United States
Securities and Exchange Commission

Washington, D.C. 20549

Form 40-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13(a) OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

Commission File Number 001-39032

Profound Medical Corp.

(Exact name of Registrant as specified in its charter)

Ontario, Canada
(Province or other jurisdiction of incorporation or organization)

3841
(Primary Standard Industrial Classification Code Number (if applicable))

Not Applicable
(I.R.S. Employer Identification Number (if applicable))

2400 Skymark Avenue, Unit 6 , Mississauga, Ontario L4W 5K5 (647) 476-1350
(Address and telephone number of Registrant's principal executive offices)

Profound Medical (U.S.) Inc.
9160 Forum Corporate Parkway, Suite 359 , Fort Myers FL 33905
(647)-476-1350

(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares	PROF	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act.

Not Applicable
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

Not Applicable
(Title of Class)

For annual reports, indicate by check mark the information filed with this Form:

☒ **Annual information form** ☒ **Audited annual financial statements**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

Common Shares as of December 31, 2021: 20,776,217

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ¨

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ¨

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ¨

Principal Documents

The following documents, filed as Exhibits 99.1 through 99.3 hereto, are hereby incorporated by reference into this Annual Report on Form 40-F:

- Annual Information Form of Profound Medical Corp. (the "**Company**") for its fiscal year ended December 31, 2021 (the "**AIF**");
- Management's Discussion and Analysis of the Company for its fiscal year ended December 31, 2021 (the " **MD&A**"); and
- Consolidated Financial Statements of the Company as at December 31, 2021 and 2020 and for the two years in the period ended December 31, 2021 and the related notes and the Report of Independent Registered Public Accounting Firm (PCAOB ID# 271) (the "Annual Financial Statements").

In addition, the certifications and consents required by Form 40-F are filed as Exhibits 99.4 through 99.6 hereto.

Disclosure Controls and Procedures

The information under the heading "Disclosure Controls and Procedures and Internal Controls over Financial Reporting" in the MD&A is incorporated by reference herein.

Management's Annual Report on Internal Control Over Financial Reporting

The information under the heading "Disclosure Controls and Procedures and Internal Controls over Financial Reporting" in the MD&A is incorporated by reference herein.

Attestation Report of the Registered Public Accounting Firm

The Company is an "emerging growth company" as defined in Rule 12b-2 of the U.S. Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and accordingly is not required to provide an attestation report of the registered public accounting firm for the year ended December 31, 2021.

Changes in Internal Control Over Financial Reporting

The information under the heading "Disclosure Controls and Procedures and Internal Controls over Financial Reporting" in the MD&A is incorporated by reference herein.

Identification of Audit Committee

The information under the heading "Item 17. Audit Committee Information" in the AIF is incorporated by reference herein.

Audit Committee Financial Expert

The Company's board of directors has determined that each of Kenneth Galbraith, Cynthia Lavoie and Murielle Lortie, members of its audit committee, is an "audit committee financial expert" (as such term is defined in Form 40-F) and that each member is "independent" (as defined in the listing standards of The Nasdaq Stock Market LLC ("**Nasdaq**")).

Code of Ethics

The Company has adopted a "code of ethics" (as that term is defined in Form 40-F), entitled "Code of Business Conduct" (the "**Code of Ethics**"), that applies to all of its directors, officers and employees. A copy of the Code of Ethics is available on our website at www.profoundmedical.com. All amendments to the Code of Ethics, and all waivers of the Code of Ethics with respect to the Company's principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions, will be posted promptly on our website. In addition, we will provide to any person without charge, upon request, a copy of such Code of Ethics by contacting: Rashed Dewan, Chief Financial Officer, VP Finance, Manufacturing and HR Operations, Profound Medical Corp., 2400 Skymark Avenue, Unit 6, Mississauga, Ontario L4W 5K5, Telephone: (647) 476-1350.

Information contained or otherwise accessed through the Company's website or any other website, other than those documents filed as exhibits hereto, does not form part of this Annual Report on Form 40-F, and any reference to the Company's website herein is as an inactive textual reference only.

Principal Accountant Fees and Services

The information under the heading "Item 17. Audit Committee Information—External Auditor Service Fees (By Category)" in the AIF is incorporated by reference herein. None of the audit-related fees, tax fees and other fees listed under such heading were approved by the audit committee pursuant to a waiver of its pre-approval policies in accordance with paragraph (c)(7)(i)(C) of Rule 2-01 of Regulation S-X in 2021 or 2020.

Notices Pursuant to Regulation BTR

None.

Comparison with Nasdaq Governance Rules

As a "foreign private issuer" (as such term is defined in Rule 3b-4 under the Exchange Act) whose common shares are listed on Nasdaq, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the Nasdaq rules. We intend to adopt and approve material changes to equity incentive plans in accordance with Toronto Stock Exchange ("**TSX**") listing rules, which do not impose a requirement of shareholder approval for such actions. In addition, we intend to follow the TSX listing rules in respect of private placements instead of Nasdaq requirements to obtain shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company) and the minimum quorum requirement for a shareholders meeting. Under Nasdaq listing rules, the required minimum quorum for a shareholders meeting is 33 1/3% of the outstanding common shares, and our minimum quorum requirement is only 10% of the total number of voting rights attaching to all outstanding Common Shares.

UNDERTAKING

The Company undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the U.S. Securities and Exchange Commission ("**Commission**") staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to: the securities registered pursuant to Form 40-F; the securities in relation to which the obligation to file an annual report on Form 40-F arises; or transactions in said securities.

CONSENT TO SERVICE OF PROCESS

Concurrently with this Annual Report on Form 40-F, the Company is filing an amended Form F-X in respect of its Common Shares, the class of securities in relation to which the obligation to file this Annual Report on Form 40-F arises. Any future change to the name or address of the Company's agent for service of process will be communicated promptly to the Commission by a future amendment to the Form F-X referencing the file number of the relevant filing of the Company.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Company certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this Annual Report on Form 40-F to be signed on its behalf by the undersigned, thereto duly authorized.

PROFOUND MEDICAL CORP.

By: /s/ Rashed Dewan
Rashed Dewan
Chief Financial Officer

Dated: March 3, 2022

EXHIBITS

99.1	Annual Information Form, dated March 3, 2022, of the Company for its fiscal year ended December 31, 202 1
99.2	Management's Discussion and Analysis of the Company for its fiscal year ended December 31, 202 1
99.3	Consolidated Financial Statements of the Company as at December 31, 2021 and 2020 and for the two years in the period ended December 31, 2021 and the related notes and the Report of Independent Registered Public Accounting Firm (PCAOB ID# 271)
99.4	Certifications required by Rule 13a-14(a) or Rule 15d-14(a), pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
99.5	Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of United States Code, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.6	Consent of Independent Registered Public Accounting Firm
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

Table of Contents

Exhibit 99.1



PROFOUND MEDICAL CORP.

ANNUAL INFORMATION FORM

FOR THE YEAR ENDED DECEMBER 31, 2021

March 3, 2022

TABLE OF CONTENTS

	Page
SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS	2
MARKET AND INDUSTRY DATA	3
TRADEMARKS AND TRADE NAMES	3
GLOSSARY	4
ITEM 1. CORPORATE STRUCTURE	8
ITEM 2. GENERAL DEVELOPMENT OF THE BUSINESS	9
ITEM 3. NARRATIVE DESCRIPTION OF THE BUSINESS	11
ITEM 4. RISK FACTORS	30
ITEM 5. ACQUISITIONS	58
ITEM 6. INTELLECTUAL PROPERTY	59
ITEM 7. HUMAN RESOURCES	59
ITEM 8. DIVIDENDS	60
ITEM 9. DESCRIPTION OF CAPITAL STRUCTURE	60
ITEM 10. MARKET FOR SECURITIES	60
ITEM 11. DIRECTOR AND OFFICERS	63
ITEM 12. PROMOTER	67
ITEM 13. LEGAL PROCEEDINGS AND REGULATORY ACTIONS	67
ITEM 14. INTEREST OF INFORMED PERSONS IN MATERIAL TRANSACTIONS	67
ITEM 15. TRANSFER AGENT AND REGISTRAR	67
ITEM 16. MATERIAL CONTRACTS	67
ITEM 17. AUDIT COMMITTEE INFORMATION	68
ITEM 18. INTEREST OF EXPERTS	70
ITEM 19. ADDITIONAL INFORMATION	70
SCHEDULE “A” PROFOUND MEDICAL CORP. AUDIT COMMITTEE CHARTER	A-1

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 consolidated subsidiaries Profound Medical Inc., Profound Medical (U.S.) Inc., Profound Medical Oy, Profound Medical GmbH, Profound Medical Technology Services (Beijing) Co., Ltd. and 2753079 Ontario Inc. 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 United States dollars unless otherwise noted. Unless otherwise stated, all references to "$" are to United States dollars and references to "C$" are to Canadian dollars. The information contained herein is dated as of December 31, 2021 (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) and the United States Private Securities Litigation Reform Act of 1995. 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, our expectations regarding commercializing our approved products and our ability to generate revenues and achieve profitability and to expand our products compatibilities, expectations regarding obtaining regulatory approvals, expectations regarding maintenance of the current regulatory approvals we have received, including our compliance with the conditions under such approvals, our ability to pursue reimbursements for our products where we have regulatory approvals, and the expectations regarding the safety and efficacy of its devices, expectations regarding the use of our devices and the revenue, expenses and operations attributable to such devices, plans for and timing of expansion of our product and service offerings, future growth plans, entry into additional manufacturing, licensing, distribution and supply agreements and arrangements in the future, ability to attract and develop and maintain relationships with suppliers, physicians, clinicians, and other key relationships, expectations regarding our ability to obtain alternative supply agreements, expectations regarding our ability to attract and retain personnel**,** expectations regarding the capacity of our manufacturing facilities to meet our manufacturing needs, expectations regarding growth in our product markets, competitive position and our expectations regarding competition, expectations regarding the development of an out of pocket market for our products, ability to raise debt and equity capital to fund future product development, expectations regarding the extent to which COVID-19 and any other pandemic or public health crises will impact our business and the regional economies within which we operate, 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 risks related to our operating history and financial condition, risks related to our business and growth strategy, risks relating to the successful completion of clinical trial phases with respect to Profound's devices, obtaining regulatory approvals in relevant jurisdictions to market Profound's devices, risks related to the regulation of Profound and its products (including general trends in the healthcare markets, lack of funding may limit the ability to commercialize and market Profound's products, fluctuating input prices, international trade and political uncertainty, healthcare regulatory regimes 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, risks relating to Profound's intellectual property (including 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, risks relating to the international scope of Profound's business and operations, risks relating to our Common Shares 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. and www.sec.gov, and on Profound's website at https://profoundmedical.com/investors. Information on the Company's website does not form a part of this AIF and shall not be deemed incorporated by reference herein. 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.

2019 Offering	has the meaning given under the heading "*General Development of the Business – Three-Year History – Recent Highlights*".
2020 Offerings	has the meaning given under the heading "*General Development of the Business – Three-Year History – Recent Highlights*".
3D	means three-dimensional.
ablation	means to remove or destroy tissue.
ACA	means the 2010 Affordable Care Act as amended by Health Care and Education Affordability Reconciliation Act of 2010.
ADT	means androgen deprivation therapy.
AIF	means this annual information form.
Akumin	means Akumin Inc.
Akumin Agreement	has the meaning given under the heading "*Fiscal 2021 Highlights*".
Articles	means our articles of incorporation, as amended.
Audit Committee	has the meaning given under the heading "*Audit Committee Information*".
BDC	means BDC Capital Inc.
Board	means the board of directors of Profound Medical Corp.
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.
Canada MDR	means the Medical Devices Regulations issued by Health Canada's Therapeutic Products Directorate.
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	means the loan in the aggregate principal amount of C$12.5 million, which was repaid in full on February 4, 2020.
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.
CMS	means the Centers for Medicare & Medicaid Services.
Common Shares	means the common shares in the capital of Profound.
Company or Profound	means Profound Medical Corp. and its consolidated subsidiaries Profound Medical Inc., Profound Medical Oy, and Profound Medical GmbH and 2753079 Ontario Inc, except where the context requires reference to Profound Medical Corp. only.
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.
EBRT	means external beam radiation therapy.
Essential Requirements	has the meaning given under the heading "*Narrative Description of the Business – Regulatory – European Union*".

False Claims Act	means the U.S. False Claims Act, 31 U.S.C. §§ 3729-3733.
FCPA	means the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq.
FDA	means the United States Food and Drug Administration, the regulatory authority in the United States that regulates companies that manufacture, repackage, relabel, distribute and/or import food, drugs and/or devices sold in the United States.
FFDCA	means the Federal Food, Drug and Cosmetic Act.
FSCAs	means Field Safety Corrective Actions.
GE	means GE Healthcare.
GE Agreement	has the meaning given under the heading *"Business Strategy"*.
General Safety and Performance Requirements	has the meaning given under the heading "*Narrative Description of the Business – Regulatory – European Union*".
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.
HDE	means a Humanitarian Device Exemption under section 520(m) of the FFDCA.
HDR	means high dose radiation.
HIFU	means high intensity focus ultrasound.
HIPAA	means Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and implementing regulations.
ICFR	means internal control over financial reporting.
IDE	means investigational device exemption; an approved IDE means that the FDA has approved the sponsor's clinical study application.
IFRS	means the International Financial Reporting Standards issued by the International Accounting Standards Board.
IIEF	means the International Index of Erectile Function.
Investment Company Act	means U.S. Investment Company Act of 1940, as amended.
IRB	means an institutional review board.
IVDR	means Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices.
JOBS Act	means the U.S. Jumpstart Our Business Startups Act of 2012, as amended.
Knight	means Knight Therapeutics Inc.
Laborie	means Laborie Medical Technologies.
MDB	means Medical Devices Bureau.
MDD	means the Medical Devices Directive.
Medical Device Directive	means the Council Directive 93/42/EEC concerning medical devices.
Medical Devices License	means 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.
Nasdaq	means The Nasdaq Stock Market LLC.
New EU MDR	has the meaning given under the heading "*Narrative Description of the Business – Regulatory – Overview – European Union Regulation*".
New Siemens Agreement	means the Agreement between PMI and Siemens, dated February 11, 2019.
NMPA	National Medical Products Administration of China.
NI 52-109	means National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings.

Notified Body	has the meaning given under the heading *"Narrative Description of the Business – Regulatory – European Union"*.
OBCA	means the *Business Corporations Act* (Ontario), as amended, together with all regulations promulgated pursuant thereto.
Offerings	means, collectively, the 2019 Offering and each of the 2020 Offerings; " **Offering**" means any of them, as the context may require.
Old PMI	has the meaning given under the heading *"Corporate Structure – Name, Address and Incorporation"*.
Options	means options issued under the Share Option Plan.
PFIC	means passive foreign investment company for U.S. federal income tax purposes.
Philips	means Koninklijke Philips N.V.
Phillips Confidentiality Agreement	has the meaning given under the heading " *Alliances and Partnerships– Philips*".
Philips Medical	has the meaning given under the heading " *Alliances and Partnerships– Philips*".
Phillips Resale Purchasing Agreement	has the meaning given under the heading *"Alliances and Partnerships– Philips"*.
Phillips Share Purchase Agreement	has the meaning given under the heading *"Alliances and Partnerships– Philips"*.
Phillips Supply Agreement	has the meaning given under the heading *"Alliances and Partnerships– Philips"*.
PMA	means a pre-market approval application for marketing approval in the United States.
PMD Act	means Japan's Pharmaceutical and Medical Device Act.
PMDA	means Japan's Pharmaceutical and Medical Device Agency.
PMI	means Profound Medical Inc.
Promoter	means a promoter as prescribed by applicable Securities Laws.
PSA	means prostate specific antigen.
QMS	means a quality management system.
QSR	means the Quality System Regulation promulgated by the FDA, 21 C.F.R. Part 820.
radical prostatectomy	means a surgical procedure that involves the removal of the whole prostate gland.
RadNet	means RadNet Inc.
Sarbanes-Oxley	means the U.S. Sarbanes-Oxley Act of 2002, as amended.
SEC	means the U.S. Securities and Exchange Commission.
Section 404	means Section 404 of Sarbanes-Oxley.
Securities Laws	means Canadian 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.
SEDAR	means the Canadian System for Electronic Document Analysis and Retrieval.
Service	means service revenue for access and support of the multi-use system components
Share Option Plan	means our amended and restated share option plan dated July 13, 2018.
Siemens	means Siemens Healthcare GmbH.
Sonalleve	means the technology acquired from Philips in 2017 underlying our Sonalleve system, which combines real-time MRI and thermometry with focused ultrasound delivered from the outside to the patient to enable precise and incision-free ablation of diseased tissue.
Sonalleve system	means our system utilizing Sonalleve technology.
SONALLEVE MR-HIFU Transaction	has the meaning given under the heading " *Narrative Description of the Business – Alliances and Partnership – Philips*".
Sunnybrook	means the Sunnybrook Health Sciences Centre.
Sunnybrook License	has the meaning given under the heading " *Intellectual Property*".
TACT	means the TULSA-PRO Ablation Clinical Trial.
TPD	means Health Canada's Therapeutic Products Directorate.
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.
TULSA-PRO system	means our leading product, which combines real-time MRI, robotically-driven transurethral sweeping action/thermal ultrasound and closed-loop temperature feedback control, and is comprised of two categories of components: one-time-use devices and the capital equipment used in conjunction with a customer's MRI scanner.
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.
United States or US	means the United States of America.
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 is the company resulting from a "three-cornered" amalgamation involving Mira, Mira Subco (a subsidiary formed to complete the amalgamation) and Profound Medical Inc. ("**Old PMI**"). Old PMI was formed by articles of incorporation under the OBCA on June 13, 2008. Mira was formed by articles of incorporation under the OBCA on July 16, 2014, and following its initial public offering in Canada, 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, in anticipation of the amalgamation, Mira changed its name to "Profound Medical Corp." (becoming "**Profound**") 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. On June 4, 2015, Mira (now "**Profound**"), Mira Subco and Old PMI completed the amalgamation, with Profound as our surviving holding company, and Mira Subco and Old PMI amalgamating to form a new OBCA subsidiary, Profound Medical Inc. ("**PMI**"), to serve as the holding subsidiary of our operating subsidiaries. Upon completion of the amalgamation, we commenced trading on the TSX-V. On July 13, 2018, we graduated from the TSX-V and commenced trading on the TSX under the symbol "PRN". On October 29, 2019, Profound commenced trading on the Nasdaq under the symbol "PROF".

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 direct subsidiary, PMI, and its indirect subsidiaries, Profound Medical Oy (Finland), Profound Medical GmbH (Germany), Profound Medical (U.S.) Inc. (United States), Profound Medical Technology Services (Beijing) Co., Ltd. (China), and 2753079 Ontario Inc. (Canada).

Profound Medical Inc. was incorporated under the OBCA on June 13, 2008 and amalgamated with Mira Subco on June 4, 2015. 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. 2753079 Ontario Inc. was established under the laws of the Province of Ontario on April 23, 2020 as a wholly owned direct subsidiary of PMI. Profound Medical Technology Services (Beijing) Co., Ltd. was established in China on April 1, 2021 as a wholly-owned direct subsidiary of 2753079 Ontario Inc.

The following diagram illustrates the organizational structure of Profound and its 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 (NASDAQ: PROF; TSX: PRN) is a commercial-stage medical device company focused on the development and marketing of customizable, incision-free therapeutic systems for the image guided ablation of diseased tissue utilizing its platform technologies and leveraging the healthcare system's existing imaging infrastructure. Profound's lead product (the "**TULSA-PRO system**") combines real-time MRI, robotically driven transurethral sweeping-action thermal ultrasound with closed-loop temperature feedback control for the ablation of prostate tissue. The product is comprised of one-time-use devices and durable equipment that are used in conjunction with a customer's existing MRI scanner.

In August 2019, the TULSA-PRO system received FDA clearance as a Class II device in the United States for thermal ablation of prescribed prostate tissue, using transurethral ultrasound ablation ("**TULSA**") based on the Company sponsored (" **TACT**") whole gland ablation pivotal clinical study. It is also CE marked in the European Union ("**EU**") for ablation of targeted prostate tissue (benign or malignant). The TULSA-PRO system was approved by Health Canada in November 2019.

Profound is deploying primarily a recurring revenue business model in the United States to market TULSA-PRO, charging a one-time bundled payment per patient that includes the supply of its one-time-use device, use of the durable device as well as the Company's customer and technological support services ("**Genius Services**") that support each TULSA center with clinical and patient recruitment. Historically, Profound generated the majority of its revenues from the limited commercialization of its systems in Europe and Asia and deployed a more traditional hybrid pricing model, in that the Company charged for the durable device separately as capital and an additional per patient charge for the one-time-use devices and associated Genius Services.

Profound's second product, the Sonalleve system, is CE marked in the EU for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone and has also been approved by the regulatory body in China for non-invasive treatment of uterine fibroids. The Sonalleve system is compatible only with certain Philips MRI's.

2.2 Three-Year History

Early 2022 Highlights

On January 5, 2022, Profound announced the joining of Kenneth Knudson as Chief Commercial Officer.

On January 18, 2022, Profound announced that the first patients have been treated in the Level 1 "CAPTAIN" trial.

On March 1, 2022, Profound confirmed that the TULSA-PRO® system's new compatibility with GE Healthcare's 3T MRI scanners.

Fiscal 2021 Highlights

On May 19, 2021, Profound announced the voting results from the 2021 Annual General Meeting of Shareholders and management changes.

On May 6, 2021, Profound announced a multi-site imaging center agreement for TULSA-PRO® with Akumin Inc. (NASDAQ/TSX:AKU) (the "**Akumin Agreement**"), a leading provider of freestanding, fixed-site outpatient diagnostic imaging services in the United States.

On March 3, 2021, Profound announced the appointment of Cynthia Lavoie to its board of directors.

Fiscal 2020 Highlights

On December 21, 2020, Profound signed an agreement with GE Healthcare to expand provider access to TULSA-PRO.

On November 30, 2020, Profound announced the resignation of Dr. Linda Maxwell from the Board and the appointment of Murielle Lortie.

On November 30, 2020, Profound received FDA Humanitarian Device Exemption (" **HDE**") approval for Sonalleve for the treatment of osteoid osteoma.

On July 21, 2020, the Company closed an underwritten offering of Common Shares of the Company at a price of $14.50 per Common Share, resulting in the issuance of 3,172,414 Common Shares for gross proceeds of $46 million (the "**July 2020 Offering**").

On April 3, 2020, Profound launched a TULSA procedure website, www.tulsaprocedure.com, as a resource for patients with prostate disease.

On February 4, 2020, Profound repaid the C$12.5 million CIBC Loan (as defined herein) ahead of schedule.

On January 27, 2020, Profound closed a public offering of 3,392,500 Common Shares at a price of $11.65 for aggregate gross proceeds of approximately $40 million (the "**January 2020 Offering**" and together with the July 2020 Offering, the " **2020 Offerings**").

On January 10, 2020, Profound and RadNet signed Profound's first multi-center commercial agreement for TULSA-PRO.

Fiscal 2019 Highlights.

On November 25, 2019, Profound announced Health Canada approval of TULSA-PRO.

On October 29, 2019, Profound's Common Shares commenced trading on the Nasdaq.

On October 18, 2019, Profound filed a final base shelf prospectus in the United States and Canada to permit offerings of up to C$100 million; the F-10 Registration Statement related thereto became effective with the SEC on October 22, 2019.

On October 11, 2019, Profound implemented a 10:1 share consolidation, effective October 16, 2019, in anticipation of its listing on the Nasdaq.

On September 20, 2019, Profound closed a public offering in Canada and a concurrent private offering in the United States of 10,454,546 units (each unit consists of one Common Share and ½ Common Share purchase warrant) at a price of C$1.10 per unit for aggregate gross proceeds of C$11.5 million (the "**2019 Offering**").

On August 16, 2019, Profound received FDA 510(k) clearance for TULSA-PRO.

On August 15, 2019, Profound appointed Steve Forte to its Board.

On July 9, 2019, Profound sold its first TULSA-PRO system in Japan.

