profound to sell equity securities at a time and price that Profound deems appropriate. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales could occur, may adversely affect prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares, investors will suffer dilution to their voting power and Profound may experience dilution in its earnings per share.

Profound expects that Profound's share price may fluctuate significantly.

The market price of securities of many companies, particularly development stage medical device companies, experience wide fluctuations in price that are not necessarily related to the operating performance, underlying asset values or prospects of such companies.

The market price of Profound's Common Shares could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond Profound's control, including:

- Adverse results or delays in TACT;
- Unanticipated efficacy, safety or tolerability concerns related to the use of TULSA-PRO and SONALLEVE;
- Regulatory actions with respect to TULSA-PRO and SONALLEVE;
- Changes in laws or regulations applicable to TULSA-PRO or SONALLEVE or any future product candidates, including but not limited to clinical trial requirements for approvals;
- Profound's inability to effectively promote and market TULSA-PRO and SONALLEVE or other product candidates in desired jurisdictions;
- Actual or anticipated fluctuations in Profound's financial condition and operating results;
- Actual or anticipated changes in Profound's growth rate relative to Profound's competitors;
- Competition from existing products or new products that may emerge;
- Announcements by Profound, Profound's collaborators or Profound's competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- Failure to meet or exceed financial estimates and projections of the investment community or that Profound provides to the public;
- Issuance of new or updated research or reports by securities analysts;
- Fluctuations in the valuation of companies perceived by investors to be comparable to Profound;
- Share price and volume fluctuations attributable to inconsistent trading volume levels of Profound's shares;
- Additions or departures of key management or scientific personnel;
- Disputes or other developments related to proprietary rights, including patents, litigation matters and Profound's ability to obtain patent protection for its products;
- Announcement or expectation of additional debt or equity financing efforts;
- Sales of Profound's Common Shares by Profound, Profound's insiders or Profound's other shareholders; and
- General economic and market conditions.

These and other market and industry factors may cause the market price and demand for Profound's Common Shares to fluctuate substantially, regardless of Profound's actual operating performance, which may limit or prevent investors from readily selling their Common Shares and may otherwise negatively affect the liquidity of Profound's Common Shares. In addition, the stock market in general, and the TSX-V and the share prices of biotechnology companies in particular, have experienced extreme price and volume

fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Profound may be subject to securities litigation, which is expensive and could divert management attention.

The market price of Profound's Common Shares may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. Profound may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact Profound's business. Any adverse determination in litigation could also subject Profound to significant liabilities.

Profound has never paid dividends on Profound's Common Shares and Profound does not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in Profound's Common Shares will likely depend on whether the price of Profound's Common Shares increases.

Profound has not paid dividends on Profound's Common Shares to date and Profound currently intends to retain Profound's future earnings, if any, to fund the development and growth of Profound's business. As a result, capital appreciation, if any, of Profound's Common Shares will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in Profound's Common Shares if the price of Profound's Common Shares increases.

If equity research analysts do not publish research or reports about Profound's business or if they issue unfavorable commentary or downgrade Profound's Common Shares, the price of Profound's Common Shares could decline.

The trading market for Profound's Common Shares will rely in part on the research and reports that equity research analysts publish about Profound and Profound's business. Profound does not control these analysts. The price of Profound's Common Shares could decline if one or more equity analysts downgrade Profound's Common Shares or if analysts issue other unfavorable commentary or cease publishing reports about Profound or Profound's business.

ITEM 5. ACQUISITIONS

On July 31, 2017, Profound entered into the Philips Agreement with Philips in order to seek to expand the existing collaboration and acquire Philip's SONALLEVE MR-HIFU business.

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

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

As part of the SONALLEVE Transaction, Philips and Profound expanded their non-exclusive strategic sales relationship for Profound's TULSA-PRO system to include distribution of SONALLEVE.

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

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

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

ITEM 6. INTELLECTUAL PROPERTY

The Company's intellectual property is comprised of a broad and world-wide portfolio of patents, patent applications, trademarks, copyrights, trade secrets and other proprietary assets. The Company's intellectual property portfolio is both growing and dynamic and includes approximately 35 patent families representing about 107 granted or allowed patents and about 60 patent applications in various stages of review and prosecution around the world.