On April 16, 2019, Profound announced the first prostate cancer treatment using a first-of-its-kind TULSA-PRO installation had been performed in Trier, Germany.

On April 4, 2019, Profound announced positive topline results from TACT Pivotal Clinical Trial of TULSA-PRO in patients with prostate cancer.

ITEM 3. NARRATIVE DESCRIPTION OF THE BUSINESS

3.1 General

We are a commercial-stage medical device company focused on the development and marketing of customizable, incision-free therapeutic systems for the ablation of diseased tissue utilizing our platform technologies. Our lead product, the TULSA-PRO system, combines real-time MRI, robotically-driven transurethral sweeping action/thermal ultrasound and closed-loop temperature feedback control to ablate whole gland or physician defined region of malignant of benign prostate tissue. The TULSA-PRO system has shown in clinical and commercial settings to be an effective tool for physicians who are treating prostate diseases including cancer and other conditions such as benign prostatic hyperplasia ("**BPH**"). In August 2019, the TULSA-PRO system received FDA clearance as a Class II device in the United States for thermal ablation of prescribed prostate tissue, using TULSA based on the Company's TACT whole gland ablation pivotal study. It is also CE marked in the EU for ablation of targeted prostate tissue (benign or malignant). The TULSA-PRO system was also approved by Health Canada in November 2019. In addition, our Sonalleve system is CE marked in the EU for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone and is also approved in China for non-invasive treatment of uterine fibroids. In November 2020, the Sonalleve system also received humanitarian device exemption (HDE) approval from the FDA for treatment of osteoid osteoma. Our systems are designed to be used with MRI scanners and are currently compatible with certain MRI scanners manufactured by Philips and Siemens. To date, we have primarily generated revenues from the commercialization of our systems in the EU and Asia and from the introduction of TULSA in the United States in Q1-2020. We continue to pursue additional regulatory approvals in international jurisdictions and invest in research and development and in clinical studies designed to increase the body of evidence necessary to support customer coverage and reimbursement by third-party payors, including government programs and private health insurance plans in order to increase commercial adoption of its products. We may also consider synergistic strategic acquisitions to expand the applications of our platform technology and expand our commercial footprint.

Profound's business model in the United States is based primarily upon recurring revenues, getting paid on a per patient treated basis for the use of its technology, one-time-use devices and its 'Profound Genius Services' that are designed to help practices come up to speed on productive use of the TULSA technology upon installation. In other international markets, Profound continues to deploy a business model that consists of two components - sales of durable goods and one-time-use devices for each patient treated.

Our financial strategy to date has been to raise sufficient funds through securities offerings and bank financings to fund specific programs within a focused budget, and following FDA clearance of our TULSA-PRO system received in August 2019, commercialization in the United States. As our commercialization efforts increase and/or further program development costs increase, we may need to raise additional capital. See Item 4, "Risk Factors" for more information.

Our Technology Platform

Based on the Company's TACT clinical data and additional studies conducted in the EU, we believe physicians may elect to use TULSA-PRO to ablate benign or malignant prostate tissue in patients with a variety of prostate diseases, including prostate cancer and BPH. Prostate cancer is one of the most common types of cancer affecting men. The annual incidence of newly diagnosed cases in 2021 is estimated to reach 248,530 in the United States according to the American Cancer Society and in 2018 there were approximately 450,000 newly diagnosed cases of prostate cancer in Europe, according to the International Agency for Research on Cancer. The American Cancer Society further estimates that there are currently 5.8 million men living with prostate cancer in these two geographic regions. Although ten-year survival outcomes for prostate cancer remain favorable, it is still one of most common causes of cancer deaths among men. BPH is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. According to the American Urological Association, BPH is nearly ubiquitous in the aging male population with worldwide autopsy proven histological prevalence increases starting at ages 40 to 45 years, reaching 60% at age 60 and 80% at age 80.

TULSA-PRO delivers its ultrasound energy through a transurethral catheter, a one-time-use device that is placed in the patient's prostate through a natural orifice. Focused ultrasound energy is then created by the catheter in the shape of a blade. Externally the catheter is connected to a software controlled robotic manipulator that can rotate 360-degree in a sweeping action to impart thermal ablation. The real time temperature measurement of the prostate is coupled with closed loop process control that meters the appropriate amount of ultrasound to gently heat the physician-prescribed region of prostate tissue to the target temperature to achieve cell death without boiling or charring the tissue. As a measure to keep the urethra within the prostate safe, the temperature of the transurethral catheter is maintained at a lower temperature by circulating water inside the catheter. Similarly, a water-cooled specially designed catheter is placed in the patient's rectum during the ablation process to protect it from thermal damage during the procedure. We believe that TULSA-PRO's controlled and relatively gentle heating process may result in lower post procedure pain, reduced potential of life affecting side effects and in highly desirable shrinkage of the prostate via resorption of the dead tissue over time, which may have longer term durability benefits.

Sonalleve delivers its ultrasound energy via a disc located outside the patient. Its ultrasound energy is focused to create small cylindrical hot spots a certain distance into the patients. Overlapping cylinders create ablation of the physician-prescribed desired tissue. Similar to TULSA-PRO, Sonalleve also provides for controlled temperature rise to achieve cell death.

The physician is in charge of using the Profound devices and decides which tissue needs to be ablated to impart the intended therapeutic effect. We believe that in the hands of trained physicians, the systems have the ability to provide customizable, incision-free ablative therapies with the precision of real-time MRI visualization and thermometry, focused ultrasound and closed-loop temperature feedback control. We believe that our technology offers clinicians and appropriate patients a better alternative to traditional surgical or radiation therapies, with respect to clinical outcomes, side effects and recovery time.

3.2 Products

TULSA-PRO

Clinical Studies

In March 2014, Profound completed enrollment and treatment of 30 patients in the Phase I TULSA multi-jurisdictional safety and precision study. Based on the Phase I clinical trial results, in April 2016, Profound received a CE Certificate of Conformity for the TULSA-PRO system from our Notified Body in the EU, and in the fourth quarter of 2016, Profound initiated a pilot commercial launch of TULSA-PRO in key European markets where the CE Mark is accepted.

Profound received FDA clearance for the TULSA-PRO system in August 2019 for transurethral ultrasound ablation of prostate tissue, based on the Company's TACT Pivotal Clinical Trial. The TACT Pivotal Clinical Trial is a prospective, open-label, single-arm pivotal clinical study, of 115 treatment-naïve localized prostate cancer patients across 13 research sites in the United States, Canada and Europe, which enrolled patients between August 2016 and February 2018.

Localized Prostate Cancer, Ablation Safety and Efficacy: TACT Pivotal Study

The TACT Pivotal Clinical Trial demonstrates that MRI-guided TULSA is a minimally invasive procedure for effective prostate cancer ablation with a favorable side effect profile, minimal impact on quality of life and low rates of residual disease[1]. In the large, multi-center prospective study in men with predominately intermediate-risk prostate cancer, whole gland ablation sparing the urethra and apical sphincter with the TULSA-PRO met its primary regulatory endpoint of prostate-specific antigen ("**PSA**") reduction in 96% of men to a median nadir of 0.34 ng/ml and 0.5 ng/ml at 12 months. Median decrease in perfused prostate volume as assessed by a central radiologist using 12-month MRI was 91%, from a median 37 cc to 2.8 cc. At 12 months, extensive biopsy sampling of the markedly reduced prostate volume demonstrated a benefit for nearly 80% of men. There was no evidence of cancer in 65% of men and 14% had low-volume clinically-insignificant disease. The authors of the TACT Pivotal Clinical Trial, however, noted that thermally-fixed non-viable cells can retain their apparently-malignant tissue morphology, confounding Gleason grading and potentially introducing false positives[2]. By two years, 7% of men sought additional treatment for their prostate cancer (prostatectomy, radiation). The study patient population, with two-thirds of those with Gleason Grade Group (GGG) ≥ 2 having either bilateral disease or at least five positive cores, allowed for evaluation of oncologically relevant secondary outcomes including PSA stability, post-treatment biopsy, and salvage treatment. Notwithstanding the limitations of comparisons between ablative and extirpative therapies, the 7% rate of salvage treatment and 20% rate of residual clinically significant prostate cancer in intermediate-risk patients are in line with accepted rates of early failure or additional intervention after standard treatments and goals for retreatment after ablative therapies.

1 Klotz et al, "MRI-guided transurethral ultrasound ablation of prostate cancer," The Journal of Urology, 2020

2 Anttinen et al, "Histopathological evaluation of prostate specimens after thermal ablation may be confounded by the presence of thermally-fixed cells," International Journal of Hyperthermia, 2019

In the TACT Pivotal Clinical Trial, TULSA was associated with a high degree of safety and maintenance of quality-of-life, comparing favorably to radical prostatectomy and other whole-gland ablation techniques. At 12 months, 96% of men returned to baseline urinary continence, and 75% of potent men maintained or returned to erections sufficient for penetration. A total of 12 grade 3 adverse events occurred in 8% of men, including genitourinary infection (4%), urethral stricture (2%), urinary retention (1.7%), urethral calculus and pain (1%), and urinoma (1%), all resolved by 12 months. There were no grade 4 events, rectal injuries, severe incontinence requiring surgical intervention, or severe erectile dysfunction unresponsive to medication.

Phase I Studies

Localized Prostate Cancer, Durability of Outcomes: Phase I Safety and Precision Study

The Phase I Clinical Trial demonstrates that MRI-guided TULSA is safe and precise for ablation in patients with localized prostate cancer, providing spatial ablation precision of ± 1.3 mm with a well-tolerated side-effect profile and minor or no impact on urinary, erectile and bowel function at 12 months[3]. There were no grade 4 or higher adverse events, one transient attributable grade 3 event (epididymitis), and notably no injury to rectal or periprostatic structures. Functional outcomes, IPSS and IIEF-15, both showed a favorable anticipated trend of initial deterioration with subsequent gradual improvement toward baseline levels. Consistent with the conservative whole-gland treatment plan which included a 3 mm circumferential margin expected to spare 10% viable prostate at the gland periphery, intra-operative MRI thermometry measured 90% thermal ablation of the prostate gland, median PSA decreased 90% from 5.8 ng/ml to nadir of 0.6 ng/ml, and median prostate volume reduced by 88% on 1-year MRI. Prostate biopsy at one year identified decreased cancer burden with 61% reduction in cancer length; however, attributable the circumferential safety margin, clinically significant cancer in 9 of 29 men (31%), and any cancer in 16 of 29 (55%).

Follow-up data to three and five years demonstrate durability of the outcomes, with continued treatment safety and stable quality of life, as well as predictable PSA and biopsy oncological outcomes based on treatment-day imaging and early PSA follow-up, without precluding any potential salvage therapy options[4]. Repeat prostate biopsy at three years demonstrated durable histological outcomes, with only one subject upgrading to GGG 1 from negative at 12 months, and one subject upgrading to GGG 2 from GGG 1 at 12 months. Between one and five years, there were no new serious adverse events. By five years, 16 men completed protocol follow-up, three withdrew with PSA <0.4 ng/ml, 10 had salvage therapy without complications (six prostatectomy, three radiation and one laser ablation), and one died of an unrelated cause. Of 16 men with complete follow-up data, five-year median PSA remained at 0.55 ng/ml. Median IPSS of 6 at baseline returned to 5 by three months, and 6.5 at five years. At baseline, 9 of 16 had erections sufficient for penetration, 11 of 16 at one year, at 7 of 16 at five years. All 16 subjects had leak-free, pad-free continence at one and five years. Predictors of salvage therapy included lower ablation coverage and higher PSA nadir. At five years after TULSA, cancer specific survival is 100%, and overall survival 97%.

3 Chin et al, “Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial,” European Urology, 2016; Bonekamp et al, “Twelve-month prostate volume reduction after MRI-guided transurethral ultrasound ablation of the prostate,” European Radiology, 2018

4 Nair et al, “MRI-Guided Transurethral Ultrasound Ablation in Patients with Localized Prostate Cancer: Three Year Outcomes of a Prospective Phase I Study”, BJU International, 2020; Nair et al, “PD17-03 Five-Year Outcomes from a Prospective Phase I Study of MRI-Guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer”, AUA 2020 Virtual Experience, Abstract in The Journal of Urology, 2020

Benign Prostatic Hyperplasia (BPH), Relief of Lower Urinary Tract Symptoms (LUTS): Phase I Studies

Promising safety and feasibility of the TULSA-PRO to relieve Lower Urinary Tract Symptoms (" **LUTS**") associated with BPH has been demonstrated in two Phase I studies showing improvements in IPSS comparable to modern minimally invasive surgical therapies[5]. A retrospective analysis of a sub-group of nine men from a localized prostate cancer study who also had LUTS (baseline IPSS ≥ 12) demonstrated significant IPSS improvement of 58% from 16.1 to 6.3 at 12 months (p=0.003), with at least a moderate (≥ 6 points) symptom reduction in eight of nine patients. IPSS Quality of Life improved in eight of nine patients. Erectile function (IIEF-EF) remained stable from 14.6 at baseline to 15.7 at 12 months. The proportion of patients with erections sufficient for penetration was unchanged. Full urinary continence (pad-free, leak-free) was achieved at 12 months in all patients. In five men who suffered from more severe symptoms (baseline IPSS ≥ 12 and Qmax < 15 ml/s), peak urine flow rate ("**Qmax"**) increased from 11.6 ml/s to 22.5 ml/s at 12 months. All adverse events were mild to moderate with no serious events reported.

A prospective study of TULSA-PRO for BPH has been conducted with early outcomes presented at the 2020 European Association of Urology Annual Conference. Urinary function improved during the initial three-month follow up among the first seven patients treated, while no adverse effects were seen on sexual and bowel functions: average IPSS decreased from 17.7 to 4.6, IPSS QoL decreased from 4.3 to 1.0, and Qmax increased from 11.5 ml/s to 26.8 ml/s, among several other improved urinary measures. A single adverse event had occurred, abscess of the epididymis requiring drainage at two weeks post therapy.

Radio-recurrent localized prostate cancer, Salvage TULSA (sTULSA): Phase I Study

Salvage ablation of radio-recurrent localized prostate cancer has been evaluated in a prospective study of TULSA-PRO with early outcomes presented at the 2020 EUA Annual Conference[6]. Ten patients were successfully treated, with a median hospitalization time of 24 hours and catheterization time of four days. Four subjects have completed 12-month follow-up, with average PSA decreased from 4.6 ng/ml to 0.6 ng/ml, and all with no evidence of recurrence on biopsy and imaging (MRI and PSMA-PET). Four patients had prolonged catheterization and subsequent urinary tract infection, and one these patients had upper urinary tract dilation treated with double-J-stents.

Palliation of symptomatic locally advanced prostate cancer, Palliative TULSA (pTULSA): Phase I Study

Patients with symptomatic locally advanced prostate cancer can suffer from severe urinary retention due to bladder outlet obstruction, intractable hematuria and frequent hospitalization. While these complications are commonly treated by palliative transurethral resection of the prostate ("**TURP**"), the improvement is often insufficient and may exclude patients who cannot discontinue anticoagulants. The safety and feasibility of MRI-guided TULSA was evaluated as an alternative palliative treatment option for men suffering from symptomatic locally advanced prostate cancer[7]. Ten patients with locally advanced prostate cancer were enrolled, half with clinical stage T4 disease and half with clinical T3. Prior to TULSA, all patients had continuous indwelling catheterization due to urinary retention, and 90% had history of recurrent and/or ongoing gross hematuria. Three patients had palliative TURP performed six months prior to receiving palliative TULSA, all of which were unsuccessful. One week after palliative TULSA, 50% of men were catheter-free. At last follow-up, 100% of men were free of gross hematuria, and 80% had an improvement in catheterization, with 70% completely catheter-free. Notably, the average hospitalization time from local complications reduced from 7.3 to 1.4 days in the six-month period before and after palliative TULSA. All adverse events were related to UTI, with two patients requiring intravenous administration of anti-biotics and three patients resolved with oral antibiotics alone. No other treatment related adverse events were recorded, with no rectal injury or fistula. Further, there was no need for blood transfusions and there was no perioperative mortality.

---

5 Elterman et al, "Relief of Lower Urinary Tract Symptoms after MRI-Guided Transurethral Ultrasound Ablation (TULSA) for localized prostate cancer: Subgroup Analyses in Patients with concurrent cancer and Benign Prostatic Hyperplasia," Journal of Endourology, 2020; Anttinen et al, "Transurethral ultrasound therapy for benign prostatic obstruction in humans," EAU 2020 Conference Presentation

6 Anttinen et al, "Early experience of salvage MRI-guided transurethral ultrasound ablation (sTULSA) for local prostate cancer recurrence after radiotherapy," EAU 2020 Conference Presentation

7 Anttinen et al, "Palliative MRI-guided transurethral ultrasound ablation for symptomatic locally advanced prostate cancer," Scandinavian Journal of Urology, 2020

CAPTAIN trial

CAPTAIN (A Comparison of TULSA Procedure vs. Radical Prostatectomy in Participants with Localized Prostate Cancer) is a prospective, multi-centre randomized controlled trial of 201 patients aimed at comparing the safety and efficacy of the TULSA procedure (performed with the TULSA-PRO system) with radical prostatectomy in men with organ-confined, intermediate-risk, Gleason Score 7 (Grade Group 2 and 3) prostate cancer. In the CAPTAIN trial, 134 patients will be randomized to receive one or two TULSA procedures and 67 patients will be randomized to receive radical prostatectomy. The trial is expected to take place at eight or more sites in the United States and two in Canada. Of those, six sites have been activated to date and are currently recruiting patients.

Radical prostatectomy is currently the gold-standard surgical treatment for intermediate-risk prostate cancer. RP effectively controls disease but carries risk of significant side effects such as long-term erectile dysfunction and urinary incontinence. The TULSA procedure combines transurethral, robotically-driven therapeutic ultrasound with real-time visualization of temperature and automated control of heating from magnetic resonance thermometry. The high spatial, thermal, and anatomic resolution of the target volume enables precise ablation of prostate tissue while sparing functionally important structures, potentially reducing the risk of side effects relative to radical prostatectomy.

The goal of CAPTAIN is to demonstrate that the efficacy of the TULSA procedure is not inferior to radical prostatectomy, while demonstrating superior quality of life outcomes. The primary safety endpoint is the proportion of patients who preserve both erectile potency and urinary continence at one year after treatment. The primary efficacy endpoint is the proportion of patients who are free from any additional treatment for prostate cancer by three years after treatment. Secondary endpoints include comparison of rates of complications, cost effectiveness, and timing of the return to baseline activity. Long-term follow-up will be gathered for up to 10 years after treatment.

Sonalleve

Profound's Sonalleve system combines real-time MRI and thermometry with focused ultrasound delivered from the outside of the patient to enable precise and incision-free ablation of diseased tissue. Profound acquired the Sonalleve technology from Philips in 2017.

The Sonalleve system is CE marked in the EU for the treatment of uterine fibroids and palliative pain treatment of bone metastases. The uterine fibroids application is also available for sale in Canada. In 2018, the Sonalleve system was also approved in China by the National Medical Products Administration for the non-invasive treatment of uterine fibroids. Philips Oy registered Sonalleve in several Middle East, North African, and South Asian countries. In 2020 Sonalleve also received HDE from the U.S. FDA for treatment of Osteoid Osteoma.

Sonalleve Clinical Applications

Uterine Fibroids and Adenomyosis

Uterine fibroids ("**UFs**") are the most common non-cancerous tumors in women of childbearing age. Both surgical and medical treatments are available and the choice depends on number, size, and location of UFs, patient's age and preferences, and pregnancy expectations. To date, symptomatic UFs have been mostly treated with radical surgery (hysterectomy) in women who have completed childbearing, or conservative surgery (myomectomy and endometrial ablation) in women who wish to preserve fertility. Today, the radiologist also has interventional options available. Minimally or non-invasive interventional radiology procedures include uterine artery embolization (UAE).

There is currently no ideal treatment for adenomyosis, and new options are needed. Drawing on experience of treatment of uterine fibroids, MR-HIFU has been explored as a potential new conservative treatment and MR-HIFU is an early-stage, noninvasive, therapeutic technology with the potential to improve the quality of life and decrease the cost of care for patients with adenomyosis.

To achieve its current regulatory clearances, the Sonalleve MR-HIFU System has undergone several studies and clinical trials for uterine applications at Sunnybrook Health Sciences Centre (Toronto, Ontario), University Medical Center Utrecht (Utrecht, the Netherlands), University Hospital St. André (Bordeaux, France), Samsung Medical Center (Seoul, Korea), Peking University First Hospital Beijing (Beijing, China), First Affiliated Hospital of Medical College of Xi'an Jiaotong University (Xi'an, China), Turku University Hospital (Turku, Finland), National Institutes of Health (Bethesda, MD, USA), St. Luke's Episcopal Hospital (Houston, TX, USA), and others.

In addition, a comprehensive literature review provides supportive evidence showcasing the beneficial action of MR-HIFU in uterine fibroid and adenomyosis therapy. These studies include the Verpalen et al. 2020, Nguyen 2020, Yeo et al. 2017, Kim et al. 2017, and Hocquelet et al. 2017 that utilized the Sonalleve MR-HIFU system. Specifically, the studies show impressive performance in terms of ablation efficiency, therapeutic efficacy, symptom reduction, and/or Quality of Life ("**QoL**") improvement. There were no treatment-related serious adverse events in any of these studies, although Browne et al. 2020 describes a procedure-related major complication in the form of deep vein thrombosis that was noted in one patient (0.8%) and subsequently and successfully treated with anticoagulation therapy. Minor adverse events, when present, typically include 1st and 2nd degree skin burns, local swelling, cramps, leg pain, abdominal pain, buttock pain, and back pain, which are all known and anticipated adverse events of MR-HIFU therapy.

Palliative Bone Pain Treatment

Pain caused by bone metastases are common in the event of malignancy and are inevitably associated with serious complications that may deteriorate the QoL of patients and become life threatening.

For patients with bone metastases, clinical evaluation reports (GCP-10277 Rev. B) were completed (Oct. 2020) showing significant decrease in pain score, dosage of medication, or quality of life are to be expected with MR-HIFU bone therapy. The randomized controlled Phase III study by Hurwitz et al. represents some of the most important clinical data that has been reported. In 112 subjects receiving MR-HIFU compared against 35 subjects receiving sham treatment, significant pain reduction at 3 months (decrease in worst NRS pain ≥ 2 without increase in pain medication) was 64.3% vs. 20.0% ($p<0.001$), with mean NRS reduction of 3.6 ± 3.1 vs. 0.7 ± 2.4 from an initial median NRS score of 7.0 in both groups. Improvement in average BPI-QoL at 3 months was 2.4 points superior in the MR-HIFU group ($p<0.001$), representing a clinically important reduction in impairment caused by bone metastasis pain.

The clinical data show that patients with bone metastases can expect a statistically significant decrease in pain scores and/or in medication dosage and increase in quality of life with MR-HIFU bone metastasis therapy.

Osteoid Osteoma Treatment

Osteoid osteoma is a relative rare, painful bone tumor that typically occurs in the cortex of long bones, especially in children and adolescents, and accounts for approximately 10% of all benign bone tumors.

Current osteoid osteoma treatment options include surgery and radiofrequency ablation, which is a less invasive option than surgical resection. Although RFA can have a high success rate, the treatment is invasive and can potentially cause minor and major complications. It also exposes patients and operators to ionizing radiation associated with the CT imaging guidance.

Sonalleve MR-HIFU provides an optimal therapy choice for osteoid osteoma which is a precise, completely non-invasive, and free from ionizing radiation treatment.

The recent studies have assessed the use of Sonalleve MR-HIFU in treatment of osteoid osteoma, showing a high clinical success rate and complete symptom resolution without any serious adverse effects and only few minor adverse effects that promptly resolve. The Sonalleve MR-HIFU device offers a novel, minimally invasive, MRI-guided method to treat osteoid osteoma safely and effectively.

3.3 Business Strategy

COVID-19 has and is altering our business through impacts in healthcare facilities' ability to make commitments and patients deciding to undergo procedures. The global response to the COVID-19 pandemic has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Additional measures may be implemented by one or more governments in jurisdictions where the Company operates. These measures have caused material disruption to businesses globally, resulting in an economic slowdown. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions required to contain the COVID-19 virus or remedy its impact, among others.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company's ability to conduct its businesses, including its ability to cultivate adoption of the TULSA-PRO technology, support clinical customers with TULSA-PRO procedures and increase the utilization of the systems and one-time-use devices.

To date, the economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for TULSA-PRO® systems and the one-time-use devices related thereto. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new TULSA-PRO user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing, and Profound continues to identify potential new TULSA-PRO user sites. The Company continues to evaluate the current and potential impact of the COVID-19 pandemic on its business, affairs, operations, financial condition, liquidity, availability of credit and results of operations.

In addition, the actual and threatened spread of COVID-19 globally could also have a material adverse effect on the regional economies in which Profound operates, could continue to negatively impact stock markets, including the trading price of the common shares in the capital of the Company ("Common Shares"), could adversely impact the Company's ability to raise capital and could cause continued interest rate volatility and movements that may make obtaining financing more challenging or more expensive.

During the year ended December 31, 2021, the Company experienced the following key impacts related to COVID-19:

- a reduction in revenue, caused by volatility in demand for systems and one-time-use devices,
- customer payments delayed due to Profound's inability to install systems because of hospital restrictions,
- a lower than anticipated amount of TULSA-PRO procedures performed and related revenue being recognized, and

The financial impacts from COVID-19 during the year ended December 31, 2021 have impacted Profound's ability to collect payments due to continuous lockdowns and hospital restrictions, which have impeded our efforts to install our systems and has delayed our collections. Profound continues to work with local authorities and team members located within these countries to help expedite the process. The COVID-19 pandemic remains uncertain in terms of its magnitude, outcome and duration, as well as further social distancing restrictions. Despite the challenging and uncertain economic environment created by the ongoing impact of the COVID-19 pandemic, our business continues to operate normally and we believe our business demonstrates resilience because of our preparation and strong relationships. Through the implementation of our detailed business continuity plan, we transitioned a significant portion of the Company's employee base to work from home. Throughout these challenging circumstances, the Company has continued to serve its customers, quickly adapting to the current environment.

Profound has primarily generated revenues from its limited commercialization of the TULSA-PRO, including one-time-use devices and related services, in the EU (principally in Germany) and Asia. For the year ended December 31, 2021, approximately 39%, 30% and 31% of revenues were generated in the EU, United States and Asia, respectively, compared to approximately 38%, 16% and 48% of revenues which were generated in the EU, United States and Asia, respectively for the year ended December 31, 2020. We expect that revenue on a quarter over quarter basis will continue to fluctuate given the Company maintaining a limited European commercial effort and remains primarily focused on expanding into the U.S. market.

On January 10, 2020, Profound announced the signing of its first-ever US multi-site imaging center agreement for TULSA-PRO with RadNet, Inc., an owner and operator of outpatient imaging centers, pursuant to which Profound will install TULSA-PRO systems at three RadNet imaging centers in the greater Los Angeles. The installation of these systems and initiation of patient treatments at these sites have been delayed as a result of the COVID-19 pandemic.

Profound's TULSA-PRO system is primarily marketed to early adopter physicians who specialize in treatment of prostate disease including urologists and radiologists at opinion leading hospitals. TULSA-PRO services are available at either independent imaging centers or at hospital-based imaging centers.

Historically treatment of conditions such as localized prostate disease and uterine fibroids have included surgical intervention. Over time, surgery has evolved from an 'open' technique, to laparoscopic, to robotic surgery. The motivation of surgeons behind this evolution has been to perform procedures that reduce invasiveness, improve clinical outcomes and reduce recovery times. Profound is now taking this concept to the next level by enabling customizable, incision-free therapies for the MRI-guided ablation of diseased tissue with the TULSA-PRO and Sonalleve systems. These incision-free and radiation-free procedures offer surgeons the option of providing predictable and customizable procedures that eliminate invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

Profound is establishing its own direct sales and marketing teams for sales of TULSA-PRO systems and the one-time-use devices related thereto, as well as for Sonalleve systems in the jurisdictions where it is approved. The primary focus of Profound's 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 one-time-use devices. Profound expects to generate recurring revenues from the use of the system, one-time-use devices, clinical support and service maintenance.

Profound also collaborates with its strategic partners Philips and Siemens for lead generation and distribution of durable equipment, which are currently available through the Philips and Siemens sales catalogs.

On December 21, 2020, Profound entered into a co-development agreement with GE Healthcare (the "**GE Agreement**") whereby GE Healthcare and Profound have agreed to a non-exclusive, worldwide license that will enable Profound to interface its TULSA-PRO system with certain GE Healthcare MRI scanners. The collaboration with GE Healthcare expands our potential to interface with a significant portion of GE's new and currently installed MRI scanners globally.

On May 6, 2021, Profound signed the Akumin Agreement. Pursuant to the Akumin Agreement, Profound expects to install TULSA-PRO systems at up to 10 Akumin centers to be outfitted with diagnostic and therapeutic imaging services specifically dedicated towards men's health. All of these TULSA-PRO systems will be placed under Profound's per procedure business model. The initial geographic focus of the relationship will be in the State of Florida, with Texas and Pennsylvania expected to follow.

3.4 Manufacturing Operations

The Company operates from leased premises in two different locations. We do 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

We manufacture TULSA-PRO and SONALLEVE systems at dedicated manufacturing facilities located in Canada and Finland which are ISO 13485 certified. Our 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. We believe our 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 TULSA-PRO system is intended to ablate benign and malignant prostate tissue, however there are other treatment options for prostate disease. There are currently no marketed devices indicated for the treatment of prostate diseases or prostate cancer and our FDA indication and CE Mark in the EU also do not include treatment of any particular disease or condition. However, there are a number of devices indicated for the destruction or removal of prostate tissue and devices indicated for use in performing surgical procedures that physicians and surgeons currently utilize when treating patients with prostate disease, including prostate cancer. Approaches that physicians and surgeons currently use to address prostate disease include: (1) watchful waiting/active surveillance; (2) simple prostectomy; (3) radical prostatectomy (includes open, laparoscopic and robotic procedures); (4) radiation therapies including, external beam radiation therapy, brachytherapy and high dose radiation; (5) cryoablation; and (6) trans-rectal high intensity focused ultrasound ("**HIFU**"). In addition, certain adjunct or less common procedures are used or are under development to address prostate disease, such as androgen deprivation therapy and proton beam therapy.

Each of the foregoing competing options have their own limitations and benefits and may only be appropriate for limited patient populations. For example, 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 options of surgery or radiation therapy impose the possibility of substantial side effects, creating a need for a less invasive methodology to remove diseased prostate tissue that is both radiation- and incision-free and provides a more favorable side-effect profile.

We believe that the flexibility of the TULSA-PRO system may allow the Company to demonstrate its use as a tool for ablating benign and malignant diseased prostate tissue with greater speed and precision than current options while minimizing potential side effects. We believe that the TULSA-PRO system may overcome certain limitations of other devices and methodologies for removing or addressing diseased prostate tissue including HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. We believe that a transurethral (inside out) ablation approach with millimeter accuracy has advantages over HIFU in ablating the whole 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.

Simple Prostatectomy

Simple prostatectomy is recommended for men with severe urinary symptoms caused by an obstructive prostate gland and whose symptoms are not responsive to other medical or minimally-invasive therapies. Simple prostatectomy involves removing only the obstructive portion of the prostate gland rather than the entire gland and surrounding tissue. A simple prostatectomy can be open or robotic. Open simple prostatectomy can be conducted through retropubic, suprapubic, or perineal routes. Simple prostatectomy has higher morbidity and longer hospitalization in comparison to less invasive therapies such as transurethral resection of the prostate. Simple prostatectomy is contraindicated in the presence of cancer.

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**")*

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 ("**HIFU**")*

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 centimeters. Patients with larger prostates need a separate surgical procedure, such as 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

Androgen deprivation therapy ("**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 defense 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 centimeters.

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.

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

- Clinically shown to have millimeter accuracy designed to ablate prostate tissue while sparing nearby critical structures, and that 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 centimeters or larger in size;
- Potential to be a single 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.

We believe that the flexibility of the TULSA-PRO system may allow us to demonstrate its use as a tool for ablating benign and malignant diseased prostate tissue with greater speed and precisions than current options while minimizing potential side effects. We believe that the TULSA-PRO system may overcome certain limitations of other devices and methodologies for removing or addressing disease prostate tissue including HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. We believe that a transurethral (inside out) ablation approach with millimeter accuracy has advantages over HIFU in ablating 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.

We believe 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.

Current osteoid osteoma treatment options include surgery and radiofrequency ablation, which is a less invasive option than surgical resection. Although RFA can have a high success rate, the treatment is invasive and can potentially cause minor and major complications. It also exposes patients and operators to ionizing radiation associated with the CT imaging guidance.

We believe that use of the Sonalleve system as a tool to ablate uterine fibroids or osteoid osteoma can provide a clinician and his or her patients with the following clinical advantages:

- Millimeter 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.

3.6 Alliances and Partnerships

Philips

On July 31, 2017, we entered into an asset and share purchase agreement dated July 31, 2017 with Philips (the " **Philips Share Purchase Agreement**") with Philips in order to expand the existing collaboration and acquire the Sonalleve technology, which we use in our Sonalleve system (the "**Sonalleve Transaction**").

Under the terms of the Philips Share Purchase Agreement, we acquired from Philips its Sonalleve assets for upfront consideration of 7,400,000 Common Shares. The Philips Share Purchase Agreement included earn-out provisions that required us to pay additional consideration of: (i) 5% of Net Sales (as defined below) 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. For the year ended December 31, 2020, Profound paid $212,000 as part of the earn-out provision for a total of $501,000 since the beginning of the earn-out period and has since fulfilled all its obligations.

"**Net Sales**" include the revenues (less any royalties) received by us or third parties on our behalf in respect of the sale or transfer of the Sonalleve technology, any subsequent, successor or next-generation treatment technology of which is primarily based on Sonalleve and which utilizes intellectual property rights acquired under the Philips Share Purchase Agreement or any future product that combines the technologies of Sonalleve and TULSA-PRO and any amounts received by us with respect to service agreements, but does not include any revenues with respect to consumables.

As part of the Sonalleve Transaction, we expanded our non-exclusive strategic sales relationship with Philips for our TULSA-PRO system to include distribution of Sonalleve.

We have also entered into several other agreements with Philips, including (1) a supply agreement (the " **Philips Supply Agreement**") dated July 31, 2017 with Philips Medical Systems Nederland B.V. (" **Philips Medical**"), pursuant to which Philips is required to manufacture our Sonalleve systems for a certain period; (2) a noncompetition, nonsolicitation and confidentiality agreement dated July 31, 2017 with Philips (the "**Philips Confidentiality Agreement**"), whereby Philips agreed to certain non-competition terms; and (3) a resale purchasing agreement dated July 31, 2017 ("**Philips Resale Purchasing Agreement**") with Philips Medical, whereby Philips is permitted to purchase and resell certain of our products to its customers. For more details on these agreements, see Item 16, "Material Contracts".

Siemens

On February 11, 2019, we entered into the New Siemens Agreement, effective as of January 21, 2019. Under the New Siemens Agreement, all prior financial commitments and obligations owed to Siemens were released and replaced with a one-time fixed license fee and per annum payments calculated based on annual volume of our systems interfaced to a Siemens MRI scanner. The initial term of the New Siemens Agreement is five years and will be automatically extended for successive terms of one year thereafter unless terminated earlier. We also obtained a non-exclusive license to Siemens Access I interface software and reasonable support for the term of the New Siemens Agreement.

GE Healthcare

On December 21, 2020, Profound entered into a co-development agreement with GE Healthcare whereby GE Healthcare and Profound have agreed to a non-exclusive, worldwide license that will enable Profound to interface its TULSA-PRO system with certain GE Healthcare MRI scanners. The collaboration with GE Healthcare expands our potential to interface with a significant portion of GE's new and currently installed MRI scanners globally.

Knight

Knight acts as our exclusive distributor for TULSA-PRO in Canada pursuant to a 10-year distribution, license and supply agreement initially entered into in April 2015 (which may be extended for successive 10-year periods at the option of either party). Currently, we are not planning any significant commercialization efforts in Canada.

Manufacturing and Supply

We rely principally on third parties for the manufacturing of the components of our system; however, we are responsible for assembly and testing.

We have designed the TULSA-PRO system to be capable of integration with some of the MRI scanners from three of the major MRI manufacturers (Philips, Siemens and GE Healthcare) and the Sonalleve system with one MRI manufacturer (Philips). As not all hospital and treatment facilities utilize MRI scanners that are compatible with the TULSA-PRO and Sonalleve systems, 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, we intend to expand compatibility of the systems with other MRI scanners in the future.

Our systems are assembled from off-the-shelf and custom-made components. We have entered into, and expect to enter into additional, manufacturing, licensing and distribution arrangements with one or more QSR compliant and FDA registered contract manufacturers for the materials and components used in our products. The TULSA-PRO and Sonalleve systems consist of common electronic components, proprietary capital equipment and proprietary one-time-use devices. We purchase 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. TULSA-PRO one-time-use devices 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. We have developed proprietary automated manufacturing test equipment to improve quality and provide scalability as demand grows and this equipment is assembled and tested in-house. We assemble and test the UA and endo-rectal cooling device in-house.

We have no long-term contracts with our suppliers, and we are not bound by any minimum purchase volume undertakings with such suppliers.

We currently rely on single source suppliers for certain components used in our systems. In connection with our anticipated commercialization of our approved products, we intend to procure alternative supply arrangements for these components. See Item 4, "Risk Factors—Risk Factors Relating to Our Business and Growth Strategy—We depend on single-source suppliers for some of the components in our systems."

3.7 Regulatory

On August 15, 2019, we obtained 510(k) clearance for commercial sale of the TULSA-PRO as a Class II device in the United States, and have previously received a CE Certificate of Conformity for our products in European Union, and we have obtained regulatory approval for Sonalleve in China. On November 25, 2019, the TULSA-PRO was approved as a class III device by Health Canada, which is key to our global expansion strategy that requires a country of origin approval for medical devices. Additionally, the TULSA-PRO system has received regulatory clearances or approvals for commercial sale in Saudi Arabia, Singapore and China, while the Sonalleve system has received regulatory clearance or approval for commercial sale in Canada, Saudi Arabia, South Korea and Malaysia. Our long-term goal is to expand our regulatory indications in Asia and other parts of the world where potential profitable business development opportunities warrant such investments.

United States

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

The TULSA-PRO system, and any future medical devices that we may develop, will be classified by the FDA under the statutory framework described in the FFDCA. Medical devices are classified into three classes from lowest risk (Class I) to highest risk (Class III). Unless an exemption applies, medical devices require FDA clearance or approval prior to commercial sale in the United States depending on the assigned risk class. Most Class I devices and some Class II devices are exempt from premarket review requirements. Class I devices are subject to the “general controls” of the FFDCA, which include facility registration and device listing, quality system requirements, labeling requirements, medical device reporting, and reporting of corrections and removals. Most Class II devices and some Class I devices require FDA clearance of a 510(k) premarket notification prior to marketing. A 510(k) premarket notification must demonstrate that the device is substantially equivalent to a legally marketed predicate device. In addition to the general controls, Class II devices are subject to “special controls,” such as performance standards and guidance documents, as identified in the classification regulation for the device type. Class III devices require FDA approval of a premarket approval application, or PMA, demonstrating reasonable assurance of safety and effectiveness of the device, 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. Class III devices are subject to the general controls and any conditions of approval in the PMA approval order, which can include postmarket study requirements. Novel devices that have not been classified and devices deemed not substantially equivalent to a predicate device are automatically classified into Class III. For such devices that are low- to moderate-risk, the manufacturer can submit a *de novo* classification request to classify the device into Class I or 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 IDE application, 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 subject to 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 IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices and informed consent.

After a device is placed on the market, numerous regulatory requirements apply. Device manufacturers and importers must register their establishments annually, list the devices they manufacture and pay an annual registration fee. Device manufacturers are also subject to the QSR, which includes both design control requirements and good manufacturing practice requirements (such as requirements for purchasing controls, document controls, production and process controls, labeling and packaging controls, control of nonconforming product, complaint handling, corrective and preventative actions, storage, handling, distribution, and servicing). Devices must be labeled in accordance with the FDA's device labeling regulations, including Unique Device Identification requirements. The FDA also regulates the promotion of medical devices, including a requirement that all device promotion be truthful and non-misleading and a prohibition against the promotion of devices for "off-label" uses, i.e., uncleared or unapproved uses. Under the medical device reporting regulations, manufacturers and initial importers must submit a report to the FDA if they become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury or malfunctioned and the malfunction would be likely to cause or contribute to a death or serious injury if it were to recur. Manufacturers must also report any corrections or removals, which can include, among other actions, repairs, adjustments, relabeling, or destruction of distributed devices, if the correction or removal was initiated to reduce a risk to health or to remedy a violation of the FFDCA caused by the device which may present a risk to health.

The FDA has broad enforcement authority to take action against a failure to comply with the clinical trial, premarket review, or postmarket regulatory requirements discussed above and the agency conducts routine inspections of device manufacturers to determine compliance with these requirements. FDA enforcement typically takes the form of inspectional observations at the close of inspection, an untitled letter (a private letter raising compliance questions), or a warning letter (a public letter alleging noncompliance). However, the FDA has authority to take additional enforcement actions including: civil monetary penalties, criminal fines and prosecution, injunctions, mandatory recall, and import detentions.

European Union

On April 5, 2017, the EU adopted a new Medical Devices Regulation (EU) 2017/745 (the " **New EU MDR**"), which repealed and replaced the Medical Devices Directive (MDD) effective May 26, 2021. Under transitional provisions, medical devices with Notified Body certificates issued under the Medical Devices Directive prior to May 26, 2021 will remain valid until the end of the period indicated on the certificate, but will become void on May 27, 2024 at the latest, except for certificates issued in accordance with Annex IV to the Active Implantable Medical Devices Directive 90/385/EEC or Annex IV to the MDD which shall become void at the latest on May 27, 2022. After the expiry of any applicable transitional period, only devices that have been CE marked under the New EU MDR may be placed on the market in the EU.

On the basis that TULSA-PRO and Sonalleve systems benefit from the New EU MDR transition period, these devices can be placed on the market under their MDD certificates provided they continue to comply with the MDD and there is no significant change in the devices' designs or intended purposes. Under the MDD, legal manufacturers of medical devices, such as the TULSA-PRO and Sonalleve systems, are required to comply with the Essential Requirements laid down in Annex I of the MDD. Active implantable medical devices and in-vitro diagnostic medical devices are regulated in separate EU directives. 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. The MDD provides for four different classifications of medical devices based on their potential risks and vulnerability of the human body: Class I, Class IIa, Class IIb and Class III. 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 a private entity designated by the competent authorities of a European Union Member State to conduct conformity assessments and to perform their tasks under the MDD (as implemented in the respective national legal system) in the public interest. Depending on the device's risk category/class, the conformity assessment of the Notified Body extends to the quality assurance system established by the manufacturer and/or the product design, as well as to the Technical Documentation to be compiled by the manufacturer for each device to demonstrate compliance with the relevant essential Requirements.

As part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices in accordance with Annex X of the MDD 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 outweigh 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.

If the Notified Body finds, as a result of its conformity assessment, that the quality assurance system and/or the product design is compliant with the applicable legal provisions, it issues a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements, which is valid for a maximum of five (5) years (although now that the New EU MDR is applicable, no new certificates under the MDD can be issued and, as explained above, no MDD certificate will remain valid from 27 May 2024). 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, followed by the ID number of the Notified Body. The CE mark allows the device to be placed on the market throughout the EU and the EEA, as well as in Switzerland and Turkey based on bi-lateral treaties (although some additional requirements might apply, for example, in Switzerland a Swiss Authorized Representative is now required as the mutual recognition agreement does not cover the New EU MDR).

The Notified Body is obliged to perform regular audits and, before the expiry date of a certificate of conformity, renewal audits at the manufacturer’s site upon prior notification. In addition to these notified audits, a Commission Recommendation of 2013 advised notified bodies to conduct unannounced audits (including testing of product samples) on a regular basis.

Therefore, when the MDD certificates become void, medical devices need to fully comply with the New EU MDR. The New EU 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 devices will need to undergo a conformity assessment under the MDR. Medical devices must comply with the General Safety and Performance Requirements set out in Annex I (replacing the Essential Requirements). Further, new classification rules apply. Additionally, the New EU MDR also envisages greater control over Notified Bodies and their standards and increased transparency through the establishment of a comprehensive EU database on medical devices.

However, regardless of whether a device is placed on the market under an existing MDD certificate or an MDR certificate, all devices must comply with the requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices set out in the New EU MDR as from May 26, 2021.

After a device is placed on the market, it remains subject to significant regulatory requirements. For CE marked devices, certain modifications to the device or quality system depending on the conformity assessment procedure used must be submitted to and approved by the Notified Body before placing the modified device on the market. Economic Operators, include device manufacturers, must register their establishments and devices in the EUDAMED database once available.

In the European Union, we must establish a medical device vigilance system (for reporting incidents) and a post-marketing surveillance system (to monitor data about the device and confirm the benefits of the device continue to outweigh the risks). Under this system, serious 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 (either temporary or permanent) or that pose a serious public health threat must be reported to the relevant authorities of the European Union Member States. Manufacturers are required to take 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. Manufacturers should report any FSCAs in respect of devices made available on the market or undertaken in a third country in relation to a device made available on the EU market. If the manufacturer of a device or its authorized representative in the EU has its registered place of business in Germany, it must appoint a safety officer having the necessary professional qualifications to fulfil the reporting requirements and to coordinate the necessary actions.

If the requirements for application of the CE mark are not (or no longer) fulfilled, or in other cases of non-compliance with applicable medical devices law:

- the Notified Body has the power to withdraw, suspend or limit the scope of the applicable certificate of conformity, in accordance with the principle of proportionality;
- the competent authorities of the EU Member States may require relevant economic operators to take the necessary actions to bring the device into compliance and/or address the risk, which can include withdrawal from the market or recall; and
- depending on the EU member state, criminal and/or administrative sanctions (e.g. fines) may apply.

The New EU MDR prohibits making any misleading claims about a device's intended purpose, safety and/or performance. Therefore, devices can only be marketed for their intended purpose. In addition, the advertising and promotion of our products in the European Union are subject to the provisions of 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 our products to the public and may impose limitations on our promotional activities with healthcare professionals. In Germany, a company which advises healthcare professionals on the handling and use of medical devices – as may be the case for the TULSA-PRO and Sonalleve devices – has to appoint a "medical devices advisor" (Medizinprodukteberater) with appropriate qualification and professional experience as set out in the German Medical Devices Act (Medizinproduktegesetz).

On December 31, 2020, the UK exited the EU (Brexit). The UK did not implement the New EU MDR into the laws of Great Britain (England, Scotland and Wales). Northern Ireland is an exception as under the Northern Irish Protocol the New MDR does apply (although the Protocol is under discussion and so could change). Great Britain instead introduced a new, standalone medical devices framework. Currently, this aligns closely to the MDD. However, the legislation has made some changes and included additional national requirements. For example, instead of a CE Mark, medical devices marketed in Great Britain must bear a UKCA mark. However, EU CE Marks will continue to be recognized in Great Britain until June 30, 2023, as will certificates issued by EU-recognized Notified Bodies. This arrangement is not reciprocated in the EU. Medical devices marketed in the UK must comply with the national laws in the UK, which going forwards may differ from the laws in the EU.

Canada

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 Class II, III or IV medical device in Canada, a manufacturer must present and/or attest to substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and the Medical Devices Regulations ("**Canada MDR**").

The Medical Devices Bureau ("**MDB**") of the TPD applies the Canada 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, including for Class II, III or IV medical devices 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 Canada MDR are met.

The Canada 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. The MDB currently recognizes the Medical Device Single Audit Program, a program designed to include compliance with the QMS requirements of the Canada MDR. We are manufacturing the TULSA-PRO system under a certified ISO 13485 Quality Management System.