Many of the Company's patents and patent applications claim electronic and mechanical aspects of hardware, software and methods related to ultrasonic ablation of tissue. The intellectual property assets are largely directed to (i) using real time MRI imaging as a tool to plan, monitor or control said ultrasonic ablation; (ii) MRI thermometry methods, especially in respect of the Company's ultrasound therapy processes and devices; (iii) the phasing, beam-forming, and control of acoustic arrays and similar energy sources; (iv) computational method to improve filtering, imaging and analyzing the results of MRI-guided thermal therapy processes; and (v) secondary and support systems such as active cooling of near-target tissues. The portfolio covers both the "TULSA" and the "SONALLEVE" families of products, as well as generic technologies and applications and extensions of the Company's products.

The Company believes that the protection of its intellectual property is an essential element of its business and the Company intends to continue its investment in the development of its intellectual property portfolio. The Company has worked over the past year to pursue, maintain and expand on the intellectual property portfolio acquired from Philips in 2017. This intellectual property has been strengthened and extended to many jurisdictions around the globe in support of the sales, development and marketing efforts of the Company.

The Company pursues a global intellectual property strategy, registering for patent protection in all jurisdictions where it intends to carry on business, including the United States, Canada, Japan, major European markets (e.g., Germany, France, U.K., Italy, Spain and Turkey) and the emerging markets (e.g., Brazil, Russia, India, and China).

The Company also relies upon trade secrets, know-how and other proprietary, confidential information for the protection of its technology. The Company requires all employees, consultants, scientific advisors and other contractors to enter into confidentiality agreements to protect against the disclosure of such proprietary information. Each inventor is required to execute a formal assignment specific to each invention that he or she is listed, and which is officially recorded in the proper patent office.

In addition to developing its own intellectual property portfolio, the Company has licensed and acquired intellectual property rights from third parties through exclusive licenses, collaborative research and asset purchase agreements. Material license agreements include an exclusive license to granted and pending patents owned by Sunnybrook, directed to MR-guided ultrasound ablation systems and methods.

ITEM 7. HUMAN RESOURCES

As of the date of this AIF, Profound has 64 full-time employees, 13 of whom are unionized. Profound believes that its relations with its employees are positive. The Company will be adding staff and consulting resources in order to support product development, market access, field support and additional clinical trials.

ITEM 8. 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.

ITEM 9. DESCRIPTION OF CAPITAL STRUCTURE

The authorized capital of Profound consists of an unlimited number of Common Shares.

Common Shares

As at December 31, 2018, there were a total of 108,054,939 Common Shares issued and outstanding. The holders of the Common Shares are entitled to receive notice of and to attend all annual and special meetings of the shareholders of the Company and to one vote in respect of each common share held at such meetings.

On March 20, 2018, the Company closed a bought deal financing, resulting in the issuance of 34,500,000 units at a price of \$1.00 per unit for gross proceeds of \$34,500,000 (\$32,027,502, net of cash transaction costs). Each unit consisted of one Common Share of the Company and one-half of one Common Share purchase warrant, resulting in the issuance of 34,500,000 Common Shares and 17,250,000 warrants. Each whole warrant has a five-year term and entitles the holder thereof to acquire one Common Share at an exercise price of \$1.40 per Common Share.

On September 20, 2017, the Company closed a bought deal financing, resulting in the issuance of 10,000,000 units at a price of \$1.00 per unit for gross proceeds of \$10,000,000 (\$8,913,868, net of cash transaction costs). Each unit consisted of one Common Share of the Company and one-half of one Common Share purchase warrant, resulting in the issuance of 10,000,000 Common Shares and 5,000,000 warrants. Each whole warrant has a three-year term and entitles the holder thereof to acquire one Common Share at a price of \$1.40 per Common Share.

Share Options and Warrants

As at December 31, 2018, a total of 6,244,779 share options were outstanding under the Company's Share Option Plan and 22,571,714 warrants were outstanding.