Regulatory Status

TULSA-PRO

On November 25, 2019, TULSA-PRO received approval as a Class III device from Health Canada, which is key to our global expansion strategy that requires a country of origin approval for medical devices. On August 15, 2019, we received 510(k) clearance for commercial sales of the TULSA-PRO as a Class II device in the United States for TULSA of prostate tissue, and in April 2016 the TULSA-PRO system was CE marked in the European Union for ablation of targeted prostate tissue (benign or malignant). Outside of these jurisdictions, the TULSA-PRO system will require country-specific pre-market clearance or approval prior to launch.

Upon completion of our Phase I safety and feasibility study for TULSA-PRO in April 2016, we were granted CE Mark approval for the commercial sale of the TULSA-PRO system in Europe and in other CE Mark jurisdictions.

In August 2016, we initiated TACT Pivotal Clinical Trial, which the FDA approved under an IDE application. The TACT Pivotal Clinical Trial was designed to support a 510(k) premarket notification submission in the United States. This submission was made in May 2019 in support of clearance of the TULSA-PRO system by the FDA for use in the ablation of prostate tissue in the United States.

In Canada, we are currently manufacturing the TULSA-PRO system under a certified ISO 13485 Quality Management System. The Canadian market is considered a lower priority from a commercialization strategy perspective in light of its relatively small size.

Sonalleve

On November 30, 2020, the Sonalleve system received an approval from the FDA under the HDE for the treatment of osteoid osteoma. Osteoid osteoma is a non-cancerous bone tumor that occurs most often in the long bones of the leg, such as the femur and tibia, of young children and adolescents. An osteoid osteoma causes a dull, aching pain that is moderate in intensity, but can worsen and become severe, especially at night. Computed tomography (CT) guided radiofrequency ablation, the most commonly used osteoid osteoma treatment, requires drilling through muscle and soft tissue into bone, and also exposes the patient to radiation from the imaging necessary to guide the probe that is inserted to heat and destroy tumor tissue.

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. We are in the process of transferring existing regulatory registrations of Sonalleve from Philips Oy to us. We are also in the 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.

In 2018, Sonalleve was also approved in China by the NMPA for the non-invasive treatment of uterine fibroids.

3.8 Reimbursement

Profound's ability to successfully commercialize the Company's products depends in large part on the extent to which coverage and adequate 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 payors. Pricing and reimbursement procedures and decisions vary from country to country. Many government health authorities and private payors condition payment on the cost-effectiveness of the product. Even if a device is FDA cleared or CE marked or has received other regulatory clearance or approval, there is no guarantee that third-party payors will reimburse providers or patients for the cost of the device and related procedures or that the amount of such reimbursement will be adequate to cover the cost of the device. The availability of coverage and adequate reimbursement to hospitals and clinicians using our products therefore is important to our ability to generate revenue and Profound plans to pursue coverage and reimbursement for the Company's products in the key markets where the Company has regulatory approvals. Successful commercialization of the Company's approved products will also depend on the cost of the system and the availability of coverage and adequate reimbursement from third-party payors.

Although we expect there to be an out-of-pocket market for our approved products, an out-of-pocket market alone is unlikely to be sufficient to support successful commercialization of our products. To date, our products do not have significant coverage or reimbursement from government or third-party payers in the jurisdictions where they are approved. In the US, a C-Code is a unique temporary product code established by CMS for the Hospital Outpatient Prospective Payment System ("**OPPS**") to promote the adoption of new medical technology that otherwise had no codes to facilitate payment. C-Codes are used on Medicare OPPS claims, but may also be recognized on claims from other providers or by other payment systems. For more information, see Item 4, "Risk Factors—Risks Related to Our Business and Growth Strategy—Successful commercialization of our approved products will also depend on the cost of the system and the availability of coverage and adequate reimbursement from third-party payers."

We plan to pursue reimbursement for our products in these and other key markets where we have regulatory approvals.

ITEM 4. RISK FACTORS

An investment in the Common Shares involves a high degree of risk and should be considered highly speculative due to the nature and present early stage of our business. The following risks are the material risks that we face; however, the risks below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Before deciding to invest in any Common Shares, investors should carefully consider the risk factors described below.

Risk Factors Relating to Our Operating History and Financial Condition

We have a limited operating history and history of operating losses.

We commenced operations in June 2008 and only began generating revenues in 2017. As of December 31, 2021, we had an accumulated deficit of $160,693,000 and had cash and cash equivalents of $67,152,000. Since inception, we have incurred significant losses each year. For the year ended December 31, 2021, we recorded a net loss of $30,699,000, and for the year ended December 31, 2020, we recorded a net loss of $21,622,000. We expect to incur significant operating losses even as we begin to commercialize the TULSA-PRO system in the United States following our recent FDA clearance, which will require significant expenditures to increase our sales and marketing capabilities and expand our manufacturing and distribution capacity, as well as other expenses related to increasing reimbursement coverage and gaining market acceptance among patients, physicians/clinicians and others in the medical community. In addition, we plan to continue product research and development and clinical trials and may pursue additional regulatory approvals. We expect to have sufficient cash to finance our operations for at least the next 18 months. There is no assurance that we will ever successfully commercialize our systems, generate significant revenues from our approved products or achieve profitability. Even if profitability is achieved, we may not be able to sustain or increase profitability. Our failure to achieve or maintain profitability could negatively impact the value of the Common Shares. We experienced a slowdown in our U.S. commercialization efforts during 2021 as a result of the ongoing COVID-19 pandemic, which has negatively affected our results during the year. We can provide no assurance that we will not continue to encounter future delays in our U.S. commercialization as a result of COVID-19, and we may need to seek additional financing to support our liquidity needs.

Our business is capital intensive and requires significant investment to increase our commercial capacity for our approved products, and the resources to do so may not be available in amounts or on terms acceptable to us, if at all.

Our business requires substantial capital investment in order to commercialize our approved products, in particular to expand our sales and marketing capabilities and increase our manufacturing capacity, as well as to conduct research and development and to obtain regulatory approvals for existing products and future product candidates. However, although we completed the 2020 Offerings, we will likely need additional capital to fund our current and planned business activities and to fund any significant expansion of operations. In order to secure financing, if available, it is likely that we would need to sell additional Common Shares and/or securities that are exchangeable for or convertible into Common Shares, incur additional indebtedness and/or enter into development, manufacturing, distribution and/or licensing relationships. Any future equity financing may be dilutive to existing shareholders. Any future debt financing arrangements we enter into (like our CIBC Loan Agreement) would likely contain restrictive covenants that would impose significant operating and, if any, financial restrictions on us. The availability of equity or debt financing will be affected by, among other things, our commercial progress and market acceptance in respect of the TULSA-PRO system and other approved products, as well as the results of our research and development, our ability to obtain regulatory approvals, the state of the capital markets generally, strategic alliance agreements, and other relevant considerations.

Any additional financing may not be obtained on favorable terms, if at all. If we cannot obtain adequate funding on reasonable terms, we may not be able advance our business strategy and/or the commercialization of our approved products, and we may need to terminate or delay clinical trials, curtail significant regulatory initiatives, and/or sell, license or assign rights to our technologies, products or product candidates.

Our cash outflows are expected to consist primarily of expenditures to increase our commercial capacity, particularly in sales and marketing, as well as in manufacturing and distribution. In addition, we intend to continue internal and external research and development efforts to develop and expand our product pipeline, as well as incur general and administrative expenditures to support our corporate infrastructure. If we do not obtain sufficient additional capital, there may be substantial doubt about our ability to continue as a going concern and realize assets and pay liabilities as they become due. Depending upon the results of our research and development programs and the availability of financial resources, we could decide to accelerate, terminate or reduce certain projects, or commence new ones. Any failure on our part to raise additional funds on terms favorable to us, or at all, may require us to significantly change or curtail 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 us not taking advantage of business opportunities, in the termination or delay of clinical trials for one or more of our product candidates, in curtailment of our product development programs designed to identify new product candidates, and/or in the sale or assignment of rights to our technologies, products or product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We are exposed to foreign currency risk, which exposure will increase as we commercialize our approved products in the United States; to date, we have not hedged against risk associated with foreign exchange rate exposure.

As we commercialize our approved products, in particular our TULSA-PRO system in the United States, we expect that a significant portion of our revenues, expenses, current assets and current liabilities will be denominated in United States dollars, Euros and other foreign currencies. Currently, our financial statements are expressed in United States dollars. A decrease in the value of such foreign currencies relative to the United States dollar could result in decreases in revenues from currency exchange rate fluctuations. To date, we have not hedged against risk associated with foreign exchange rate exposure. Consequently, our results of operations may be negatively affected by foreign currency exchange rate fluctuations, which could have a negative impact on the market price of our Common Shares.

Risks Related to Our Business and Growth Strategy

We currently rely on our collaborative partners, and we may rely on additional collaborative partnerships, to assist in the sales and marketing and/or distribution of our approved products.

We currently rely on our collaborative partnerships for the sales and marketing and/or distribution of our approved products, in particular Philips, Siemens and GE Healthcare, who promote our systems that are compatible with the MRI scanners produced and sold by them to end users, including hospitals and clinics. In the future, we intend to enter into similar arrangements with other producers of MRI scanners to increase the compatibility of our products and to promote and increase market acceptance among hospitals, clinics and other end-users. However, we can provide no assurance that we will be successful in establishing such additional arrangements, which could negatively impact our commercialization strategy and may have a material adverse effect on our business, results of operations and financial condition. See “—We rely on the compatibility of our products with MRI scanners in the successful commercialization of our products” above.

We may also seek out, evaluate and negotiate other third-party marketing and/or distribution arrangements for our products in the jurisdictions where they are approved, which may involve the commitment of substantial time and effort and may not ultimately result in an arrangement that is favorable to our commercialization goals (e.g. if such third-party marketing or distribution partners are not as successful in promoting our products as anticipated). If any of these third-party collaborators are unable or unwilling to promote and/or deliver our products to our customers in an effective manner, then our business, financial condition and operating results could be materially impacted.

Additionally, if any of our relationships with third-party collaborators is terminated, whether by us or the third-party for any reason, there can be no assurance that we will be able to obtain alternative sales and marketing and/or distribution channels rapidly or effectively enough to prevent disruptions in sales generated in those markets or otherwise to ensure the success of our products in those markets. Any such termination may have a material adverse impact on our business, results of operations and financial condition.

We may not achieve our commercialization and future product development goals in the time frames expected, or at all.

We may set goals for and make public statements regarding the timing of the accomplishment of objectives material to our success, such as the timing and extent of product launches in the jurisdictions where they are approved for marketing and sale, in particular our expected commercialization of the TULSA-PRO system following FDA clearance in the United States; third-party reimbursement for our approved products; the timing and terms of any collaborations, partnerships, licenses, acquisitions or other agreements; the commencement and completion of clinical trials, including follow-up data on our TACT Pivotal Clinical Trial; and anticipated regulatory submission and approval dates for our products in additional jurisdictions, and for future product candidates. The actual timing of these events can vary dramatically due to factors such as the ongoing COVID-19 pandemic, the uncertainties inherent in the arrangements sufficient to commercialize our products, including in respect of manufacturing, distribution and marketing, as well as market competition and adverse results from our clinical trials, and other factors and described herein, many of which are beyond our control. There can be no assurance that we will achieve our commercialization goals in respect of the TULSA-PRO system in the United States, or that future efficacy and safety results from our TACT Pivotal Clinical Trial will be favorable. If we fail to commercialize the TULSA-PRO system in the United States or any other approved products in the time frame and to the extent that we anticipate, our business, results of operations and financial condition may be materially adversely affected, and the price of the Common Shares could decline.

Our products, including the TULSA-PRO system, may not achieve or maintain expected levels of market acceptance.

The commercial success of our approved products, including the TULSA-PRO system which was recently FDA-cleared in the United States in August 2019, 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 our products could be impacted by several factors, many of which are not within our control, including but not limited to:

- safety, efficacy, convenience and cost-effectiveness of our systems as a method of ablation of prostate tissue, uterine fibroids, bone metastases compared to products of our competitors or other forms of treatment;
- scope of approved uses and marketing approval or clearance;
- timing of market entry of our products versus those of our competitors;
- difficulties in, or excessive costs required in the process of, manufacturing our products;
- expanding compatibility of our systems to work with MRI scanners other than those made by Philips and Siemens, and maintaining our existing relationships with Philips, Siemens and GE Healthcare;
- infringement or alleged infringement of the patents or intellectual property rights of others;
- acceptance of the price of our products relative to those of our competitors;
- acceptance and adoption of our products by patients, physicians/clinicians and the medical community;
- the availability of training necessary for proficient use of our products, as well as willingness of physicians and technicians to participate in such training;
- the perceived risks generally associated with the use of new products and procedures;
- the placement of our products in treatment guidelines published by leading medical organizations;
- the size and growth rate of the market for our products in the major geographies in which we operate or intend to operate, in particular in the United States; and
- acceptance of our products by government and third-party payers for adequate reimbursement coverage.

In addition, the success of any new product will depend on our ability to either successfully build our in-house sales and marketing capabilities or to maintain or secure new, or to realize the benefits of existing or future arrangements with, third-party marketing or distribution partners. See “Risk Factors—We intend to rely primarily on our in-house sales and marketing capabilities for our commercialization strategy, which will require substantial build-up and commitment of resources” and “Risk Factors—We currently rely on our collaborative partners, and we may rely on additional collaborative partnerships, to assist in the sales and marketing and/or distribution of our approved products” below. If we are unable to commercialize new products successfully, whether through a failure to achieve market acceptance, a failure to build our own in-house sales and marketing capabilities, a failure to maintain or secure new or existing marketing partners or to realize the benefits of our arrangements with our marketing and distribution partners, there may be a material adverse effect on our business, financial condition and results of operations and it could cause the market value of our Common Shares to decline.

Market acceptance of our approved products also depends on our ability to identify and address the relevant market. For example, our TULSA-PRO system is FDA-cleared in the United States for transurethral ultrasound ablation of prostate tissue and is not specific to any particular condition or disease. For more information, see “We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or “off-label” uses or engaged in false or misleading promotion.” below. Furthermore, our 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 will actually be used by patients. Our failure to successfully introduce and market our approved products could have a material adverse effect on our business, financial condition, and results of operations.

Successful commercialization of our approved products, including the TULSA-PRO system, and future product development depends upon our maintaining strong working relationships with physicians/clinicians.

If we fail to maintain positive working relationships with physicians/clinicians, our approved products, including our TULSA-PRO system, may not achieve the level of market acceptance sufficient for successful commercialization of the products. It is important for us to market our approved systems successfully to physicians/clinicians who we expect will use our approved products, and we depend on our sales and marketing personnel (and those of our collaborative partners, e.g., Philips, Siemens and GE Healthcare) to do so in an effective manner. We can provide no assurance that physicians/clinicians will prescribe or otherwise utilize our TULSA-PRO systems based on our existing clinical data (such as our TACT data) or the results of any future clinical trials, or at all. See “Risk Factors—Data from our clinical trials may not support regulatory approvals or clearances and/or reimbursement coverage for our products” below. We also rely on our relationships with physicians/clinicians to further develop our existing products and develop future product candidates in line with the clinical needs and expectations of the professionals who we expect will use and support the devices. These development efforts are similarly dependent upon us and our collaborative partners maintaining working relationships with physicians/clinicians.

In addition, we rely on physicians/clinicians to provide considerable knowledge and experience that assists us in the marketing and sale of our approved products and development of our products and product candidates. Physicians/clinicians assist us as researchers, marketing and product consultants, inventors and public speakers. If we are unable to maintain strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and operating results.

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

There is a risk that physicians/clinicians may misuse our products, such as not following the instructions for use, not using our products on the intended patient population, using our products 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, and may result in adverse safety or efficacy results. Any of the foregoing could result in negative publications, negative sentiment or adverse events or regulatory actions in respect of our products, thereby limiting market acceptance and sales of our products, which could have a material adverse effect on our business, financial condition and results of operations.

We rely on the compatibility of our products with MRI scanners in the successful commercialization of our products.

We have designed our TULSA-PRO system to be capable of integration with some of the MRI scanners from three of the major MRI manufacturers (Philips, Siemens and GE Healthcare), and the Sonalleve system with one MRI manufacturer (Philips). Although we believe that our approved products can be used by the vast majority of hospitals and treatment facilities, not all such facilities utilize MRI scanners that are compatible with the TULSA-PRO and Sonalleve systems, and such facilities would be required to acquire (or outsource to other facilities that already have) compatible MRI equipment, which may increase their costs and which could restrict or delay utilization of our systems by such facilities. Accordingly, we intend to expand compatibility of the systems with other MRI scanners in the future, which would require design changes to our systems, collaboration with the manufacturer of the MRI scanner and may require additional regulatory approvals. We may be unsuccessful in making the necessary design changes and, if required, receiving the necessary regulatory approvals for such changes, and the terms of any such arrangements that we may enter into in the future with the MRI scanner manufacturers may not be on as favorable terms. Accordingly, we can provide no assurance that we will be successful in any such expansion of the compatibility of our products to other MRI scanners.

Successful commercialization of our approved products will also depend on the cost of the system and the availability of coverage and adequate reimbursement coverage from third-party payers.

Successful commercialization of our approved products, including our TULSA-PRO system, depends largely upon the cost of the system and the availability of coverage and adequate reimbursement for the system, and the 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. We expect that our systems will be purchased by health-care providers, including clinics and hospitals that use MRI scanners that are compatible with our systems, and that these providers will subsequently bill various third-party payers or will be responsible for covering the costs of the system through the provider's operating budget. Although we expect there to be an out-of-pocket market for our approved products, an out-of-pocket market alone is unlikely to be sufficient to support successful commercialization of our products. To date we have not secured significant coverage or reimbursement for any of our products from government or third-party payers in the jurisdictions where we have regulatory approvals, including our TULSA-PRO system in the United States. We can provide no assurance that third-party payers will provide coverage and adequate reimbursement for our TULSA-PRO system to treat our targeted indications based on our existing clinical data (such as our TACT data) or the results of any future clinical trials, or at all. See "Risk Factors —Data from our clinical trials may not support regulatory approvals or clearances and/or coverage and reimbursement for our products" below. Accordingly, we likely will need to conduct additional research and successfully complete additional clinical trials in order to obtain such coverage (e.g., follow-up data from our TACT Pivotal Clinical Trial). Such additional research and clinical trials may require significant time and resources, and may not be successful, which could result in the postponement of or inability to obtain coverage and reimbursement for our approved products, which could significantly delay or otherwise negatively affect our commercialization strategy. Any of the foregoing could, in turn, have a material adverse effect on our business, results of operations and financial condition.

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 our products and approach are superior from a long-term cost containment standpoint. Third-party payers may determine that our 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 our 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. We are 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 our business.

We intend to rely primarily on our in-house sales and marketing capabilities for our commercialization strategy, which will require substantial build-up and commitment of resources.

We intend to rely primarily on our in-house sales and marketing capabilities in order to advance our commercialization strategy, particularly in the United States in respect of our recently FDA-cleared TULSA-PRO system. This will require a substantial commitment of time and resources in the near-term, and we may be unsuccessful in executing on this strategy, which could negatively impact our anticipated commercialization. As a result of the COVID-19 pandemic, we remain in the early stages of expanding our U.S. sales and marketing capabilities and can provide no assurance that we will be successful in establishing a marketing presence and sales force sufficient to commercialize the TULSA-PRO system successfully in the United States.

In addition, by relying on an in-house sales and marketing function, we may have less visibility in the U.S. market (particularly among hospitals) than we would have if we had significant third-party distribution relationships. Any shortcomings in our in-house sales force may have a material adverse effect on our business, results of operations and financial condition.

We may experience manufacturing scaling issues in connection with our commercialization strategy, as we have limited experience assembling and testing our approved products, including the TULSA-PRO system, at a significant scale.

As we implement our commercialization strategy, in particular in respect of the TULSA-PRO system in the United States, we may not be able to produce sufficient quantities of systems or maintain consistent quality control in the production of our systems. We have limited experience in assembling and testing our approved products, including our TULSA-PRO system, on a commercial scale. To commercialize our approved products successfully and become profitable, we must be able to assemble and test such in commercial quantities in compliance with applicable regulatory requirements, and at an acceptable cost. Increasing our capacity to assemble and test our products on a commercial scale will require us to improve internal efficiencies, including hiring additional experienced personnel, which may result in significant capital expenditures. We may encounter a number of difficulties in increasing our 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 U.S. and Canadian regulations (including at the state, provincial and/or federal levels) and applicable foreign regulations.

In particular, our ability to increase our assembly and testing capacity successfully will greatly depend on our ability to hire, train and retain an adequate number of employees, in particular employees with the appropriate level of knowledge, background and skills to assemble and test our products. We compete with several other medical device companies to hire and retain these skilled employees, and we may be unable to hire and retain such employees in numbers sufficient to increase our in-house capabilities.

We currently intend to partner with one or more additional QSR-compliant and FDA-registered contract manufacturers for our TULSA-PRO systems in the United States. However, we may not be successful in establishing or maintaining such partnerships on acceptable terms or in the timeframe necessary to commercialize our products successfully, or at all.

In addition, we may encounter difficulties in scaling our manufacturing operations, whether in-house or through third-party contract manufacturers, as a result of, among other things, quality control and quality assurance issues and availability of components and raw material supplies. Any such quality control issues may negatively affect production and sales of our products, and may require 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 could negatively affect our business and reputation.

If we are unable to satisfy commercial demand for our products, in particular our TULSA-PRO system in the United States, due to our inability (or the inability of any of our contract manufacturers) to assemble and test such products in sufficient quantities with consistent quality control, and in compliance with applicable regulatory requirements (and in a cost-efficient manner), our ability to commercialize such products successfully, and market acceptance of our products could be adversely affected as our target customers may instead purchase or use our competitors' products. This, in turn, could have a material adverse effect on our business, results of operations and financial condition.

We rely on third parties to manufacture and supply components of our systems.

The TULSA-PRO and Sonalleve systems consists of common electronic components, proprietary capital equipment and proprietary one-time-use devices. We purchase standard electronic components for our systems from a number of third-party vendors. The capital equipment consists of custom system electronics, a treatment delivery console, fluid circuits and an MRI compatible robotic positioning system. Printed circuit boards and assemblies and custom mechanical parts are outsourced from approved suppliers.

We cannot be certain that manufacturing sources for all components will continue to be available or that we can continue to outsource the manufacturing of our components on reasonable or acceptable terms. If we encounter delays or difficulties with contract manufacturers, delivery of our products could be delayed. In addition, we could be forced to secure new or alternative contract manufacturers or suppliers. Securing a replacement contract manufacturer or supplier could be difficult, and we may not be able to do so in a timely manner or without significant expense. Any loss of a manufacturer or any difficulties that could arise in the manufacturing process could significantly affect our ability to supply sufficient amounts of our products to our customers on a timely basis, which may negatively affect our market share and, correspondingly, could have a material adverse effect on our business, results of operations and financial condition.

In addition, not all of our suppliers provide us with guaranteed minimum production levels, and we rely on single-source suppliers for some of our components. See "Risk Factors—We depend on single-source suppliers for some of the components in our systems" below. Furthermore, we do not currently have long-term supply contracts, and accordingly, our suppliers could terminate their services at any time without penalty within agreed notice periods. As a result, there can be no assurance that we will be able to obtain sufficient quantities of components in the future necessary to commercialize our approved products.

Our reliance on third-party manufacturers and suppliers involves a number of additional 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 our products or cause delays in shipments of products;
- we or our contract manufacturers and suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, our suppliers may have excess or inadequate inventory of materials and components;
- we or our contract manufacturers and suppliers may be subject to price fluctuations of raw materials and key components due to a lack of long-term supply arrangements for key components;
- we or our contract manufacturers and suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our products;
- we may experience delays in delivery by our contract manufacturers and suppliers as a result of the ongoing COVID-19 pandemic or due to changes in demand from us or our other customers;
- fluctuations in demand for products that our 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;
- we may not be able to find new or alternative components or reconfigure our 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 our demand, which could inhibit their ability to fulfill orders and meet our requirements.