ITEM 10. MARKET FOR SECURITIES

10.1 Trading Prices and Volume

Profound's Common Shares are listed and posted for trading on the TSX under the trading symbol "PRN". The following table sets forth the price range per Common Share and trading volume for the Common Shares on the TSX-V and TSX, for the period indicated:

Month	High	Low	Volume
January 2018	\$1.08	\$0.78	1,869,733
February 2018	\$1.19	\$0.95	2,521,973
March 2018	\$1.17	\$0.91	2,112,264
April 2018	\$1.06	\$0.88	1,057,666
May 2018	\$1.25	\$0.91	4,190,932
June 2018	\$1.10	\$0.96	486,890
July 2018	\$1.03	\$0.90	566,938
August 2018	\$1.07	\$0.80	1,164,485
September 2018	\$0.92	\$0.69	1,353,023
October 2018	\$0.73	\$0.54	3,068,582
November 2018	\$0.75	\$0.56	2,045,337
December 2018	\$0.69	\$0.46	1,852,493

10.2 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
March 28, 2018	\$0.99	33,000
May 22, 2018	\$1.19	918,000
June 15, 2018	\$1.02	115,500
August 23, 2018	\$0.93	900,000
November 19, 2018	\$0.60	33,000

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
March 20, 2018	\$1.00	34,500,000
May 7, 2018	\$0.24	100,000
June 11, 2018	\$0.24	226,562
June 27, 2018	\$0.24	100,000
September 24, 2018	\$0.30	11,000

Warrants

The following table summarizes the issuances of Warrants for the most recently completed financial year.

Date of Issuance	Exercise Price (\$)	Number of Options Granted
March 20, 2018	\$1.40	17,250,000
July 31, 2018	\$0.97	321,714

Share Option Plan

The Share Option Plan is administered by the board of directors of the Company 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 Company on June 4, 2015, and then amended and restated on December 8, 2016 and again on July 13, 2018.

The Share Option Plan provides that the board of directors of the Company 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 Company non-transferable options to purchase Common Shares, *provided 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.

The aggregate number of Common Shares that may be (i) issued to insiders of the Company within any one-year period, or (ii) issuable to insiders of the Company at any time, in each case, under the Share Option Plan alone or when combined with all other security-based compensation arrangements of the Company cannot exceed 10% of the outstanding Common Shares.

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 exercised, cancelled, expired, surrendered or otherwise terminated will once again be available for purchase pursuant to an option granted under the Share Option Plan;
2. the expiry date for an Option shall not be later than the 10th anniversary of the date an Option is granted, subject to the expiry date falling with a corporate blackout period or within 5 business days following the expiry of such a blackout period, in which case the expiry date will be extended to the 10th business day following the expiry of the blackout period; and
3. unless otherwise specified by the board of directors, each Option generally vests and becomes exercisable as to 1/4 of the optionee's Common Shares on the first anniversary of the date of grant and as to 1/36 of the optionee's Common Shares on the first day of each calendar month thereafter.

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

As of the date of this AIF, there are Options for 5,409,779 Common Shares under the Share Option Plan with a weighted-average exercise price of \$1.15 and a weighted-average contractual life of 7.81 years.

10.3 Escrowed Securities and Securities subject to Contractual Restriction or Transfer

The following table sets forth, as of the date of this AIF, the number of securities of each class of securities of the Company held, to the knowledge of the Company, in escrow or that is subject to a contractual restriction on transfer, and the percentage that number represents of the outstanding securities of that class.

Designation of Class	Number of Securities held in Escrow or that are Subject to a Contractual Restriction on Transfer	Percentage of Class ⁽¹⁾
Common Shares	-	-%
Options	4,554,779	84.0%
Warrants	-	-%

Notes:

- (1) Together this represents an approximate 3.3% interest in the Company.

ITEM 11. DIRECTOR AND OFFICERS

11.1 Directors and Executive Officers

Set out below is information with respect to the directors and officers of the Company as of December 31, 2018:

Name and Place of Residence	Age	Positions with the Company and Date First Appointed to the Board (if applicable)	Principal Occupation for the Past 5 years
DAMIAN LAMB ⁽¹⁾⁽⁹⁾ Toronto, Ontario, Canada	47	Director June 4, 2015	Co-Founder of Genesys Capital (since April 2000)
JEAN-FRANÇOIS PARISEAU ⁽²⁾⁽⁵⁾⁽⁶⁾ Montréal, Québec, Canada	49	Director June 4, 2015	Partner, BDC Capital Healthcare Fund (since July 2001).
WILLIAM CURRAN ⁽⁵⁾⁽⁶⁾⁽⁷⁾ Rye, New York, USA	70	Director June 4, 2015	Director, Chairman of Audit Committee and member of Compensation Committee of 3D Systems Corporation (since 2008); previously non-Executive Chairman and Director of Resonant Medical Inc.
ARUN MENAWAT ⁽⁶⁾ Oakville, Ontario, Canada	64	Chief Executive Office August 15, 2016 Director June 4, 2015	President and Chief Executive Officer of Novadaq Technologies Inc. (from April 2003 to July 2016).
SAMIRA SAKHIA ⁽³⁾⁽⁶⁾ Montreal, Quebec, Canada	50	Director March 3, 2017	President of Knight (since August 2016); Chief Financial Officer of Knight (since October 2017); Interim Chief Financial Officer of Antibe Therapeutics Inc. (from August 2015 to December 2015); Chief Financial Officer of Paladin Labs Inc. (from 2001 to 2015).
KENNETH GALBRAITH ⁽⁴⁾⁽⁶⁾⁽⁸⁾ White Rock, British Columbia, Canada	56	Director January 17, 2017	Founder and Managing Director of Five Corners Capital (since September 2013); General Partner for Venture West Capital (from February 2007 to September 2013).
BRIAN ELLACOTT ⁽⁴⁾⁽⁶⁾ Sanibel Island, Florida, USA	61	Director June 14, 2018	Chief Executive Officer Belmont Instrument (since December 2017); Chief Executive Officer Laborie Medical Technology (July 2013 to September 2017)
ARTHUR L. ROSENTHAL ⁽⁶⁾ Oro Valley, Arizona, USA	72	Director June 14, 2018	Co-Founder and Chief Executive officer of gEyeCue, Ltd. (since December 2011); Professor of Practice in the Biomedical Engineering Department at Boston University (since June 2010).
LINDA MAXWELL ⁽⁶⁾ Toronto, Ontario, Canada	44	Director October 9, 2018	Surgeon (since 2005); Executive Director Biomedical Zone Ryerson University (since June 2015); Technology Transfer Manager University of Oxford (June 2013 to July 2014).
AARON DAVIDSON Caledon, Ontario, Canada	50	Chief Financial Officer and Senior Vice President of Corporate Development May 3, 2018	Chief Financial Officer and SVP of Corporate Development, Profound Medical Inc. (since May 3, 2018); Co-Head and Managing Director of H.I.G. (from January 2004 to May 2, 2018).

Name and Place of Residence	Age	Positions with the Company and Date First Appointed to the Board (if applicable)	Principal Occupation for the Past 5 years
RASHED DEWAN Toronto, Ontario, Canada	51	Vice President of Finance Interim Chief Financial Officer November 17, 2015	Vice President of Finance, 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 Human Resource and Corporate Governance Committee.
- (6) Member of the Board of Directors.
- (7) Chair of the Audit Committee.
- (8) Chair of the Human Resource and Corporate Governance Committee.
- (9) Chair of the Board of Directors.

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

As of December 31, 2018, the directors and executive officers of Profound as a group beneficially own, directly or indirectly, or exercise control or direction, 28,186,536 of the issued and outstanding Common Shares, representing approximately 24.8% of the total votes attaching to all of the then outstanding voting securities of Profound before giving effect to the exercise of options and warrants held by such directors and executive officers (and assuming exercise of all options and warrants held by such individuals, 33,778,815 Common Shares representing approximately 24.7% of the total outstanding voting securities of Profound).

11.2 Director Biographies

Arun Menawat – Chief Executive Officer and Director – Dr. Menawat has an accomplished history of executive leadership success in the healthcare industry. Prior to joining Profound, he served as the Chairman, President and CEO of Novadaq Technologies Inc., a TSX and NASDAQ listed company that marketed medical imaging and therapeutic devices for use in the operating room, since April 2003. Previously, he was President and Chief Operating Officer and Director of another publicly listed medical imaging software company, Cedara Software. 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.