If any of these risks materialize, it could significantly increase costs and impact our ability to meet demand for our products, in particular in respect of our planned commercialization of TULSA-PRO in the United States. If we are unable to satisfy commercial demand for the TULSA-PRO system or other approved products in a timely manner, our ability to generate revenue could be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use competitors' products. As a result, our business, results of operations and financial condition may be materially adversely affected.

We depend on single-source suppliers for some of the components in our systems.

We currently rely on a single source for the manufacture of some of the components of our TULSA-PRO and Sonalleve systems. Although we intend to procure alternative supply sources for our components as our commercialization efforts increase, we can provide no assurance that we will be successful. Establishing additional or replacement suppliers for these components will take a substantial amount of time and could result in increased costs and impair our ability to produce our products. In addition, our products are highly technical and are required to meet exacting specifications, and any quality control problems that we experience from such alternative supply sources could negatively affect our reputation and market acceptance of our products.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities. The failure of our 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. See "Risk Factors—Risks Relating to the Regulation of the Company and Our Products" below for more information.

If we fail to procure alternative supply sources on acceptable terms or at all, our planned commercialization of TULSA-PRO in the United States could be negatively affected, which could have a material adverse effect on our business, operating results and financial condition.

We face significant competition in the markets for our products, and in particular, there are numerous devices and procedures that compete with our TULSA-PRO system.

Our products face significant competition from currently available and future medical devices or surgical methodologies that are used in the same patient populations as our products. See Item 3.5, "Narrative Description of the Business—Competition". Some of these available options are well-established, and our competitors have greater financial resources, development, selling and marketing capabilities than we do. We may face further competition from medical equipment/supply companies that focus their efforts on developing and marketing products that are similar in nature to our products, but that in some instances offer improvements over our products. Our competitors may succeed in developing technologies and products that are more effective or less expensive to use than our products. These developments could render our products uncompetitive, which would have a material adverse effect on our 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 our competitors.

Further, our 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. Our success will depend, in part, on our ability to achieve technological superiority in our products and operations and maintain such superiority in the face of new technologies. No assurance can be given that further modification of our product offerings will not be required in order to meet demands or to make changes necessitated by developments made by competitors that might render our products less competitive. Our future success will be influenced by our ability to continue to develop, test and market our products and future product candidates, including increasing and/or maintaining their compatibility with MRI scanners. Although we have committed resources to these efforts, there can be no assurance that we will be successful.

Data from our clinical trials may not support regulatory approvals or clearances and/or reimbursement coverage for our products.

Regulatory clearances and approvals for the commercial sale of any of our product candidates require that we demonstrate through clinical trials that the product candidate is safe and effective for its intended use or, to receive 510(k) clearance in the United States, that the product candidate is substantially equivalent to an existing predicate device for its intended use. While we have obtained 510(k) clearance for TULSA-PRO, additional follow-up data from our TACT Pivotal Clinical Trial may not be consistent with our 12-month data in terms of efficacy and/or side effect profile, which in certain circumstances may result in the FDA taking regulatory actions that are adverse to us. In addition, our TACT Pivotal Clinical Trial involves a relatively small patient population. Because of the small sample size, the results may not be indicative of future results.

We believe that third-party payers, in determining reimbursement coverage for our products, including the TULSA-PRO system, generally would rely upon our clinical trial results, such as TACT, that were obtained in support of our regulatory approvals; however, we may be required to provide additional data from our existing trials and/or conduct additional clinical trials prior to obtaining reimbursement coverage for the TULSA-PRO system and other approved products, which would likely involve significant time and expense, and may have a material adverse effect on our business, results of operations and financial condition.

In the future, we may also seek regulatory approvals, which may include 510(k) clearance, for other product candidates, which likewise could be adversely affected by insufficient clinical trial results. 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. In addition, a regulatory authority may disagree with our interpretation of the data from our clinical trials, or may find the clinical trial data inadequate to support clearance or approval, and may require us to extend existing clinical trials and/or pursue additional clinical trials, which would increase costs and could further delay regulatory approval or clearance of our products, or cause such regulatory approvals or clearances to be denied altogether.

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;
- changes in regulatory requirements, policies or guidelines;
- the interim or final results are insufficient (including in respect of the time period for which results were obtained), inconclusive or unfavorable as to the safety or efficacy of the device;
- the FDA or other regulatory authorities concluding that a clinical trial design is inadequate to demonstrate safety and efficacy for a particular use, or to demonstrate substantial equivalence to a predicate device; and
- the FDA or other regulatory authorities concluding that the trial was not conducted in compliance with regulatory requirements or lacked controls necessary to ensure the integrity of the trial data.

We, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time if it is determined that patients may be or are being exposed to unacceptable health risks, including the risk of death, that our devices are not manufactured under acceptable conditions or with acceptable quality, or that the trial is not being conducted according to the protocol and in compliance with Good Clinical Practice and regulatory requirements. 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. We cannot be sure that the later trials will replicate the results of prior trials.

Even if our clinical trials are completed as planned, there can be no certainty that trial results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them or agree that they are adequate to support approval or clearance. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, negatively affect our ability to commercialize our systems and generate revenues.

If our products do 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 or third-party payers, if the clinical studies do not support our product candidate claims or if they result in the discovery of adverse side effects, then our regulatory approvals and reimbursement coverage (as applicable) may be delayed or denied altogether, and our business, financial condition and results of operation could be materially adversely affected.

We may rely on third parties to perform clinical trial planning and to facilitate obtaining regulatory approvals or clearances for our product candidates.

We may rely on third parties to provide clinical trial planning and regulatory services for our product candidates. We may be unable to find suitable partners, external consultants or service providers to provide such services or such arrangements may not be available on commercially reasonable terms. Further, we 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, we may not be able to successfully manage such services, execute clinical trials or obtain regulatory approvals or clearances for our product candidates, which may negatively affect our business. If we fail to establish such arrangements when, and as necessary, we could be required to undertake these activities at our own expense, which would significantly increase capital requirements and may delay the development, approval and future commercialization of our product candidates, which could have a material adverse effect on our business, financial condition and operating results.

We depend on key managerial personnel for our continued success.

We are highly dependent upon our small team of managerial personnel, particularly that of our Chief Executive Officer, Arun Menawat. We do not maintain any “key man” insurance policies on Dr. Menawat or any other members of senior management. Our 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, we may not be able to attract and retain the qualified personnel necessary for the development of our business. We must continue to retain, motivate and recruit executives and other key employees. The failure to motivate, or 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 our business development programs, and our 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 our business, financial condition and results of operations.

Research and development carries substantial risk and we may not be able to expand our product portfolio.

Future growth may also depend on, among other factors, our ability to successfully develop new product candidates and make product improvements to meet evolving market needs. We may not be able to successfully expand our product portfolio to generate new revenue opportunities in the future. Although we believe we have the scientific and technical resources available to improve our 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. In addition, any such research and development activities may involve significant capital expenditures. There can be no assurance that we will be able to successfully develop future products and tests, which would prevent us from introducing new products in the marketplace and negatively impact our ability to grow revenues and become profitable.

In addition, the identification of new product candidates for development may require that we enter into licensing or other collaborative agreements with others, including medical device and pharmaceutical companies and research institutions. These collaborative agreements may require that we pay license fees, make milestone payments or pay royalties or grant rights, including marketing rights, to one or more parties, and such amounts may be material to our results of operations and financial condition. Moreover, these arrangements may contain covenants restricting our product development or business efforts in the future. Any such arrangements would also increase our reliance on third parties.

We may be subject to product liability claims, which can be expensive, difficult to defend and may result in large judgments or settlements, and/or warranty claims on our products.

The use of medical devices for treatment of humans, whether in clinical trials or after marketing clearance or 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 us. In addition, third-party collaborators and licensees may not protect us from product liability claims.

We currently maintain product liability insurance in connection with the use of our products in clinical trials and in commercial use; however, we may not have adequate protection against all potential liabilities under these insurance policies. If we are unable to obtain sufficient levels of insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to product liability claims. A successful product liability claim in excess of our insurance coverage could harm our financial condition, results of operations and prevent or interfere with our commercialization efforts and future product development. In addition, any successful claim may prevent us 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.

We also bear the risk of warranty claims on our products, generally for one year after sale. We may not be successful in claiming recovery of the relevant components from our suppliers in the event of a successful warranty claim against us by a customer, or that any recovery from such suppliers would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after the expiration of our corresponding warranty with our third-party suppliers, which would require us to bear the burden of any such warranty claims.

Rising insurance costs could negatively impact our 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 particular, our product liability insurance is subject to price increases if we experience product liability claims. In response, we may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverages, could have a negative impact on our business, financial condition and results of operations.

We are increasingly dependent on sophisticated information technology systems to operate our business and if we fail to properly maintain the integrity of our data or we experience a cyber-attack or other breach of these systems, our business could be adversely affected.

We are increasingly dependent on sophisticated information technology for our development activities, products and infrastructure. We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The complexity of our information technology systems makes them vulnerable to increasingly sophisticated cyber-attacks, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Any such event could be prolonged and/or could go undetected for a significant period of time. Our products and their 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 our products or systems and may obtain data relating to patients, our products or our proprietary information. If we fail to maintain or protect our information systems and data integrity effectively, we 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. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

A portion of our employees are unionized, and our good labor relations may not continue.

As of December 31, 2021, 18 of our employees in Vantaa, Finland were unionized. Currently, labor relations are good; however, the maintenance of a productive and efficient labor environment cannot be assured. If any of our employees at our other manufacturing facilities unionize in the future, or if protracted and extensive work stoppages occur, labor disruptions such as strikes or lockouts could have a material adverse effect on our business, financial condition and results of operations.

If our facilities are damaged or destroyed, we may experience delays that could negatively impact our revenues.

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

We face risks associated with acquisition of businesses and technologies.

As part of our growth strategy, we intend to evaluate and may pursue additional acquisitions of, or significant investments in, complementary companies or technologies to increase our technological capabilities and expand our product offerings. For example, in July 2017, we acquired from Philips the technologies and asset underlying our Sonalleve system. Acquisitions and the successful integration of new technologies, products, assets or businesses may require significant attention from our management and could result in a diversion of resources from our existing business, which in turn could have an adverse effect on our business operations. Other risks typically encountered with acquisitions include disruption of our ongoing business; difficulties in integration of the acquired operations and personnel; inability of our management to maximize our financial and strategic position by the successful implementation or integration of the acquired technology into our product offerings; being subject to known or unknown contingent liabilities, including taxes, expenses and litigation costs; and inability to realize expected synergies or other anticipated benefits which may, among other things, also lead to goodwill impairments or other write-offs. For example, our ability to achieve the anticipated benefits of the Sonalleve Transaction depends in part on our ability to realize the anticipated growth opportunities and synergies from the acquired assets and technologies, including our further development of the Sonalleve system.

We cannot assure you that we will be successful in overcoming these risks or any other problems we may encounter in connection with the Sonalleve Transaction or potential future acquisitions. Our inability to successfully integrate the operations of an acquired business, including a successful implementation of the technologies and assets we acquire, and realize anticipated benefits associated with an acquisition, could have a material adverse effect on our business, financial condition, results of operations and cash flows. Acquisitions or other strategic transactions may also result in dilution to our existing shareholders if we issue additional equity securities as consideration or partial consideration as well as in the incurrence of indebtedness if we borrow funds to finance such transactions.

Risks Relating to Regulation of the Company and Our Products

Our business is subject to limitations imposed by government regulations.

The preclinical testing and clinical trials of any products developed by us and the manufacturing, labeling, sale, distribution, export or import, marketing, advertising and promotion of any of those products are subject to rigorous regulation by U.S., Canadian, EU and other foreign regulatory authorities at the federal, provincial, state, national and local governmental levels, as applicable. Our 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 (supervising Notified Bodies and manufacturers of medical devices), in Canada by Health Canada (particularly, the TPD), and by other similar regulatory authorities in other jurisdictions. Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products.

We may be unable to obtain, or experience significant delays in obtaining, FDA clearances or other regulatory approvals for our product candidates and/or enhancements to our approved or cleared products.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities and Notified Bodies. 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 we may not be able to obtain these clearances or approvals on a timely basis, if at all. We expect to generate a significant portion of our revenues from sales of our marketed systems, in particular our FDA-cleared TULSA-PRO system, but may be unable to do so if the systems do not continue to prove to be safe and effective for our intended use in clinical trials to the satisfaction of the relevant regulatory authorities in the United States, EU Member States, China or other countries. In addition, no assurance can be given that our other product candidates will prove to be sufficiently safe and effective in clinical trials or that we will receive regulatory approvals in the jurisdictions where we seek to market the systems. In addition, no assurance can be given that current regulations relating to regulatory approval will not change or become more stringent.

Any delay in, or failure to receive or maintain, regulatory clearance or approval of other products under development would adversely affect our ability to commercialize those products, thereby adversely affecting operations and could prevent us from generating revenue from these products or achieving profitability. Any failure to obtain regulatory clearance or approval would materially adversely affect our business, financial condition and results of operations.

If clinical trials are conducted in a manner that fails to meet all FDA requirements, the FDA may delay our clearances or approvals, or the deficiencies may be so great that the FDA could refuse to accept all or part of our 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 and involve a significant risk device require an IDE application to be approved in advance by the FDA for a specified number of patients and study sites. Clinical trials involving a non-significant risk device do not require FDA approval of an IDE application and are subject to abbreviated requirements under the IDE regulation. Further, some clinical trials are exempted from the IDE regulation. Although we do not expect to submit any additional IDE applications for any further clinical trials involving TULSA-PRO system, we may need to obtain an IDE application for any clinical trials designed to expand the indications for the TULSA-PRO.

In addition, FDA approval of IDE applications may be required in support of clinical trials involving other product candidates. 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, we must also obtain the patients' informed consent that complies with FDA requirements, state and federal privacy regulations and human subject protection regulations. We, 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, we may decide at any time, for business or other reasons, to terminate a clinical trial. Even if a clinical 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 clinical trial, we 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 our product. In addition, the FDA may perform a bioresearch monitoring inspection of a study and if it finds deficiencies, we 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.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements or if we experience unanticipated problems with our products, we could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory clearance or approval, and the manufacturing processes, postmarket surveillance and reporting, post-approval clinical testing and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other regulatory bodies. In particular, we and some of our suppliers are required to comply with the QSR and international standards 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 we obtain regulatory clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections.

The failure by us or one of our 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;
- customer notifications for repair, replacement or refunds;
- recall, withdrawal, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- operating restrictions;
- withdrawing PMA approvals that have already been granted;
- suspension, variation, or withdrawal of our CE Certificates of Conformity;
- refusals to allow imports and/or to issue documentation necessary to facilitate exports;
- refusal to grant export approval for our products; or
- imposition of civil, administrative or criminal penalties.

If any of these actions were to occur, we may be required to expend significant time and resources to address or defend such actions, and our reputation may be harmed and our product sales and/or profitability may be negatively affected. Furthermore, key component suppliers may not currently be, or may not continue to be, in compliance with all applicable legal requirements or our supplier control requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of certain adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our 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 (which may require new marketing applications or supplements), 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 product we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would have a material adverse effect on our business, financial condition, and results of operations.

Our products that have received regulatory clearance or approval are subject to extensive post-market regulation that could affect sales, marketing and profitability.

With respect to the products for which we have obtained regulatory clearance or approval, we are 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 our ability to successfully commercialize approved products.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses or engaged in false or misleading promotion.

Regulatory clearances and approvals may be subject to limitations on the intended uses for which our products may be marketed and reduce our potential to successfully commercialize our products. While physicians/clinicians, in most jurisdictions, can use our products in ways or circumstances other than those strictly within the scope of the regulatory clearance or approval, we are required, in many jurisdictions, to limit our training and promotion of our products to the cleared or approved intended uses. For example, if the FDA determines that our promotional materials, labeling, training or other marketing constitutes promotion of an uncleared or unapproved, or "off-label" use, it could request that we modify or cease use of those training or promotional materials until we obtain FDA clearance or approval for those uses or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and/or criminal penalties. Discussions that may be viewed as off-label promotion by FDA include discussions regarding treatment of a specific disease or condition when FDA has cleared or approved a device with a general tool-type indication that does not mention any particular disease or condition. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our 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, our reputation could be damaged and adoption of our products would be impaired.

In addition to promoting our products in a manner consistent with our clearances and approvals, we must have adequate substantiation for the claims we make for our products. If any of our claims are determined to be false, misleading or deceptive, we could be subject to enforcement action. In addition, unsubstantiated claims also present a risk of consumer class action or consumer protection litigation and competitor challenges.

Modifications to our cleared or approved products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until such additional clearances or approvals are obtained.

Certain modifications to our products may require the submission of new 510(k) notifications, PMA supplements, or other regulatory agency approval applications or documents. If a modification is implemented to address a safety concern, we may also need to initiate a recall or cease distribution of the affected device. The FDA can review a manufacturer's decision not to submit a new 510(k) notification, PMA supplement or PMA for 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. We may make additional modifications to our products in the future that we believe do not or will not require clearance of a new 510(k) or approval of a new PMA. If we begin manufacture and distribution of the modified devices and the FDA later disagrees with our determination and requires the submission of a new 510(k) or PMA for the modifications, we may also be required to recall the distributed modified devices and to stop distribution of the modified devices until we have received approval or clearance for the modified device, which could have an adverse effect on our business. If the FDA does not clear or approve the modified devices, we may need to redesign the devices, which could also harm our business. When a device is marketed without a required clearance or approval, the FDA has the authority to take informal enforcement actions such as the issuance of a Warning Letter, or bring a formal enforcement action, including injunction, seizure and criminal prosecution. The FDA considers formal enforcement actions generally when there is a serious risk to public health or safety or the company's corrective and preventive actions are inadequate to address the FDA's concerns.

Where we determine that modifications to our products require clearance of a new 510(k) or approval of a new PMA or PMA supplement, we 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 EEA, we must notify an EU Notified Body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm its future growth.

Our contract manufacturers are subject to regulatory compliance by the FDA, Health Canada and regulatory authorities in the EU and other jurisdictions.

Our 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 our contract manufacturers do not or cannot comply with these requirements, our ability to commercialize our approved products may be adversely affected.

The introduction of new or alternative manufacturers or suppliers also may require manufacturing or design changes to our 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 our quality system or result in design changes to our products which could affect compliance with the Essential Requirements for the Notified Body's certificate under the MDD (which continues to be valid during the transition period) and with the General Safety and Performance Requirements once a Notified Body certificate under the New EU MDRs is required.

If a substantial change is made to a device relying on an MDD certificate it will no longer benefit from the transition period set out in the New EU MDR. In this case the product would need to be CE marked under the New EU MDR to be placed on the market. Once CE marked under the New EU MDR these changes must be disclosed to our Notified Body in the EU before implementation. The Notified Body will then assess the changes and verify whether they affect the products' conformity with the General Safety and Performance Requirements. If the assessment is favorable the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing certificates attesting compliance with the General Safety and Performance Requirements. We may also be required to assess the new manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to manufacture our products in a timely manner. As a result, we could incur increased production costs, experience delays in deliveries of our products, suffer damage to our reputation, and experience a material adverse effect on our business, financial condition, and results of operations.

Our products may in the future be subject to product recalls that could harm our 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. In addition, we may initiate voluntary recalls of our products in the future to the extent we experience safety or other concerns with such products. For voluntary corrections or removals, the FDA requires that manufacturers report to the FDA within 10 working days after the correction or removal is initiated if the action 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 corrections and removals, even if they are not reportable to the FDA. We may determine that any particular voluntary recall that we initiate does not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

In the European Union, incidents and serious 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. The timing and means of making the report depend on the severity of the incident (for example, serious incidents that resulted in death or serious deterioration require immediate reporting to competent authorities, whereas incidents might be included in the periodic safety update report and/or trend reporting). For purposes of these regulations, an "incident" is defined as any malfunction or deterioration in the characteristics and/or performance of a device, including user-error due to ergonomic features, as well as any inadequacy in the labeling or the instructions for use and any undesirable side-effect. "Serious incident" is defined as any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. An FSCA is defined as a corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. In addition, governmental or other competent bodies or authorities 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 us or one of our 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 could have an adverse effect on our financial condition and results of operations.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, and such events can result in voluntary corrective actions or agency enforcement actions.

Under FDA medical device reporting regulations, 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 we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Similar enforcement action could be taken by the competent authorities in the European Union if we do not comply with our medical devices vigilance obligations. In addition, our EU Notified Body could decide to suspend or withdraw our 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 our reputation and could have a material adverse effect on our business, financial condition and operating results.

Legislative or regulatory reform of the healthcare systems in which we intend to operate may affect our ability to sell our products profitably and could adversely affect our business.

The governments and regulatory authorities in the United States, the European Commission, Canada and other markets in which we expect to sell our devices may propose and adopt new legislation and regulatory requirements relating to medical product approval criteria, manufacturing and marketing requirements. In addition, regulations and guidance promulgated by the FDA, the European Commission, and other regulatory bodies are often revised or reinterpreted by the agency and other relevant regulatory bodies in ways that may significantly affect our 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 changes in regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States, 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 impacted FDA 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 FFDCA, including a 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 us and delay our 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 our 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 our products would have a material adverse effect on our business, financial condition and operating results.

On April 5, 2017, the EU adopted the New EU MDR, which became fully applicable on May 26, 2021, and a new Regulation on *in vitro* diagnostic medical devices (Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices (“**IVDR**”)), which will become fully applicable on May 26, 2022. The Regulations do not set out a substantially different regulatory system, but contemplate, 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 and an extension of transparency requirements through the establishment of a comprehensive EU database on medical devices and of a device traceability system allowing a device to be traced from its manufacturer through the supply chain to the final user. The New EU MDR and the IVDR also introduce new classification rules according to which manufacturers must test their products and adapt their documentation. For example, stricter clinical requirements now apply to Class III medical devices and implants under the New EU MDR.

After the expiry of the transitional periods as provided by the New EU MDR and the IVDR, respectively, only devices that have been CE marked under the New EU MDR/IVDR may be placed on the market in the EU. The latest a certificate from a Notified Body under the MDD will expire is May 27, 2024; however, some devices may not benefit from this transition period at all and/or will not benefit for the entire period. Fewer Notified Bodies currently have a notification under the New EU MDR as compared with the MDD. The new legislation may therefore delay the CE marking of our product candidates under development or impact our ability to renew the CE marking of our currently CE marked products on a timely basis. Further, there is no guarantee that products approved under the MDD can or will be approved under the New EU MDR in their current form.

The UK exited the EU on December 31, 2020 (Brexit). The UK did not implement the New EU MDR into the laws of Great Britain (England, Scotland and Wales) but the New EU MDR does apply in Northern Ireland currently. Great Britain instead kept the existing legal framework (based on the MDD) and updated it so it existed as a standalone medical devices framework. The UK's regulatory framework has introduced some changes. For example, instead of a CE mark, medical devices marketed in Great Britain must bear a UKCA mark. However, EU CE marks will continue to be recognized in Great Britain until June 30, 2023, as will certificates issued by EU-recognized notified bodies. This arrangement is not reciprocated in the EU. Each medical device that we wish to market in the UK must comply with the national laws in the UK, which going forwards may differ from the laws in the EU (notably, in October 2021, the UK's competent authority published proposed changes to the medical device regulatory framework with the aim of changes coming into force in July 2023).

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, our 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 we 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 our existing and potential products.

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.

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 former United States President and certain members of the U.S. Congress indicated their desire to repeal and replace all or portions of the ACA and to decrease fiscal burdens. Recently enacted legislation addresses certain ACA measures and effectively repeals the individual mandate insurance requirement. In addition, in December 2018, a federal district court judge in Texas found the ACA's individual mandate to be unconstitutional and therefore the entire law to be invalid. In December 2019, the Fifth Circuit affirmed the ruling regarding the individual mandate but remanded the case to the district court for additional analysis of the question of severability and whether portions of the law remain valid. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Further, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which ran until August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In June 2021 the United States Supreme Court held that the individual plaintiffs and states lacked standing to challenge the constitutionality of the ACA. Any additional healthcare reform legislation or court challenges to the ACA, or other potential changes resulting from any amendment, repeal, replacement or invalidation of these programs, including any reduction in the future availability of healthcare insurance benefits, may decrease the number of people who are insured, which could adversely affect our business and future results of operations

The Trump Administration implemented regulatory changes to healthcare insurance exchange parameters. According to the Trump administration's statements describing the changes, they are intended to increase flexibility, improve affordability, promote stability, and reduce unnecessary burdens. The Biden Administration has not yet articulated a position on these changes. We cannot predict the continuing existence or 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 deny or restrict coverage or lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and results of operations. Changes in the law or regulatory framework that reduce our revenues or increase our costs would have a material adverse effect on our business, financial condition and results of operations and cash flows.