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 is Partner in the BDC Healthcare Fund. He joined BDC Venture Capital in 2001 and has over 20 years of investment and entrepreneurial experience in the healthcare sector. Prior to joining BDC, Jean-François was an investment manager with CDP Capital Technology Ventures, a \$2 billion global fund investing in healthcare, information technology and advanced technologies, where he was responsible for healthcare investments in Canada and the United States. He has invested and managed more than \$200 million in biopharmaceutical and medical device companies in North America. His experience includes transactions in private and in public companies, IPOs, M&A and fund investments. Prior to this, he was CEO of a consulting company specializing in regulatory affairs, and was VP, R&D for a pharmaceutical-product distribution company, both of which he founded. Jean-François also sits on the board of directors of AngioChem, Clementia Pharmaceutical, Imagia Cybernetics, MedDev Commercialization Centre for medical devices and is an advisor to Hacking Health. Jean-François 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.

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.

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 Inc.'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 British Columbia in 2013.

Arthur L. Rosenthal – Director – Dr. Rosenthal is director and Chair of Compensation Committee for LivaNova PLC, a UK global medical technology company. Prior, Dr. Rosenthal served on the Cyberonics

board of directors as a non-executive director and Chair of the Compensation Committee from January 2007 to October 2015. Since June 2010, Dr. Rosenthal has served as Professor of Practice in the Biomedical Engineering Department at Boston University. Since December 2011, Dr. Rosenthal has also served as CEO of gEyeCue, Ltd., which he co-founded, a development stage medical device company working on a guided biopsy for lower and upper gastrointestinal cancer screening. From June 2011 until July 2012, Dr. Rosenthal served as executive vice chairman of Cappella Medical Devices Ltd. (now ArraVasc Ltd.), a development-stage company focused on novel device solutions for coronary artery disease. From June 2009 until June 2011, Dr. Rosenthal served as President and CEO of Cappella, Inc. Dr. Rosenthal served as chairman, from January 2002, and CEO, commencing in January 2005, of Labcoat, Ltd. until its acquisition by Boston Scientific Corporation in December 2008. From January 1994 to May 2000, Dr. Rosenthal was a Senior Vice President, Corporate Officer, and Chief Development Officer of Boston Scientific, and from May 2000 until his retirement in January 2005, he was a Senior Vice President, Chief Scientific Officer, and Executive Committee Member of Boston Scientific. From 2000 until 2010, Dr. Rosenthal served as a non-executive director, and from 2006 through 2009, as chairman of the Remuneration Committee, of Renovo, Ltd., a U.K. based pharmaceutical company that became publicly traded in 2006. In July 2009, Dr. Rosenthal joined the board of Interface Biologics, Inc., a Toronto-based development stage company focused on drug delivery devices, as a non-executive director. In April 2011, Dr. Rosenthal was elected Chairman at Interface Biologics, Inc. From April 2013 to May 2015, Dr. Rosenthal served as non-executive director and Member of the Compensation Committee of Arch Technologies, Inc. and is currently and member of Arch's Clinical Advisory Board. In 2015, Dr. Rosenthal was appointed to the Industrial Advisory Committee, CURAM (National University in Galway, Ireland). Dr. Rosenthal is a Fellow of the American Institute of Medical and Biological Engineering since 2003.

Brian Ellacott – Director – Mr. Ellacott is an experienced global medical device executive. Mr. Ellacott joined Belmont Instrument as Chief Executive Officer in December 2017. Belmont Instrument is a Boston based private equity owned medical device company with a leading global position in fluid warming and infusion systems. Prior to Belmont Instrument, Mr. Ellacott was the President and CEO of Laborie Medical Technologies (“Laborie”). Laborie is a Urology and Gastroenterology medical device company based in Toronto with manufacturing facilities in Toronto, Montreal, Enschede NL, Attikon Switzerland and Portsmouth New Hampshire. Mr. Ellacott joined private equity owned Laborie as President and CEO in July 2013 and in four years completed 14 global acquisitions tripling Laborie’s revenue and increasing EBITDA eight fold. The company was ranked as one of the fastest growing and most profitable medical device companies in the world. Prior to joining Laborie, Mr. Ellacott served as Executive Vice President and General Manager of Invacare’s (NYSE:IVC) \$1 billion North and South American homecare and rehabilitation business. Mr. Ellacott has also held executive positions with Baxter International and American Hospital Supply, with assignments in Canada, Australia and the United States. Mr. Ellacott serves on the board of Belmont and is the past Chairman of the board of the Canadian Assistive Devices Association. Mr. Ellacott holds a Bachelor of Business Administration Degree from Laurier University, Waterloo, Ontario Canada and is a dual United States and Canadian citizen.