Other legislation or regulatory proposals may adversely affect our revenues and profitability.

Existing and proposed changes in the laws and regulations affecting public companies may cause us to incur increased costs as we evaluate 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 we 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 us to attract and retain qualified persons to serve on our Board, or as executive officers. We may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause our general and administrative costs to increase beyond what we currently have planned. Although we intend to evaluate and monitor developments with respect to these rules, we cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs.

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

Our business is subject to the FCPA, which generally prohibits U.S. companies and their officers, directors and employees from giving, promising, offering or authorizing, directly or indirectly, any payments or anything of value to foreign officials for the purpose of obtaining or retaining business, securing an improper advantage, or influencing a foreign official to do or omit to do something in violation of their lawful duty. The FCPA also requires issuers to maintain accurate books and records and adequate internal controls. In addition, we are subject to anti-bribery laws of the nations in which we conduct business (e.g., Bribery Act 2010 in the United Kingdom, Articles 299a and 299b of the German Criminal Code specifically addressing bribery in the healthcare sector, the Corruption of Foreign Public Officials Act in Canada and laws adopted pursuant to the Organisation for Economic Co-operation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions). If our employees or our agents are found to have engaged in prohibited conduct under our policies and procedures, or under the FCPA or other anti-bribery laws to which we may be subject, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Our 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 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 approximately $24,000 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 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 U.S. states, Canadian 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 our 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 us to significant liability.

We may use hazardous materials in our research and development and manufacturing processes. We are subject to various regulations governing use, storage, handling and disposal of these materials and associated waste products. We 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. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources and any applicable insurance. We would also likely incur expenses related to any such incidents. Such future expenses or liability could have a significant negative impact on its business, financial condition and results of operations. Further, we cannot assure that the cost of compliance with these laws and regulations will not materially increase in the future. We may also be subject to liability in respect of the operations of prior owners or operators of any properties we may own, at manufacturing sites where operations have previously resulted in spills, discharges or other releases of hazardous substances into the environment. We could be held strictly liable under environmental laws for contamination of property that we occupy without regard to fault or whether our actions were in compliance with law at the time. Our liability could also increase if other responsible parties, including prior owners or operators of our facilities, fail to complete their clean-up obligations or satisfy indemnification obligations to us. Similarly, if we fail to ensure compliance with applicable environmental laws in foreign jurisdictions in which we operate, we may not be able to offer our products and may be subject to civil or criminal liabilities.

Risk Factors Relating to Intellectual Property

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

We license certain development and commercialization rights for certain technologies used in our systems and expect to enter into similar licenses in the future. For instance, we license exclusive intellectual property rights from Sunnybrook that enable us to use, manufacture, distribute and sell the TULSA-PRO system. Under this royalty-free license, we are subject to various obligations, including the milestone payment of C$250,000 we paid upon obtaining FDA clearance of our TULSA-PRO system, and legal costs associated with patent application preparation, filing and maintenance. If we breach or otherwise terminate any of the agreements under which we license rights to our technology from third parties, we could lose intellectual property rights that are important to our business and incur other liabilities. Certain of our license agreements may not provide an adequate remedy for their breach by the licensor. The loss or breach of any of these license agreements could have a material adverse effect on our business, results of operations and financial condition.

Our proprietary rights may not adequately protect our technologies.

Our commercial success will depend on our ability to obtain patents (or exclusive rights thereto) and to maintain adequate protection for our technologies in the United States, Europe, Canada and other countries. We own or have exclusive rights to multiple issued United States patents and several pending United States patent applications in respect of our products. For the TULSA-PRO system, our patent rights include rights licensed to us from Sunnybrook and other intellectual property that we have developed. We acquired the patent rights for the Sonalleve system from Philips. We or our licensors will be able to protect such proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

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

- we or our licensors were the first to make the inventions covered by each of our licensed or issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, or will not be challenged by third parties;
- we will develop or in-license additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our 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 our or our 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. Our or our licensors' ability to maintain and solidify our or our licensors' proprietary position for our products will depend on our or our licensors' success in obtaining effective patent claims and enforcing those claims once granted. Our or our 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 us 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 our 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 our patent applications and the enforcement or defense of our 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 our 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 our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business, financial condition and operating results.

Moreover, we or our 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 partes* review or interference proceedings, or other preissuance or post-grant proceedings in the United States or other jurisdictions, challenging our or our 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, our or our licensors' patent rights, allow third parties to commercialize our technology or product and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. Changes to the current patent statutes may adversely affect the protection afforded by our patents and/or open our 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 our business.

We also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or our collaboration partners' employees, consultants, contractors or scientific and other advisors may unintentionally or wilfully disclose our 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 our efforts and attention from other aspects of our business. In addition, non-U.S. courts are sometimes less willing than courts in the United States to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates, and products and services, when and if we have any, in every jurisdiction would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop competing products. These products may compete with our products, when and if we have any, and may not be covered by any of our or our 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 favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology and/or pharmaceuticals, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

The patent protection for our technologies may expire before we are able to maximize our commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our technologies have varying expiration dates; although the patents for the technologies we use are not expected to expire in the near term, when these patents expire, we may be subject to increased competition and may not be able to recover our development costs or license fees. 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, we 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 we or our licensors are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our or our licensors' patents in the United States or elsewhere.

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

If we choose to go to court to try to stop or prevent a third-party from using the inventions claimed in our or our 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 we 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 our business. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do 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 our rights.

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

If we wish to use the technology in issued and unexpired patents owned by others, we 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 we infringed these patents. The failure to obtain a license for technology or the failure to challenge an issued patent owned by others that we may require to develop or commercialize our product candidates may have a material adverse impact on us.

In addition, if a third-party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our 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 our business;
- substantial damages for past infringement, including possible treble damages in some jurisdictions, which we may have to pay if a court determines that our product candidates, offerings or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our technologies unless the third-party licenses patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third-party, we may have to pay substantial royalties or lump sum payments or grant cross licenses to our 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 we are sued for patent infringement, we would need to demonstrate that our 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 we 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 we believe 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 our business, we cannot predict the outcome of any invalidity challenge. Alternatively, it is possible that we may determine it is prudent to seek a license from a patent holder to avoid potential litigation and other potential disputes. We cannot be sure that a license would be available to us 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, we cannot be certain that others have not filed patent applications for technology covered by our or our licensors' issued patents or our pending applications or our licensors' pending applications, or that we or our licensors were the first to invent the technology.

Patent applications filed by third parties that cover technology similar to ours may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party files a United States patent application on an invention similar to ours, we 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 our United States patent position with respect to such inventions.

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

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

Risks Relating to the International Scope of our Business

Our business, financial condition, cash flows and results of operations are subject to risks arising from our international operations.

We conduct a portion of our business outside Canada and the U.S. and in the future expect to expand our operations into new international jurisdictions, including emerging markets.

Our foreign operations are subject to risks inherent in conducting business abroad, such as: difficulties in coordinating and managing foreign operations, price and currency exchange controls, political and economic instability, compliance with multiple regulatory regimes, differing degrees of protection for intellectual property, unexpected changes in foreign regulatory requirements and restrictive governmental actions. Adverse economic conditions impacting our customers or uncertainty about global economic conditions could cause purchases of our products to decline, which would adversely affect our revenues and operating results. Moreover, our projected revenues and operating results are based on assumptions concerning certain levels of customer spending and ongoing use of our TULSA-PRO system.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and on January 20, 2020, the World Health Organization declared the outbreak a global health emergency. In China, reactions to, or efforts to contain the spread of this coronavirus have led to, among other things, significant restrictions on travel, temporary business closures, quarantines and a general reduction in consumer activity. These disruptions could impact our salespeople, potential purchasers of our Sonalleve system and health care professionals based in China, which in turn could adversely impact our operating results. While these effects are expected to be temporary, the duration of the business disruption in China and related financial impact cannot be reasonably estimated at this time. Similarly, we cannot estimate whether or to what extent this outbreak and potential financial impact may extend to countries outside of China. At this point, the extent to which the coronavirus may impact our results is uncertain, however, it is possible that our consolidated results in 2022 may be negatively impacted by this event.

Risk Factors Relating to Our Common Shares

Future sales or the issuances of our securities may cause the market price of our Common Shares to decline.

The market price of our Common Shares could decline as a result of issuances of securities (including our Common Shares) by us, exercises of outstanding options or warrants for additional Common Shares or sales by our existing shareholders of Common Shares in the market, or the perception that these issuances or sales could occur. Sales of Common Shares by shareholders may make it more difficult for us to sell equity securities at a time and price that we deem appropriate. As at December 31, 2021, there were a total of 2,092,596 outstanding share options issued under our Share Option Plan, 232,317 Restricted Stock Units ("**RSUs**") and 724,983 outstanding warrants issued. In addition, as at December 31, 2021, 608,312 Options remained available for future grant under the Share Option Plan. Sales or issuances of substantial numbers of Common Shares, or the perception that such sales or issuances could occur, may adversely affect prevailing market prices of the Common Shares. With any such sale or issuance of Common Shares, investors may suffer dilution and we may experience dilution in our earnings per share.

We expect that the price of our Common Shares may fluctuate significantly.

The market price of securities of many companies, particularly development and early commercial 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 our Common Shares could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- delays in respect of our commercialization of the TULSA-PRO system in the United States;
- adverse results or delays in our future planned data collection for the TACT Pivotal Clinical Trial and any future clinical trials that we may conduct;
- regulatory actions with respect to our products and/or product candidates;
- changes in laws or regulations applicable to our products or any future product candidates, including but not limited to clinical trial requirements for approvals;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our 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 we provide 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 us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;

- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for its products;
- announcement or expectation of additional debt or equity financing efforts;
- sales or issuances of our Common Shares by us, our insiders or our other shareholders, including by exercise of outstanding options or warrants; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our Common Shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their Common Shares and may otherwise negatively affect the liquidity of our Common Shares. In addition, stock markets in general, and the TSX, the Nasdaq and the share prices of biotechnology companies in particular, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

If equity research analysts research or reports about our business or if they issue unfavorable commentary or downgrade our Common Shares, the price of our Common Shares could decline.

The trading market for our Common Shares will rely in part on the research and reports that equity research analysts publish about us and our business, over which we have no control. The price of our Common Shares could decline if one or more equity analysts downgrade our Common Shares or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

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

The market price of our 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. We 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 our business. Any adverse determination in litigation could also subject us to significant liabilities.

We have never paid dividends on our Common Shares and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our Common Shares will likely depend on whether the price of our Common Shares increases.

We have not paid dividends on our Common Shares to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our 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 our Common Shares if the price of our Common Shares increases.

If we are unable to satisfy the requirements of Sarbanes-Oxley, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned.

We are subject to certain of the requirements of Sarbanes-Oxley following the list of our Common Shares on Nasdaq in October 2019. Section 404 of Sarbanes-Oxley ("**Section 404**") requires companies subject to the reporting requirements of the U.S. securities laws to complete a comprehensive evaluation of our internal controls over financial reporting. To comply with this statute, we are required to document and test our internal control procedures and our management are required to assess and issue a report concerning our internal controls over financial reporting. Pursuant to the JOBS Act, we are classified as an "emerging growth company." Under the JOBS Act, emerging growth companies are exempt from certain reporting requirements, including the independent auditor attestation requirements of Section 404(b) of Sarbanes-Oxley. Under this exemption, our independent auditor is not required to attest to and report on management's assessment of our internal controls over financial reporting during a five-year transition period. We need to prepare for compliance with Section 404 by strengthening, assessing and testing our system of internal controls to provide the basis for our report. However, the continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming. Furthermore, we believe that our business will grow both domestically and internationally, in which case our internal controls will become more complex and will require significantly more resources and attention to ensure our internal controls remain effective overall. During the course of our testing, our management may identify material weaknesses or significant deficiencies, which may not be remedied in a timely manner to meet the deadline imposed by Sarbanes-Oxley. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting, or our independent registered public accounting firm identifies material weaknesses in our internal controls, investor confidence in our financial results may weaken, and the market price of our securities may suffer.

As a foreign private issuer whose shares are listed on Nasdaq, we intend to follow certain home country corporate governance practices instead of certain Nasdaq requirements.

As a foreign private issuer whose shares are listed on Nasdaq, we are permitted to follow certain home country corporate governance practices instead of certain requirements of the Nasdaq rules. We intend to adopt and approve material changes to equity incentive plans in accordance with TSX listing rules, which do not impose a requirement of shareholder approval for such actions. In addition, we intend to follow the TSX listing rules in respect of private placements instead of Nasdaq requirements to obtain shareholder approval for certain dilutive events (such as issuances that will result in a change of control, certain transactions other than a public offering involving issuances of a 20% or greater interest in us and certain acquisitions of the stock or assets of another company) and the minimum quorum requirement for a shareholders meeting. Under Nasdaq listing rules, the required minimum quorum for a shareholders meeting is 33 1/3% of the outstanding Common Shares, and our minimum quorum requirement is only 10% of the total number of voting rights attaching to all outstanding Common Shares. Accordingly, our shareholders may not be afforded the same protection as provided under Nasdaq corporate governance rules for domestic issuers.

We will incur significantly increased costs and devote substantial management time as a result of operating as a U.S. public company.

As a U.S. public company, we have and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company or as a Canadian public company. For example, we are subject to the reporting requirements of the U.S. Exchange Act, and are required to comply with the applicable requirements of Sarbanes-Oxley and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC and the including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements has increased and likely will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, management and other personnel have needed to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404, which involve annual assessments of a company's internal controls over financial reporting. We may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and may need to establish an internal audit function. We cannot predict or estimate the amount of such additional costs we may incur as a result of becoming a U.S. public company or the timing of such costs.

We may lose foreign private issuer status in the future, which could result in significant additional costs and expenses.

We may in the future lose foreign private issuer status if a majority of our Common Shares are held in the United States and we fail to meet the additional requirements necessary to avoid loss of foreign private issuer status, such as if: (i) a majority of our directors or executive officers are U.S. citizens or residents; (ii) a majority of our assets are located in the United States; or (iii) our business is administered principally in the United States. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer will be significantly more than the costs incurred as an SEC foreign private issuer. If we are not a foreign private issuer, we would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are generally more detailed and extensive than the forms available to a foreign private issuer. In addition, we may lose the ability to rely upon exemptions from corporate governance requirements that are available to foreign private issuers.

It may be difficult for United States investors to effect service of process or enforcement of actions against us or certain of our directors and officers under U.S. federal securities laws.

Profound is incorporated under the laws of the Province of Ontario, Canada. A majority of our directors and officers reside in Canada. Because all or a substantial portion of our assets and these persons are located outside the United States, it will be difficult for United States investors to effect service of process in the United States upon us or our directors or officers, or to realize in the United States upon judgments of United States courts predicated upon civil liabilities under the U.S. Exchange Act or other United States laws. It may also be difficult to have a judgment rendered in a U.S. court recognized or enforced against us in Canada.

We may be a passive foreign investment company ("PFIC") for U.S. federal income tax purposes, which generally would result in certain adverse U.S. federal income tax consequences to our U.S. shareholders.

In general, a non-U.S. corporation is a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the value of its assets consists of assets that produce, or are held for the production of, passive income. Generally, "passive income" includes interest, dividends, rents, royalties and certain gains, and cash generally is a passive asset for PFIC purposes. We have made no determination as to whether we are classified as a PFIC for U.S. federal income tax purposes. The determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and is also affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (i) the market price of the Common Shares, which is likely to fluctuate, and (ii) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. If we were a PFIC for any taxable year during which a U.S. shareholder owned the Common Shares, such U.S. shareholder generally will be subject to certain adverse U.S. federal income tax consequences, including increased tax liability on gains from dispositions of the Common Shares and certain distributions and a requirement to file annual reports with the Internal Revenue Service. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year. Prospective investors should consult their own tax advisers regarding our PFIC status.

If we are required to register as an "investment company" under the Investment Company Act, significant compliance costs and applicable restrictions could have a material adverse effect on our business.

We do not believe that we are an "investment company" under the Investment Company Act, but we can provide no assurance that we will not be deemed an "investment company" in the future.

Section 3(a)(1)(A) of the Investment Company Act defines the term “investment company” to mean any issuer that “is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, or trading in securities.” Section 3(a)(1)(C) of the Investment Company Act defines “investment company” as any issuer which “is engaged or proposes to engage in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having a value exceeding 40 per centum of the value of such issuer’s total assets (exclusive of government securities and cash items) on an unconsolidated basis.” Generally, any issuer meeting the definition of an investment company is subject to all applicable provisions of the Investment Company Act and must register with the Commission under Section 8 of the Investment Company Act, unless it meets the terms and conditions of various exceptions provided by the Investment Company Act or in rules adopted by the SEC under the Investment Company Act. The term “investment securities” is very broadly defined in the Investment Company Act. We believe that the cash on our balance sheet is held in a manner so that it constitutes “cash items” instead of “investment securities” within the meaning of the Investment Company Act, and accordingly, we do not believe we are required to register as an investment company; however, if we no longer hold our cash in this manner, we may need to find another available exemption from registration under the Investment Company Act.

For example, Rule 3a-2 of the Investment Company Act provides that inadvertent or transient investment companies will not be treated as investment companies subject to the provisions of the Investment Company Act, provided the issuer has the requisite intent to be engaged in a non-investment business, evidenced by the issuer’s business activities and an appropriate resolution of the issuer’s board of directors, within one year from the commencement of the earlier of (1) the date on which the issuer owns securities and/or cash having a value exceeding 50% of the value of such issuer’s total assets on either a consolidated or unconsolidated basis, or (2) the date on which an issuer owns or proposes to acquire investment securities (as defined in section 3(a) of the Investment Company Act) having a value exceeding 40% of the value of such issuer’s total assets (exclusive of government securities and cash items) on an unconsolidated basis. If the Company becomes an inadvertent investment company, and fails to meet the requirements of the transient investment company exemption under Rule 3a-2 of the Investment Company Act, then we will be required to register as an investment company with the SEC.

However, if we were to be deemed an investment company, we would be required to register as an investment company or adjust our business strategy and assets. If we were required to register as an investment company under the Investment Company Act, we would incur substantial expenses associated with such registration, and we would become subject to substantial regulation with respect to our capital structure, management, operations, transactions with affiliated persons, asset composition, including restrictions with respect to diversification and industry concentration, and other matters, which would have a material adverse effect on our business.

ITEM 5. ACQUISITIONS

On July 31, 2017, Profound entered into the Philips Share Purchase 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 Share Purchase Agreement, Philips transferred its Sonalleve assets to Profound for upfront consideration of 7,400,000 Common Shares. Under the Philips Share Purchase Agreement, the earn-out provisions included 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.

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.

We continue 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 we acquire new operating entities. Over the past year, we have enhanced our corporate development capabilities to execute transactions, through significant investments in people, technology and other organizational resources, and have 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.

We 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 our product and service offering.

ITEM 6. INTELLECTUAL PROPERTY

Our intellectual property is comprised of a broad and world-wide portfolio of patents, patent applications, trademarks, copyrights, trade secrets and other proprietary assets. Our intellectual property portfolio is both growing and dynamic and includes approximately 37 patent families representing approximately 139 granted or allowed patents and 37 patent applications in various stages of review and prosecution around the world.

Many of our 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 our 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 our products.

We believe that the protection of our intellectual property is an essential element of our business and we intend to continue our investment in the development of our intellectual property portfolio. We have 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 our sales, development and marketing efforts.

We pursue a global intellectual property strategy, registering for patent protection in all jurisdictions where we intend 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).

We also rely upon trade secrets, know-how and other proprietary, confidential information for the protection of our technology. We require 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 has listed, and which is officially recorded in the proper patent office.

In addition to developing our own intellectual property portfolio, we have 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 with Sunnybrook entered into on May 16, 2011 (the "**Sunnybrook License**"). Under the Sunnybrook License, Sunnybrook granted us 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, we are subject to various obligations, including a milestone payment of C$250,000 that was paid in connection with our recent FDA clearance of TULSA-PRO in August 2019. In addition, we are required to pay 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 our agreement 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 our customers to do so) and not to breach confidentiality obligations.

ITEM 7. HUMAN RESOURCES

As of the date of this AIF, we have 146 full-time employees, 18 of whom are unionized. We believe that our relations with our 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

We have not declared or paid any dividends since incorporation and we have 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 based upon our 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. As at the date of this AIF, there were 20,776,217 Common Shares issued and outstanding. The holders of Common Shares are entitled to: (i) one vote for each Common Share held at all meetings of shareholders of Profound; (ii) the right to receive any dividend declared by Profound; and (iii) the right to receive the remaining property and assets of Profound upon dissolution.

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" and on the Nasdaq under the trading symbol "PROF". The following table sets forth the price range per Common Share and trading volume for the Common Shares on the TSX, for the period indicated:

Month	High (C$)	Low (C$)	Volume
January 2021	34.76	26.84	1,743,957
February 2021	36.73	26.67	908,700
March 2021	30.08	23.81	867,138
April 2021	26.25	22.01	744,187
May 2021	25.00	19.25	548,042
June 2021	23.67	19.57	285,352
July 2021	22.75	17.70	333,519
August 2021	22.63	16.79	709,399
September 2021	20.61	17.06	758,801
October 2021	19.13	15.94	906,073
November 2021	17.25	13.57	1,295,819
December 2021	15.50	12.96	1,237,740

10.2 Prior Sales

Profound has not issued or sold any securities convertible into Common Shares during the year ended December 31, 2021, except as set forth below.

Date of Issuance/Grant	Exercise Price C($)	Number and Designation of Securities
January 27, 2021	8.50	546 Options
February 9, 2021	9.20	104 Options
March 3, 2021	9.30	31,644 Options
March 9, 2021	8.50	676 Options
May 12, 2021	9.20	66 Options
May 18, 2021	9.20	373 Options
May 20, 2021	9.20	202 Options
May 20, 2021	21.42	1,234 RSU
June 7, 2021	11.23	3,751 Options
June 14, 2021	17.44	2,500 Options
June 17, 2021	11.99	222 Options
August 12, 2021	11.23	384 Options
September 9, 2021	9.20	32,608 Options
September 23, 2021	8.50	832 Options
November 12, 2021	2.40	5,000 Options
December 17, 2021	8.50	300 Options
December 22, 2021	14.95	1,666 RSU

Share Option Plan

The Share Option Plan is administered by the Board which may, from time to time, delegate to a committee of the Board, all or any of the powers conferred to the Board under the Share Option Plan. The Share Option Plan was originally adopted by the Board on June 4, 2015, and then amended and restated on December 8, 2016 effective January 26, 2017 and again on July 13, 2018.

The Share Option Plan provides that the Board 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 is equal to 13% of the issued and outstanding shares in the capital of the Company at the time of any option grant. If any option is exercised, cancelled, expired, surrendered or otherwise terminated for any reason, the number of Common Shares in respect of which the option is exercised, cancelled, expired, surrendered or otherwise terminated, as the case may be, will again be available for purchase pursuant to options granted under the plan. As at December 31, 2021, 2,092,596 Options had been granted under the Share Option Plan with a weighted average contractual life of 7.95 years, and 608,312 Options were available for future grant under the Share Option Plan.

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 Board shall determine the exercise price of the options, provided that, it cannot be less than the Market Price of the Common Shares on the date of grant. 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 (currently, the TSX), for the five trading days immediately preceding the relevant date on which the Market Price is to be determined.

The expiry date for an option under the Share Option Plan shall not be later than the 10th anniversary of the date such 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.

Unless otherwise specified by the Board, each option under the Share Option Plan generally vests and becomes exercisable as to 1/4 on the first anniversary of the date of grant and as to 1/36 on the first day of each calendar month thereafter. The Board has the discretion to permit accelerated vesting of options.