Linda Maxwell – Director – Dr. Maxwell, a seasoned surgeon and entrepreneur, is the Founding and Executive Director of the Biomedical Zone, a business incubator for emerging health technology companies. It is an innovative strategic partnership between St. Michael’s Hospital and Ryerson University. Under Dr. Maxwell’s stewardship, the Biomedical Zone has gone from concept to creation to going concern, supporting Toronto’s leading health technology businesses and driving disruption and innovation adoption in the clinical setting. Dr. Maxwell’s breadth of experience and scope of expertise is founded on over a decade and a half as an accomplished head and neck/facial plastic surgeon. Her academic medical career is distinguished by university appointments as a clinical instructor, medical school faculty member, and published scientific author. A frequent public speaker and panelist, Dr. Maxwell has addressed national and international communities on scientific research, innovation, and entrepreneurship. Additionally, Dr. Maxwell has worked internationally as a senior tech transfer manager and partnership leader for innovation and commercialization for the National Health Service and University of Oxford. She also worked for Medtronic on business strategy for South America (Brazil) and continues to consult to Medtronic on

international clinical trials as an external medical monitor. In addition to her professional endeavors, Dr. Maxwell is a member of the Institute of Corporate Directors. She serves as a director for Profound Medical, MedicAlert Foundation Canada and Economic Club of Canada. She serves as an innovation and health technology subject matter expert for the Federal government, Canadian Space Agency, Canadian Medical Association, Ontario Chief Innovation Strategist. Dr. Maxwell earned a Bachelor's degree with honors from Harvard University (Biology, cum laude), M.D. from Yale University, and M.B.A. from University of Oxford. She completed six years of residency and fellowship training in surgery at the University of Toronto. Additionally, Dr. Maxwell successfully completed Royal College of Canada, American College of Surgery, and American Board of Facial Plastic Reconstructive Surgery certifications.

11.3 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 and no shareholder holding a sufficient number of securities of Profound to affect materially the control of Profound is as at the date of this AIF, 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 and no shareholder holding a sufficient number of securities of Profound to affect materially the control of Profound is as at the date of this AIF, 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.

ITEM 12. PROMOTER

There are no Promoters of Profound.

ITEM 13. 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.

ITEM 14. INTEREST OF INFORMED PERSONS IN MATERIAL TRANSACTIONS

To the knowledge of management of the Company, 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 Company, directors, proposed directors or officers of the Company, any shareholder who beneficially owns more than 10% of the Common Shares of the Company, or any associate or affiliate of these persons in any transaction since the commencement of the Company's last completed fiscal year or in any proposed transaction, which has materially affected or would materially affect the Company other than as disclosed herein or in the financial statements of the Company for the fiscal year ended December 31, 2017. Reference should be made to the notes to the audited financial statements for a more detailed description of any material transaction.

ITEM 15. TRANSFER AGENT AND REGISTRAR

The Company's registrar and transfer agent is TSX Trust Company at its principal office located in Toronto, Ontario.

ITEM 16. MATERIAL CONTRACTS

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

- Amended and Restated Technology License Agreement dated May 16, 2011 between PMI and Sunnybrook (the "Sunnybrook License");
- Philips Agreement – see "*Alliances and Partnerships – Philips*" and "*Acquisitions*";
- Knight Loan Agreement;
- Transitional Services Agreement dated July 31, 2017 between Philips and PMI (the "Transitional Services Agreement").
- Supply Agreement dated July 31, 2017 between PMI and Philips Medical Systems Nederland B.V. ("Philips Medical") (the "Supply Agreement");
- Intellectual Property Assignment dated July 31, 2017 between Philips and PMI (the "IP Assignment");
- License Agreement dated July 31, 2017 between PMI and Philips (the "License Agreement");
- Noncompetition, Nonsolicitation and Confidentiality Agreement dated July 31, 2017 between Philips and PMI (the "Confidentiality Agreement");
- Resale Purchasing Agreement dated July 31, 2017 between Philips Medical and PMI (the "Resale Purchasing Agreement");
- Share Acquisition Agreement dated July 31, 2017 between Philips and Profound Medical Inc. (the "Share Acquisition Agreement");
- CIBC Loan Agreement; and

Copies of the foregoing documents are available on SEDAR at www.sedar.com.

Sunnybrook License

PMI entered into the Sunnybrook License with Sunnybrook on May 16, 2011, pursuant to which Sunnybrook granted to Profound an exclusive worldwide and royalty-free right to use certain defined Sunnybrook technology in connection with, among other things, manufacturing, marketing and selling products such as the TULSA-PRO system, in the field of MRI-guided transurethral ultrasound therapy. Under the license, Profound is subject to various obligations, including a milestone payment of \$250,000 upon clearance by the FDA of Profound's first product for sale for human use and payment of legal costs associated with patent application preparation, filing and maintenance. If either party to the Sunnybrook License breaches or fails to perform a material obligation and fails to cure such breach or perform such obligations within a 30 day cure period, the non-breaching party may terminate the agreement. Material obligations include Profound agreeing not to use the technology or intellectual property outside of the license scope, not to use the technology or intellectual property outside the field of MRI-guided transurethral ultrasound therapy (or permitting Profound's customers to do so) and not to breach confidentiality obligations.

CIBC Loan Agreement

PMI entered into the CIBC Loan Agreement with CIBC on July 30, 2018, for initial gross proceeds of \$12,500,000 with an interest rate based on prime plus 2.5%. PMI is required to make interest only payments for the first 15 months and monthly repayments on the principal plus accrued interest afterwards for 33 months. All obligations of PMI under the CIBC Loan Agreement are guaranteed by the Company and certain of its current and future subsidiaries and include first priority security interests in the assets of the Company and such subsidiaries. PMI has the ability to draw an additional \$6,250,000 subject to the achievement of certain financing and product development milestones. In connection with the CIBC Loan Agreement, the Company also issued Common Share purchase warrants to CIBC, with each warrant entitling the holder to acquire one Common Share at a price of \$0.97 per Common Share until the date that is 60 months from the closing of the CIBC Loan Agreement, with a cashless exercise feature.

Knight Loan Agreement

PMI entered into the Knight Loan Agreement with Knight on April 30, 2015, pursuant to which Knight loaned \$4,000,000 to PMI. Profound has granted a security interest over all assets (including the shares owned by Profound). The term of the Knight Loan Agreement is initially four years with an interest rate of 15% per annum. Provided that certain conditions are satisfied, PMI has the option to request extensions of the maturity date in one-year increments to a maximum of four times, resulting in a potential eight year term of the Knight Loan Agreement. Following an event of default under the Knight Loan Agreement, an additional 5% interest will be added to the then effective annual rate of interest. Knight was also granted a royalty of 0.5% on net sales resulting from global sales of each of the Company's products, processes or services under development, developed, manufactured, licensed, distributed, marketed or sold by PMI or similar products or services in which PMI has any proprietary rights or beneficial interests for the duration of the Knight Loan Agreement.

Transitional Services Agreement

PMI entered into the Transitional Services Agreement with Philips in connection with the SONALLEVE MR-HIFU Transaction. For a limited time following the transition of the SONALLEVE MR-HIFU business to PMI, Philips and its affiliates will provide services including: information technology support, use of certain Philips' labs and offices and knowledge transfer to Profound personnel. Profound is obliged to use its reasonable endeavours to eliminate its reliance on these transitional services as soon as is reasonably practicable after closing. Payment from Profound to Philips for transitional services provided will be in accordance with the terms listed in Schedule 2 to the Transitional Services Agreement. The Transitional Services Agreement with Philips are all terminated except for the Research and Development scanner use.

Supply Agreement

PMI entered into the Supply Agreement with Philips Medical in connection with the SONALLEVE MR-HIFU Transaction. Under the terms of the Supply Agreement and until such time as the manufacturing of SONALLEVE MR-HIFU is assumed by PMI, Philips Medical agrees to serve as a contract manufacturer to PMI for SONALLEVE MR-HIFU. Both PMI and Philips Medical will work together to ensure that production capacity and delivery times are appropriate to meet PMI's sales forecasts.