We do not provide any financial assistance to optionees to facilitate the purchase of Common Shares issued pursuant to the exercise of options under the Share Option Plan. Options granted under the Share Option Plan are not transferable or assignable (except to an optionee's estate) and no options may be exercised by anyone other than the optionee or his or her legal representative during the lifetime of the optionee.

We intend to adopt and approve material changes to the Share Option Plan, and any other equity incentive plans that we may have in the future, in accordance with TSX listing rules, which do not impose a requirement of shareholder approval for such actions.

In addition, we have filed a registration statement on Form S-8 to register the Common Shares issuable upon exercise of options and RSUs granted under the Share Option Plan. At December 31, 2021 there were 876,486 Options issued and 232,317 RSUs issued under the S-8.

10.3 Escrowed Securities and Securities subject to Contractual Restriction or Transfer

As of the date of this AIF, to the knowledge of the Company, the Company has no escrowed securities or securities subject to contractual restriction on transfer.

ITEM 11. DIRECTORS 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, 2021:

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
ARUN MENAWAT[2] Bonita Springs, Florida, USA	67	Chief Executive Officer August 15, 2016 Director June 4, 2015	Chief Executive Officer and Director of the Company (since August 2016); Chairman, President and Chief Executive Officer of Novadaq Technologies Inc. (from 2003 to 2016).
BRIAN ELLACOTT[5][7] Sanibel Island, Florida, USA	64	Director June 14, 2018	Chief Executive Officer Belmont Instrument (since December 2017); Chief Executive Officer of Laborie Medical Technology (July 2013 to September 2017)
KENNETH GALBRAITH[3][5][7] White Rock, British Columbia, Canada	59	Director January 17, 2017	Executive in Residence at Syncona Limited (since April 2021) Chief Executive Officer of Liminal BioSciences (April 2019 to November 2020); Founder of Five Corners Capital, a venture capital management company (since 2013).
CYNTHIA LAVOIE[5][6] Gloucester, Ontario, Canada	54	Director March 2, 2021	President and Managing Director of AllosteRx Capital Management (Canada) Inc. (since 2018). President and Chief Investment Officer CCRM Enterprises Inc. (since Aug 2020). General Partner with TVM Life Science Management Inc. (March 2012 to March 2017)
MURIELLE LORTIE[5][6] Pointe-Claire, Québec, Canada	52	Director November 30, 2020	Chief Financial Officer Claridge Inc. (since September 2021); Chief Financial Officer and VP Finance of Liminal BioSciences (September 2018 to September 2021); Consultant, Corporate Finance, Mergers and Acquisitions (March 2018 to September 2018); VP and Chief Financial Officer Pharmascience (January 2014 to October 2017).
JEAN-FRANÇOIS PARISEAU[1][5][7] Montréal, Québec, Canada	52	Director June 4, 2015	Co-Founder and Partner at Amplitude Ventures (since July 2018); Partner, BDC Capital Healthcare Fund, a venture capital company (since July 2001 to June 2018).
ARTHUR L. ROSENTHAL[4][5] Oro Valley, Arizona, USA	75	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); Director at LivaNova PLC (since 2015).
AARON DAVIDSON Caledon, Ontario, Canada	53	Senior Vice President of Corporate Development May 3, 2018	Senior Vice President of Corporate Development, Profound Medical Inc. (since May 2018); Chief Financial Officer, Profound Medical Inc. (May 2018 to May 2021); Co-Head and Managing Director of H.I.G. (from January 2004 to May 2018).
RASHED DEWAN Toronto, Ontario, Canada	54	Chief Accounting Officer and Vice President of Finance November 17, 2015	Chief Accounting Officer (since May 2021) Vice President of Finance, Profound Medical Inc. (since November 2015).
GOLDDY KAUR Oakville, Ontario, Canada	56	Vice President, Product Leader Sonalleve December 1, 2011	Product Leader Sonalleve, Profound Medical Inc. (since January 2021); Vice President of Regulatory Affairs and Product Management, Profound Medical Inc. (December 2011 to January 2021)
MATHIEU BURTNYK Toronto, Ontario, Canada	40	Senior Vice-President, Product Leader TULSA-PRO July 7, 2011	Senior Vice-President, Product Leader TULSA-PRO, Profound Medical Inc. (since January 2021); Vice President of Clinical Affairs, Profound Medical Inc. (July 2019 to January 2021).

Notes:

(1) The Common Shares are controlled and held by BDC.
(2) Chair of the Board.
(3) Chair of the Audit Committee.
(4) Chair of the Human Resource and Corporate Governance Committee.

(5) Member of the Board.
(6) Member of the Audit Committee.
(7) Member of the Human Resource and Corporate Governance Committee

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, 2021, the directors and executive officers of Profound as a group beneficially own, directly or indirectly, or exercise control or direction, 315,196 of the issued and outstanding Common Shares, representing approximately 1.52% of the total votes attaching to all of the then outstanding voting securities of Profound before giving effect to the exercise of options, RSUs and warrants held by such directors and executive officers (and assuming exercise of all options, RSUs and warrants held by such individuals, 1,502,366 Common Shares representing approximately 4.3% 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. Since April 2003 until 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. 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, D.C., and a 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 M.B.A. from the J.L. Kellogg School of Management, Northwestern University, Evanston, IL.

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. 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 Instrument and is the past Chairman of the board of the Canadian Assistive Devices Association. Mr. Ellacott holds a Bachelor of Business Administration Degree from Wilfrid Laurier University, Waterloo, Ontario, Canada and is a dual United States and Canadian citizen.

Kenneth Galbraith – Director – Mr. Galbraith is an accomplished life sciences industry veteran with over 30 years of experience acting as an executive, director, investor and advisor to companies in the biotechnology, medical device, pharmaceutical and healthcare sectors. Mr. Galbraith currently serves as the Chair and Chief Executive officer of Zymeworks Inc. (NYSE: ZYME) a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Most recently he served as the Executive in Residence at Syncona Investment Management Inc. (LON:SYNC), a FTSE250 company focused on founding, building and funding healthcare companies to deliver transformational treatments to patients. Mr. Galbraith formerly served as the Chief Executive Officer of Liminal BioSciences Inc. (TSX: LMNL), a biotechnology company. 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 Inc. 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.

Cynthia Lavoie – Director – Dr. Lavoie is currently President and Managing Director of AllosteRx Capital Management ("AllosteRx"). She also serves as President and Chief Investment Officer of CCRM Enterprises. Prior to co-founding AllosteRx, Cynthia was a General Partner with TVM Life Science Management Inc. ("TVM"), a global venture capital group with main offices in Munich and Montreal. She was recruited to TVM from VG (VenGrowth) Partners Inc., where she was a Partner and co-headed its life sciences fund. Along with her role on the Board of Profound Medical, Cynthia is currently co-founder and board director of Delta TpX, an immune oncology start-up in Austin, TX and a board director at Fibrocor Therapeutics, a fibrosis company in Toronto. A seasoned healthcare investment professional with 19 years of experience in venture capital, Dr. Lavoie's expertise includes creating companies de novo and leading investments into businesses developing therapeutics, devices, and diagnostic tools. Cynthia has taken active roles on boards of companies located in Canada and the US from start-up to revenue-generating stages. These include Acer Therapeutics (NASDAQ: ACER), Cytochroma (acquired by OPKO Health), VisualSonics (acquired by SonoSite, now FujiFilm SonoSite), and Trillium Therapeutics (NASDAQ: TRIL) (acquired by Pfizer). Before joining the investment community, Dr. Lavoie served in a variety of academic and scientific leadership positions for 10 years, working with research institutes and life science companies. Cynthia earned her MBA with first class honors from Rotman School of Management at the University of Toronto and earned her Ph.D in Molecular Biology with Dean's honors from McGill University.

Murielle Lortie – Director – Ms. Lortie has an accomplished history of financial leadership success within the global life science industry. She currently serves as Chief Financial Officer of Claridge Inc. Prior to joining Claridge Inc., Ms. Lortie was Chief Financial Officer Liminal BioSciences Inc. ("**Liminal**"), a Nasdaq-listed, clinical-stage biopharmaceutical company. Prior to joining Liminal, Ms. Lortie was Vice President & Chief Financial Officer and Advisor to the CEO, Global Strategy, Mergers & Acquisitions at Pharmascience Inc. Previously, she has held senior positions in finance at Bristol Myers Squibb, including Vice-President of Finance for Bristol Myers Squibb Canada Co. and Global Director of Finance supporting BMS Headquarters. Ms. Lortie is a Chartered Professional Accountant and member of the Ordre des comptables professionnels agrées du Québec. She holds a Graduate Diploma in Accountancy from Concordia University and a Bachelor of Business Administration Bishop's University. She has extensive corporate governance experience, previously serving on the Boards of Bellus Health Inc. and Pharmascience Barbados Ltd. & Pharmascience International Ltd. Ms. Lortie is currently a Board member of Finance Executives International (FEI) Canada.

Jean-François Pariseau – Director – Mr. Pariseau is co-founder and Partner at Amplitude Ventures. Amplitude Ventures is a capital catalyst for highly innovative companies at the point of value acceleration. Amplitude Ventures works with Canada's most promising healthcare companies, with a shared vision of bringing groundbreaking technologies to patients. Amplitude Ventures is focused on building world-class Canadian companies in precision medicine and next-generation medical devices. Before co-founding Amplitude Ventures, Mr. Pariseau was Partner at the Healthcare Fund of BDC Capital and 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. Prior to joining the investment world, Jean-Francois was CEO of a consulting company specializing in regulatory affairs, and VP, R&D for a pharmaceutical-product distribution company, both of which he founded. Mr. Pariseau holds a Bachelor of Science in Biotechnology from Université de Sherbrooke, a Master of Science in Biomedical Sciences from Université de Montréal, and an M.B.A. from HEC Montréal.

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 a member of Arch's Clinical Advisory Board. In 2015, Dr. Rosenthal was appointed to the Industrial Advisory Committee, CURAM (National University in Galway, Ireland). Since 2003, Dr. Rosenthal has been a Fellow of the American Institute of Medical and Biological Engineering.

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.

Except as set forth below, 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.

Dr. Menawat was a director of Spartan Bioscience Inc. (" **Spartan**") from September 2020 to July 2021. On April 5, 2021, Spartan filed a Notice of Intention to File a Proposal (the "**NOI**") under the Bankruptcy and *Insolvency Act* with the Office of the Superintendent in Bankruptcy. On June 21, 2021, the NOI proceeding was continued under the *Companies' Creditors Arrangement Act*. On December 1, 2021, the bankruptcy of Spartan occurred.

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

From time to time, we may become involved in legal or regulatory proceedings arising in the ordinary course of business. During the most recently completed fiscal year: (a) there were no legal proceedings to which we were a party, or by which any of our 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 us that would likely be considered important to a reasonable investor making an investment decision and (c) we have 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 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, 2021. 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

Our registrar and transfer agent is TSX Trust Company at its principal office located in Toronto, Ontario. Our transfer agent in the United States is Computershare Trust Company, N.A., located in Canton, MA.

ITEM 16. MATERIAL CONTRACTS

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

- the Sunnybrook License;
- the Philips Supply Agreement;
- the Philips Confidentiality Agreement;
- the Philips Resale Purchasing Agreement;
- the New Siemens Agreement; and
- the Akumin Agreement.

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 us 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, we are subject to various obligations, including a milestone payment of C$250,000 that was paid in connection with our recent FDA clearance of TULSA-PRO. In addition, we are required to pay 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 our agreement 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 our customers to do so) and not to breach confidentiality obligations.

Philips Supply Agreement

On July 31, 2017, we entered into the Philips Supply Agreement with Philips Medical in connection with the Sonalleve Transaction. Under the terms of the Philips Supply Agreement and until such time as the manufacturing of our Sonalleve systems is assumed by us, Philips Medical agrees to serve as a contract manufacturer to us for our Sonalleve systems. We work together with Philips Medical to ensure that production capacity and delivery times are appropriate to meet our sales forecasts.

Philips Confidentiality Agreement

On July 31, 2017, we entered into the Philips Confidentiality Agreement with Philips in connection with the Sonalleve Transaction. Under the terms of the Philips Confidentiality Agreement, Philips has agreed to (i) not compete in related lines of business, anywhere in the world, for period of three years after closing; (ii) not solicit any of our employees for so long as agreements related to the Sonalleve Transaction are in force, plus an additional two years; and (iii) maintain in confidence any confidential information that if disseminated would be detrimental to our business, for a period of ten years after closing.

Philips Resale Purchasing Agreement

On July 31, 2017, we entered into the Philips Resale Purchasing Agreement with Philips Medical in connection with the Sonalleve Transaction. Under the terms of the agreement, Philips Medical is permitted to purchase certain of our products for the purpose of reselling such products to its customers. In addition, we are permitted to sell additional products directly to customers of Philips Medical upon an initial sale of the Philips products to such customers.

Siemens Agreement

On February 11, 2019, we entered into the New Siemens Agreement, effective as of January 21, 2019. Under the New Siemens Agreement, all prior financial commitments and obligations owed to Siemens were released and replaced with a one-time fixed license fee and per annum payments calculated based on annual volume of our systems interfaced to a Siemens MRI scanner. The initial term of the New Siemens Agreement is five years, but will be automatically extended for successive terms of one year thereafter unless terminated earlier. We also obtained a non-exclusive license to Siemens Access I interface software and reasonable support for the term of the New Siemens Agreement.

Akumin Agreement

On May 6, 2021, Profound signed the Akumin Agreement. Pursuant to the Akumin Agreement, Profound expects to install TULSA-PRO systems at up to 10 Akumin centers to be outfitted with diagnostic and therapeutic imaging services specifically dedicated towards men's health. All of these TULSA-PRO systems will be placed under Profound's per procedure business model. The initial geographic focus of the relationship will be in the State of Florida, with Texas and Pennsylvania expected to follow.

ITEM 17. AUDIT COMMITTEE INFORMATION

Set out below is the information with respect to the audit committee of Profound's Board (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.

Our Audit Committee consists of all independent directors within the meaning of Nasdaq listing standards and Rule 10A-3 under the U.S. Exchange Act. Currently, the members of the Audit Committee are Kenneth Galbraith (Chair), Cynthia Lavoie and Murielle Lortie. The Audit Committee oversees the accounting and financial reporting practices and procedures of our financial statements. The principal responsibilities of the Audit Committee include: (i) overseeing the quality and integrity of our internal controls and accounting procedures, including reviewing our procedures for internal control with our external auditor and CFO; (ii) reviewing and assessing the quality and integrity of our 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 our external auditor and independent audit fees; (v) reviewing the qualifications, performance and independence of our external auditor, considering the external auditor's recommendations and managing the relationship with the external auditor, including meeting with the external auditor as required in connection with the audit services provided to us; (vi) assessing our financial and accounting personnel; (vii) reviewing our risk management procedures; (viii) reviewing any significant transactions outside of our ordinary course of business and any pending litigation involving us; and (ix) examining improprieties or suspected improprieties with respect to accounting and other matters that affect financial reporting.

Audit Committee Charter

The Audit Committee reviews and reassesses the adequacy of its charter periodically as it deems appropriate and recommend changes to the Board. The performance of the Audit Committee is evaluated with reference to its charter annually or otherwise periodically as deemed appropriate by the Board. A copy of our Audit Committee's charter is available on our website at https://profoundmedical.com/investors/#governance. The information on our website is not incorporated by reference into this AIF and should not be considered a part of this AIF, and the reference to our website in this AIF is an inactive textual reference only.

Composition of the Audit Committee

The following are the current members of the Audit Committee:

Name	Independence	Financial Literacy
Kenneth Galbraith	Independent	Financially Literate
Cynthia Lavoie	Independent	Financially Literate
Murielle Lortie	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 Nasdaq, 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 our most recently completed financial period was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board.

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	Tax Fees[2]	All Other Fees
December 31, 2021	$ 277,000	$ 0	$ 100,000	$ 0
December 31, 2020	$ 361,000	$ 0	$ 72,000	$ 0

Notes:

(1) Audit fees includes annual audit, quarterly reviews and work performed in relation to the bought deals and offerings.

(2) 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 independent registered public accounting firm is PricewaterhouseCoopers LLP, Licensed Public Accountants, who issued a Report of Independent Registered Public Accounting Firm dated March 3, 2022 in respect of the Company's consolidated financial statements as at December 31, 2021 and 2020 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 and the rules of the US Securities and Exchange Commission and the requirements of the Public Company Accounting Oversight Board Rule 3520, *Auditor Independence*.

ITEM 19. ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com and on EDGAR at www.sec.gov, and on our website at https://profoundmedical.com/investors. Information on our website does not form a part of this AIF and shall not be deemed incorporated by reference herein. 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.

Exhibit 99.2



PROFOUND MEDICAL CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

DECEMBER 31, 2021

PRESENTED IN US DOLLARS (000s)

The following Management's Discussion and Analysis ("**MD&A**") prepared as of March 3, 2022 should be read in conjunction with the December 31, 2021 audited consolidated financial statements and related notes of Profound Medical Corp. ("**Profound**" or the "**Company**"). The audited consolidated financial statements of Profound and related notes were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("**IFRS**"). Unless stated otherwise, all references to "$" are to United States dollars and all references to "C$" are to Canadian dollars. In this MD&A, unless the context requires otherwise, references to "Profound", "the Company", "we", "us" or "our" are references to Profound Medical Corp. and its subsidiaries.

FORWARD-LOOKING STATEMENTS

This MD&A contains "forward-looking statements" within the meaning of Section 27A of the U.S. Securities Act and Section 21E of the Exchange Act pursuant to the "safe harbor" provisions of the United States Private Securities Litigation Reform Act of 1995, and "forward-looking information" within the meaning of applicable Canadian securities laws, which include all statements other than statements of historical fact contained in this MD&A, such as statements that relate to the Company's current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to", "is/are projected to" or the negative of these terms, or other similar expressions intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to:

- our expectations regarding commercializing our approved products (particularly the TULSA-PRO ® system following U.S. Food and Drug Administration ("**FDA**") clearance) and our ability to generate revenues and achieve profitability;
- our expectations regarding the safety, efficacy and advantages of our products over our competitors and alternative treatment options;
- our expectations regarding our products fulfilling unmet clinical needs and achieving market acceptance among patients, physicians and clinicians;
- our expectations regarding reimbursement for our approved products from third-party payors;
- our expectations regarding an out-of-pocket market for the Company's products;
- our expectations regarding our relationships with Koninklijke Philips N.V. (" **Phillips**"), Siemens Healthcare GmbH ("**Siemens**") and GE Healthcare (" **GE**"), and our ability to achieve compatibility of our systems with magnetic resonance imaging ("**MRI**") scanners produced by other manufacturers;
- our expectations regarding our ability to expand the installation of TULSA-PRO® systems in Akumin Centres outside of the State of Florida pursuant to our multi-site imaging agreement (the "**Akumin Agreement**") with Akumin Inc. (" **Akumin**");
- our ability to attract, develop and maintain relationships with other suppliers, manufacturers, distributors and strategic partners;
- our expectations regarding our pipeline of product development, including expanding the clinical application of our products to cover additional indications;
- our expectations regarding current and future clinical trials, including the timing, enrollment and results thereof;
- our expectations regarding maintenance of the current regulatory approvals we have received, including our compliance with the conditions under such approvals, and the receipt of additional regulatory approvals for our products and future product candidates;
- our mission and future growth plans;
- our ability to attract and retain personnel;
- our expectations regarding our competitive position for each of our products in the jurisdictions where they are approved;

- our expectations regarding the impact of COVID-19 on the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations;
- our ability to raise debt and equity capital to fund future product development, pursue regulatory approvals and commercialize our approved products;
- our remediation plan with respect to our internal controls over financial reporting; and
- anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Profound to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section entitled "Risk Factors" in the Company's Annual Information Form prepared as of March 3, 2022 for the year ended December 31, 2021 (the "**AIF**"), available on SEDAR at www.sedar.com and filed as an exhibits to the Company's annual report on Form 40-F, filed on March 3, 2022 (the "**40-F**"), available on EDGAR at www.sec.gov, such as:

- risks related to our limited operating history and history of net losses;
- risks related to our liquidity and financing needs;
- risks related to our ability to commercialize our approved products, including realizing the anticipated benefits of our commercial agreement with RadNet Inc. ("**RadNet**"), the Akumin Agreement and our co-development agreement with GE (the "**GE Agreement**"), expanding our sales and marketing capabilities, increasing our manufacturing and distribution capacity, increasing reimbursement coverage for our approved products and achieving and maintaining market acceptance for our products;
- risks related to the regulation of our products, including in connection with obtaining regulatory approvals as well as post-marketing regulation;
- risks related to our successful completion of clinical trials with respect to our products and future product candidates;
- risks related to managing growth, including in respect of obtaining additional funding and establishing and maintaining collaborative partnerships, to achieve our goals;
- risks related to competition that may impact market acceptance of our products and limit our growth;
- risks relating to fluctuating input prices and currency exchange rates;
- risks related to the reimbursement models in relevant jurisdictions that may not be advantageous;
- risks related to reliance on third parties, including our collaborative partners, manufacturers, distributors and suppliers, and increasing the compatibility of our systems with MRI scanners;
- risks related to intellectual property, including license rights that are key to our business;
- the extent and impact of COVID-19 and the related response from the Company, government (federal, provincial, municipal and state) and regulatory authorities; and
- risks related to the loss of key personnel.

Forward-looking statements contained herein are made as of the date of this MD&A and Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable laws. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them. Readers are cautioned that while Profound believes it has accurately summarized all clinical studies cited in this MD&A, readers should review the full publications of the studies prior to making an investment decision in the Company.

COVID-19

The global economy has significantly changed during the past year. The spread of the COVID-19 virus, declared on March 11, 2020 as a pandemic by the World Health Organization (WHO), has led many governments to adopt exceptional measures to slow the advancement of COVID-19. These events cause significant uncertainties and material disruptions to businesses globally, resulting in an economic slowdown that could damage the Company's activities. At the current time, it is not possible to reliably estimate the duration and impact of these events may have on the Company's future financial results because of the uncertainties about future developments. Thus far, the Company has experienced volatility in demand for systems and one-time-use devices which has resulted in a reduction in anticipated sales and Profound's ability to collect certain payments. For more information on COVID-19 and its impact on Profound's business, please refer to the section "Business Update and Sales Strategy".

BUSINESS OVERVIEW

Profound (NASDAQ: PROF; TSX: PRN) is a commercial-stage medical device company focused on the development and marketing of customizable, incision-free therapeutic systems for the image guided ablation of diseased tissue utilizing its platform technologies and leveraging the healthcare system's existing imaging infrastructure. Profound's lead product (the "**TULSA-PRO® system**") combines real-time MRI, robotically driven transurethral sweeping-action thermal ultrasound with closed-loop temperature feedback control for the ablation of prostate tissue. The product is comprised of one-time-use devices and durable equipment that are used in conjunction with a customer's existing MRI scanner.

In August 2019, the TULSA-PRO® system received FDA clearance as a Class II device in the United States of America ("**United States**" or "**US**") for thermal ablation of prescribed prostate tissue, using transurethral ultrasound ablation ("**TULSA®**") based on the Company sponsored (" **TACT**") whole gland ablation pivotal clinical study. It is also CE marked in the European Union ("**EU**") for ablation of targeted prostate tissue (benign or malignant). The TULSA-PRO® system was approved by Health Canada in November 2019.