IP Assignment

PMI entered into the IP Assignment with Philips in connection with the SONALLEVE MR-HIFU Transaction. Under the terms of the IP Assignment, PMI is assigned certain intellectual property assets from Philips, including applications and registrations for patents and trademarks, related to SONALLEVE MR-HIFU.

License Agreement

PMI entered into the License Agreement with Philips in connection with the SONALLEVE MR-HIFU Transaction. Under the terms of the License Agreement, PMI receives a worldwide license to, among other things, manufacture, sell and lease SONALLEVE MR-HIFU. The license is exclusive to PMI and its affiliates for a period of three years following the date of the License Agreement, after which time the license has a modified exclusivity period of two years and is non-exclusive thereafter.

Confidentiality Agreement

PMI entered into the Confidentiality Agreement with Philips in connection with the SONALLEVE MR-HIFU Transaction. Under the terms of the Confidentiality Agreement, Philips covenants and obliges, among other things, to: i) not compete in the Line of Business, anywhere in the Territory (as defined in the Confidentiality Agreement) for period of three years after closing; ii) not solicit any employee of PMI or any of its affiliates for so long as agreements related to the SONALLEVE MR-HIFU Transaction are in force, plus an additional two years; and iii) maintain in confidence any confidential information that if disseminated would be detrimental to the business, for a period of ten years after closing.

Resale Purchasing Agreement

PMI entered into the Resale Purchasing Agreement with Philips Medical in connection with the SONALLEVE MR-HIFU Transaction. Under the terms of the Resale Purchasing Agreement, Philips Medical is permitted to purchase certain products for the purpose of reselling such products to its customers. PMI is permitted to sell additional consumables directly to a customer of Philips Medical, but only after an initial sale of consumables by Philips and subject to certain conditions in the Resale Purchasing Agreement.

Share Acquisition Agreement

Profound entered into the Share Acquisition Agreement with Philips as part of the payment for the transfer of the SONALLEVE MR-HIFU business to PMI. Under the terms of the Share Acquisition Agreement, Philips acquired 7,400,000 Common Shares, at a price of \$1.10 per Common Share.

ITEM 17. 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 Company'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 Company, including reviewing the Company's procedures for internal control with the Company's auditor and chief financial officer; (ii) reviewing and assessing the quality and integrity of the Company'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 Company and independent audit fees; (v) reviewing the qualifications, performance and independence of the auditor of the Company, 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 Company; (vi) assessing the Company's financial and accounting personnel; (vii) reviewing the Company's risk management procedures; (viii) reviewing any significant transactions outside of the Company's ordinary course of business and any pending litigation involving the Company; 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
KENNETH GALBRAITH	Independent	Financially Literate
WILLIAM CURRAN	Independent	Financially Literate
BRIAN ELLACOTT	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 Company as required by the TSX 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 Company's financial statements.

Audit Committee Oversight

At no time since the commencement of the Company'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 Company's external auditor in the last two fiscal years as follows:

Financial Year Ending	Audit Fees⁽¹⁾	Audit Related Fees⁽²⁾	Tax Fees⁽³⁾	All Other Fees⁽⁴⁾
December 31, 2018	\$365,776	\$0	\$ 61,215	\$0
December 31, 2017	\$313,400	\$29,700	\$186,000	\$0

Notes:

- (1) Audit fees includes annual audit, quarterly reviews and work performed in relation to the bought deals.
- (2) Audit related fees includes work performed on acquisitions.
- (3) Tax fees includes fees related to annual tax returns and scientific research credit return along with tax and transfer pricing advice.

ITEM 18. INTEREST OF EXPERTS

The Company's auditors are PricewaterhouseCoopers LLP, Chartered Professional Accountants, who have prepared an independent auditor's report dated March 7, 2019 in respect of the Company's consolidated financial statements as at December 31, 2018 and December 31, 2017 and for years then ended. PricewaterhouseCoopers LLP has advised that they are independent with respect to the Company within the meaning of the Chartered Professional Accountants of Ontario CPA Code of Professional Conduct.

ITEM 19. ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com. 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 international financial reporting standards (“**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 IFRS 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 Company’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 the 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 Chair of the Committee. If the Chair of the Committee faces a potential or actual conflict of interest, the Chair of the Committee shall advise the Chair of the Board. If the Chair of the Committee, 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 the 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 Company 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.