[1] Klotz et al, "MRI-guided transurethral ultrasound ablation of prostate cancer," The Journal of Urology, 2020
[2] Anttinen et al, "Histopathological evaluation of prostate specimens after thermal ablation may be confounded by the presence of thermally-fixed cells," International Journal of Hyperthermia, 2019
[3] Chin et al, "Magnetic Resonance Imaging-Guided Transurethral Ultrasound Ablation of Prostate Tissue in Patients with Localized Prostate Cancer: A Prospective Phase 1 Clinical Trial," European Urology, 2016; Bonekamp et al, "Twelve-month prostate volume reduction after MRI-guided transurethral ultrasound ablation of the prostate," European Radiology, 2018

Profound believes that, based on the Company's TACT clinical data and additional studies conducted in the EU, physicians may elect to use TULSA-PRO® to ablate benign or malignant prostate tissue in patients with a variety of prostate diseases. Prostate diseases include prostate cancer and benign prostatic hyperplasia ("**BPH**"). Prostate cancer is one of the most common types of cancer affecting men. The annual incidence of newly diagnosed cases in 2021 is estimated to reach 248,530 in the United States according to the American Cancer Society and in 2018 there were approximately 450,000 newly diagnosed cases of prostate cancer in Europe, according to the International Agency for Research on Cancer. The American Cancer Society further estimates that there are currently 5.8 million men living with prostate cancer in these two geographic regions. Although ten-year survival outcomes for prostate cancer remain favorable, it is still one of most common causes of cancer deaths among men. BPH is a histologic diagnosis that refers to the proliferation of smooth muscle and epithelial cells within the prostatic transition zone. According to the American Urological Association, BPH is nearly ubiquitous in the aging male population with worldwide autopsy proven histological prevalence increases starting at ages 40 to 45 years, reaching 60% at age 60 and 80% at age 80.

Profound initiated the commercial launch of its lead product, the TULSA-PRO ® system in the United States in Q4 2019, treating the first patient in a non-trial setting in January 2020. In addition, Profound continues to support additional clinical trials in the United States and abroad to further increase the body of clinical evidence that may be needed particularly for reimbursement and coverage of its technologies by private and government healthcare providers. The Company continues to expand the compatibility of its TULSA-PRO® system with additional MRI brands to broaden its ability to utilize the global MRI installed base and seek regulatory approvals of its products in additional international jurisdictions.

Profound's second product, the Sonalleve® system, is CE marked in the EU for the treatment of uterine fibroids and palliative pain relief associated with metastases in bone and has also been approved by the National Medical Products Association, the regulatory body in China, for non-invasive treatment of uterine fibroids. In late 2020, Sonalleve® received Humanitarian Device Exemption (HDE) approval from the FDA for the treatment of Osteoid Osteoma in the United States. The Sonalleve® system is only compatible with certain Philips MRI's.

Profound deploys a recurring revenue business model in the United States to market TULSA-PRO ®, charging a one-time bundled payment per patient that includes the supply of its one-time-use devices, use of the system, as well as the Company's customer and technological support ("**Genius**") services that support each TULSA center with clinical and patient recruitment. The Sonalleve® product is marketed primarily outside North America in European and Asian countries, deploying a capital sales model. Outside of North America, Profound generates most of its revenues from its system sales in Europe and Asia, where the Company deploys a more traditional hybrid business model, charging for the system separately as a capital sale and an additional per patient charge for the one-time-use devices and associated Genius services.

[4] Nair et al, "MRI-Guided Transurethral Ultrasound Ablation in Patients with Localized Prostate Cancer: Three Year Outcomes of a Prospective Phase I Study", BJU International, 2020; Nair et al, "PD17-03 Five-Year Outcomes from a Prospective Phase I Study of MRI-Guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer", AUA 2020 Virtual Experience, Abstract in The Journal of Urology, 2020

[5] Elterman et al, "Relief of Lower Urinary Tract Symptoms after MRI-Guided Transurethral Ultrasound Ablation (TULSA) for localized prostate cancer: Subgroup Analyses in Patients with concurrent cancer and Benign Prostatic Hyperplasia," Journal of Endourology, 2020; Anttinen et al, "Transurethral ultrasound therapy for benign prostatic obstruction in humans," EAU 2020 Conference Presentation

[6] Anttinen et al, "Early experience of salvage MRI-guided transurethral ultrasound ablation (sTULSA) for local prostate cancer recurrence after radiotherapy," EAU 2020 Conference Presentation

[7] Anttinen et al, "Palliative MRI-guided transurethral ultrasound ablation for symptomatic locally advanced prostate cancer," Scandinavian Journal of Urology, 2020

Profound's Technology

TULSA-PRO® and Sonalleve® share the common technological concept of using MRI to enable visualization by the surgeon of desired tissue in real time. Both products also use thermal ultrasound technology to gently heat and ablate tissue using the real-time thermometry capability of the MRI.

TULSA-PRO® delivers its ultrasound energy through a transurethral catheter, a one-time-use device that is placed in the patient's prostate through a natural orifice. Focused ultrasound energy is then delivered by the catheter in the shape of a blade. Externally the catheter is connected to a software controlled robotic manipulator that rotates up to 360-degree in a sweeping action to impart thermal energy and thus ablation of tissue. The real time temperature measurement of the prostate is coupled with closed loop process control that meters the appropriate amount of ultrasound energy to gently heat the physician-prescribed region of prostate tissue to the target temperature to achieve cell kill without boiling or charring the tissue. As a measure to keep the urethra within the prostate viable, the temperature of the transurethral catheter is maintained at an appropriate level by circulating water inside the catheter. Similarly, a water-cooled specially designed catheter is placed in the patient's rectum during the ablation process to keep it protected from thermal damage during the procedure. Profound believes that TULSA-PRO®'s controlled and relatively gentle heating process may result in lower post procedural pain, reduced potential of life affecting side effects and in significantly desirable shrinkage of the prostate via resorption of the dead tissue over time, which may provide a longer-term durable benefit.

Sonalleve® delivers its ultrasound energy via a disc located outside the patient. Its ultrasound energy is focused to create small cylindrical hot spots a certain distance into the patient. Overlapping cylinders create ablation of the physician-prescribed desired tissue. Similar to TULSA-PRO, Sonalleve® also provides for controlled temperature increases to achieve cell kill.

The physician is in charge of using the Profound devices and decides which tissue needs to be ablated to impart therapeutic effect. Profound believes that in the hands of trained physicians, its systems have the ability to provide customizable, incision-free ablative therapies with the precision of real-time MRI visualization and thermometry, focused ultrasound and closed-loop temperature feedback control. Profound believes that its technology offers clinicians and appropriate patients a better alternative to traditional surgical or radiation therapies, with respect to clinical outcomes, side effects and recovery time.

TULSA-PRO®

Clinical Studies

In March 2014, Profound completed enrollment and treatment of 30 patients in the Phase I TULSA multi-jurisdictional safety and precision study. Based on the Phase I clinical trial results, in April 2016, Profound received a CE Certificate of Conformity for the TULSA-PRO® system from our notified body in the EU, and in the fourth quarter of 2016, Profound initiated a pilot commercial launch of TULSA-PRO® in key European markets where the CE mark is accepted.

Profound received FDA clearance for the TULSA-PRO® system in August 2019 for transurethral ultrasound ablation of prostate tissue, based on the Company's TACT Pivotal Clinical Trial. The TACT Pivotal Clinical Trial is a prospective, open-label, single-arm pivotal clinical study, of 115 treatment-naïve localized prostate cancer patients across 13 research sites in the United States, Canada and Europe, which enrolled patients between August 2016 and February 2018.

Localized Prostate Cancer, Ablation Safety and Efficacy: TACT Pivotal Study

The TACT Pivotal Clinical Trial demonstrates that MRI-guided TULSA is a minimally invasive procedure for effective prostate cancer ablation with a favorable side effect profile, minimal impact on quality of life and low rates of residual disease[1]. In the large, multi-center prospective study in men with predominately intermediate-risk prostate cancer, whole gland ablation sparing the urethra and apical sphincter with the TULSA-PRO® met its primary regulatory endpoint of prostate-specific antigen("**PSA**") reduction in 96% of men to a median nadir of 0.34 ng/ml and 0.5 ng/ml at 12 months. Median decrease in perfused prostate volume as assessed by a central radiologist using 12-month MRI was 91%, from a median 37 cc to 2.8 cc. At 12 months, extensive biopsy sampling of the markedly reduced prostate volume demonstrated a benefit for nearly 80% of men. There was no evidence of cancer in 65% of men and 14% had low-volume clinically-insignificant disease. The authors, however, noted that thermally-fixed non-viable cells can retain their apparently-malignant tissue morphology, confounding Gleason grading and potentially introducing false positives[2]. By two years, 7% of men sought additional treatment for their prostate cancer (prostatectomy, radiation). The study patient population, with two-thirds of those with Gleason Grade Group (GGG) ≥ 2 having either bilateral disease or at least five positive cores, allowed for evaluation of oncologically relevant secondary outcomes including PSA stability, post-treatment biopsy, and salvage treatment. Notwithstanding the limitations of comparisons between ablative and extirpative therapies, the 7% rate of salvage treatment and 20% rate of residual clinically significant prostate cancer in intermediate-risk patients are in line with accepted rates of early failure or additional intervention after standard treatments and goals for retreatment after ablative therapies.

TULSA was associated with a high degree of safety and maintenance of quality-of-life, comparing favorably to radical prostatectomy and other whole-gland ablation techniques. At 12 months, 96% of men returned to baseline urinary continence, and 75% of potent men maintained or returned to erections sufficient for penetration. A total of 12 grade 3 adverse events occurred in 8% of men, including genitourinary infection (4%), urethral stricture (2%), urinary retention (1.7%), urethral calculus and pain (1%), and urinoma (1%), all resolved by 12 months. There were no grade 4 events, rectal injuries, severe incontinence requiring surgical intervention, or severe erectile dysfunction unresponsive to medication.

Localized Prostate Cancer, Durability of Outcomes: Phase I Safety and Precision Study

The Phase I Clinical Trial demonstrates that MRI-guided TULSA is safe and precise for ablation in patients with localized prostate cancer, providing spatial ablation precision of ± 1.3 mm with a well-tolerated side-effect profile and minor or no impact on urinary, erectile and bowel function at 12 months[3]. There were no grade 4 or higher adverse events, one transient attributable grade 3 event (epididymitis), and notably no injury to rectal or periprostatic structures. Functional outcomes, International Prostate Symptom Score ("**IPSS**") and IIEF-15, both showed a favorable anticipated trend of initial deterioration with subsequent gradual improvement toward baseline levels. Consistent with the conservative whole-gland treatment plan which included a 3 mm circumferential margin expected to spare 10% viable prostate at the gland periphery, intra-operative MRI thermometry measured 90% thermal ablation of the prostate gland, median PSA decreased 90% from 5.8 ng/ml to nadir of 0.6 ng/ml, and median prostate volume reduced by 88% on 1-year MRI. Prostate biopsy at one year identified decreased cancer burden with 61% reduction in cancer length; however, attributable to the circumferential safety margin, clinically significant cancer in 9 of 29 men (31%), and any cancer in 16 of 29 (55%).

Follow-up data to three and five years demonstrate durability of the outcomes, with continued treatment safety and stable quality of life, as well as predictable PSA and biopsy oncological outcomes based on treatment-day imaging and early PSA follow-up, without precluding any potential salvage therapy options[4]. Repeat prostate biopsy at three years demonstrated durable histological outcomes, with only one subject upgrading to GGG 1 from negative at 12 months, and one subject upgrading to GGG 2 from GGG 1 at 12 months. Between one and five years, there were no new serious adverse events. By five years, 16 men completed protocol follow-up, three withdrew with PSA <0.4 ng/ml, 10 had salvage therapy without complications (six prostatectomy, three radiation and one laser ablation), and one died of an unrelated cause. Of 16 men with complete follow-up data, five-year median PSA remained at 0.55 ng/ml. Median IPSS of 6 at baseline returned to 5 by three months, and 6.5 at five years. At baseline, 9 of 16 had erections sufficient for penetration, 11 of 16 at one year, and 7 of 16 at five years. All 16 subjects had leak-free, pad-free continence at one and five years. Predictors of salvage therapy included lower ablation coverage and higher PSA nadir. At five years after TULSA, cancer specific survival is 100%, and overall survival 97%.

Benign Prostatic Hyperplasia (BPH), Relief of Lower Urinary Tract Symptoms (LUTS): Phase I Studies

Promising safety and feasibility of the TULSA-PRO® to relieve Lower Urinary Tract Symptoms ("**LUTS**") associated with BPH has been demonstrated in two Phase I studies showing improvements in IPSS comparable to modern minimally invasive surgical therapies[5]. A retrospective analysis of a sub-group of nine men from a localized prostate cancer study who also had LUTS (baseline IPSS ≥ 12) demonstrated significant IPSS improvement of 58% from 16.1 to 6.3 at 12 months (p=0.003), with at least a moderate (≥ 6 points) symptom reduction in eight of nine patients. IPSS Quality of Life ("**QoL**") improved in eight of nine patients. Erectile function (IIEF-EF) remained stable from 14.6 at baseline to 15.7 at 12 months. The proportion of patients with erections sufficient for penetration was unchanged. Full urinary continence (pad-free, leak-free) was achieved at 12 months in all patients. In five men who suffered from more severe symptoms (baseline IPSS ≥ 12 and Qmax < 15 ml/s), peak urine flow rate ("**Qmax**") increased from 11.6 ml/s to 22.5 ml/s at 12 months. All adverse events were mild to moderate with no serious events reported.

A prospective study of TULSA-PRO® for BPH has been conducted with early outcomes presented at the 2020 European Association of Urology ("**EAU**") Annual Conference. Urinary function improved during the initial three-month follow up among the first seven patients treated, while no adverse effects were seen on sexual and bowel functions: average IPSS decreased from 17.7 to 4.6, IPSS QoL decreased from 4.3 to 1.0, and Qmax increased from 11.5 ml/s to 26.8 ml/s, among several other improved urinary measures. A single adverse event had occurred, abscess of the epididymis requiring drainage at two weeks post therapy.

Radio-recurrent localized prostate cancer, Salvage TULSA (sTULSA): Phase I Study

Salvage ablation of radio-recurrent localized prostate cancer has been evaluated in a prospective study of TULSA-PRO® with early outcomes presented at the 2020 EAU Annual Conference [6]. Ten patients were successfully treated, with a median hospitalization time of 24 hours and catheterization time of four days. Four subjects have completed 12-month follow-up, with average PSA decreased from 4.6 ng/ml to 0.6 ng/ml, and all with no evidence of recurrence on biopsy and imaging (MRI and PSMA-PET). Four patients had prolonged catheterization and subsequent urinary tract infection, and one of these patients had upper urinary tract dilation treated with double-J-stents.

Palliation of symptomatic locally advanced prostate cancer, Palliative TULSA (pTULSA): Phase I Study

Patients with symptomatic locally advanced prostate cancer can suffer from severe urinary retention due to bladder outlet obstruction, intractable hematuria and frequent hospitalization. While these complications are commonly treated by palliative transurethral resection of the prostate ("**TURP**"), the improvement is often insufficient and may exclude patients who cannot discontinue anticoagulants. The safety and feasibility of MRI-guided TULSA was evaluated as an alternative palliative treatment option for men suffering from symptomatic locally advanced prostate cancer[7]. Ten patients with locally advanced prostate cancer were enrolled, half with clinical stage T4 disease and half with clinical T3. Prior to TULSA, all patients had continuous indwelling catheterization due to urinary retention, and 90% had history of recurrent and/or ongoing gross hematuria. Three patients had palliative TURP performed six months prior to receiving palliative TULSA, all of which were unsuccessful. One week after palliative TULSA, 50% of men were catheter-free. At last follow-up, 100% of men were free of gross hematuria, and 80% had an improvement in catheterization, with 70% completely catheter-free. Notably, the average hospitalization time from local complications reduced from 7.3 to 1.4 days in the six-month period before and after palliative TULSA. All adverse events were related to urinary tract infections, with two patients requiring intravenous administration of antibiotics and three patients resolved with oral antibiotics alone. No other treatment related adverse events were recorded, with no rectal injury or fistula. Further, there was no need for blood transfusions and there was no perioperative mortality.

[9] Anttinen et al, "Early experience of salvage MRI-guided transurethral ultrasound ablation (sTULSA) for local prostate cancer recurrence after radiotherapy," EAU 2020 Conference Presentation
[10] Anttinen et al, "Palliative MRI-guided transurethral ultrasound ablation for symptomatic locally advanced prostate cancer," Scandinavian Journal of Urology, 2020

CAPTAIN trial

CAPTAIN (A Comparison of TULSA Procedure vs. Radical Prostatectomy in Participants with Localized Prostate Cancer) is a prospective, multi-centre randomized controlled trial of 201 patients aimed at comparing the safety and efficacy of the TULSA procedure (performed with the TULSA-PRO® system) with radical prostatectomy ("RP") in men with organ-confined, intermediate-risk, Gleason Score 7 (Grade Group 2 and 3) prostate cancer. In the CAPTAIN trial, 134 patients will be randomized to receive one or two TULSA procedures and 67 patients will be randomized to receive RP. The trial is expected to take place at eight or more sites in the United States and two in Canada. Of those, six sites have been activated to date and are currently recruiting patients.

RP is currently the gold-standard surgical treatment for intermediate-risk prostate cancer. RP effectively controls disease but carries risk of significant side effects such as long-term erectile dysfunction and urinary incontinence. The TULSA procedure combines transurethral, robotically-driven therapeutic ultrasound with real-time visualization of temperature and automated control of heating from magnetic resonance thermometry. The high spatial, thermal, and anatomic resolution of the target volume enables precise ablation of prostate tissue while sparing functionally important structures, potentially reducing the risk of side effects relative to RP.

The goal of CAPTAIN is to demonstrate that the efficacy of the TULSA procedure is not inferior to RP, while demonstrating superior quality of life outcomes. The primary safety endpoint is the proportion of patients who preserve both erectile potency and urinary continence at one year after treatment. The primary efficacy endpoint is the proportion of patients who are free from any additional treatment for prostate cancer by three years after treatment. Secondary endpoints include comparison of rates of complications, cost effectiveness, and timing of the return to baseline activity. Long-term follow-up will be gathered for up to 10 years after treatment.

Sonalleve®

Profound's Sonalleve® system combines real-time MRI and thermometry with focused ultrasound delivered from the outside of the patient to enable customized incision-free ablation of diseased tissue. Profound acquired the Sonalleve® technology from Philips in 2017.

The Sonalleve® system is CE marked in the EU for the treatment of uterine fibroids and palliative pain treatment of bone metastases. The uterine fibroids application is also available for sale in Canada. In 2018, the Sonalleve® system was also approved in China by the National Medical Products Administration for the non-invasive treatment of uterine fibroids. Philips Oy registered Sonalleve® in several Middle East, North African, and South Asian countries. In 2020, Sonalleve® also received HDE from the U.S. FDA for treatment of Osteoid Osteoma.

Sonalleve® Clinical Applications

Uterine Fibroids and Adenomyosis

Uterine fibroids are the most common non-cancerous tumors in women of childbearing age. Both surgical and medical treatments are available, and the choice depends on number, size, and location of uterine fibroids, patient's age and preferences, and pregnancy expectations. To date, symptomatic uterine fibroids have been mostly treated with radical surgery (hysterectomy) in women who have completed childbearing, or conservative surgery (myomectomy and endometrial ablation) in women who wish to preserve fertility. Today, the radiologist also has interventional options available. Minimally or non-invasive interventional radiology procedures include uterine artery embolization.

There is currently no ideal treatment for adenomyosis, and new options are needed. Drawing on experience of treatment of uterine fibroids, MR-High Intensity Focused Ultrasound ("**MR-HIFU**") has been explored as a potential new

conservative treatment and MR-HIFU is an early-stage, non-invasive, therapeutic technology with the potential to improve the QoL and decrease the cost of care for patients with adenomyosis.

To achieve its current regulatory clearances, the Sonalleve ® MR-HIFU System has undergone several studies and clinical trials for uterine applications at Sunnybrook Health Sciences Center (Toronto, Ontario), University Medical Center Utrecht (Utrecht, the Netherlands), University Hospital St. André (Bordeaux, France), Samsung Medical Center (Seoul, Korea), Peking University First Hospital Beijing (Beijing, China), First Affiliated Hospital of Medical College of Xi'an Jiaotong University (Xi'an, China), Turku University Hospital (Turku, Finland), National Institutes of Health (Bethesda, MD, USA), St. Luke's Episcopal Hospital (Houston, TX, USA), amongst others.

In addition, a comprehensive literature review provides supportive evidence showcasing the beneficial action of MR-HIFU in uterine fibroid and adenomyosis therapy. These studies include the Verpalen et al. 2020, Nguyen 2020, Yeo et al. 2017, Kim et al. 2017, and Hocquelet et al. 2017 that utilized the Sonalleve® MR-HIFU System. Specifically, the studies show impressive performance in terms of ablation efficiency, therapeutic efficacy, symptom reduction, and/or QoL improvement. There were no treatment-related serious adverse events in any of these studies, although Browne et al. 2020 describes a procedure-related major complication in the form of deep vein thrombosis that was noted in one patient (0.8%) and subsequently and successfully treated with anticoagulation therapy. Minor adverse events, when present, typically include 1st and 2nd degree skin burns, local swelling, cramps, leg pain, abdominal pain, buttock pain, and back pain, which are all known and anticipated adverse events of MR-HIFU therapy.

Palliative Bone Pain Treatment

Pain caused by bone metastases is common in the event of malignancy and is inevitably associated with serious complications that may deteriorate the QoL of patients and become life threatening.

For patients with bone metastases, clinical evaluation reports were completed in October 2020, showing significant decrease in pain score, dosage of medication, or QoL are to be expected with MR-HIFU bone therapy. The randomized controlled Phase III study by Hurwitz et al. represents some of the most important clinical data that has been reported. In 112 subjects receiving MR-HIFU compared against 35 subjects receiving sham treatment, significant pain reduction at three months (decrease in worst NRS pain ≥ 2 without increase in pain medication) was 64.3% vs. 20.0% ($p<0.001$), with mean Numeric Pain Scale ("**NRS**") reduction of 3.6 ± 3.1 vs. 0.7 ± 2.4 from an initial median NRS score of 7.0 in both groups. Improvement in average Brief Pain Inventory-Quality of Life at three months was 2.4 points superior in the MR-HIFU group ($p<0.001$), representing a clinically important reduction in impairment caused by bone metastasis pain.

The clinical data above shows that patients with bone metastases can expect a statistically significant decrease in pain scores and/or in medication dosage and increase in quality of life with MR-HIFU bone metastasis therapy.

Osteoid Osteoma Treatment

Osteoid osteoma is a relatively rare, painful bone tumor that typically occurs in the cortex of long bones, especially in children and adolescents, and accounts for approximately 10% of all benign bone tumors.

Current osteoid osteoma treatment options include surgery and radiofrequency ablation (" **RFA**"), which is a less invasive option than surgical resection. Although RFA can have a high success rate, the treatment is invasive and can potentially cause minor and major complications. It also exposes patients and operators to ionizing radiation associated with the CT imaging guidance.

Sonalleve® MR-HIFU provides an optimal therapy choice for osteoid osteoma which is a precise, completely non-invasive, and free from ionizing radiation treatment.

The recent studies have assessed the use of Sonalleve ® MR-HIFU in treatment of osteoid osteoma, showing a high clinical success rate and complete symptom resolution without any serious adverse effects and only few minor adverse effects that promptly resolve. The Sonalleve® MR-HIFU device offers a novel, minimally invasive, MRI-guided method to treat osteoid osteoma safely and effectively.

Business Update and Sales Strategy

COVID-19 is altering our business through impacts in healthcare facilities' ability to make commitments and patients deciding to undergo procedures. The global response to the COVID-19 pandemic has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Additional measures may be implemented by one or more governments in jurisdictions where the Company operates. These measures have caused material disruption to businesses globally, resulting in an economic slowdown. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions required to contain the COVID-19 virus or remedy its impact, among others.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company's ability to conduct its businesses, including its ability to cultivate adoption of the TULSA-PRO® technology, support clinical customers with TULSA-PRO® procedures and increase the utilization of the systems and one-time use devices.

To date, the economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for TULSA-PRO® systems and the one-time-use devices related thereto. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new TULSA-PRO® user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing, and Profound continues to identify potential new TULSA-PRO® user sites. The Company continues to evaluate the current and potential impact of the COVID-19 pandemic on its business, affairs, operations, financial condition, liquidity, availability of credit and results of operations.

In addition, the actual and threatened spread of COVID-19 globally could also have a material adverse effect on the regional economies in which Profound operates, could continue to negatively impact stock markets, including the trading price of the common shares in the capital of the Company ("**Common Shares**"), could adversely impact the Company's ability to raise capital and could cause continued interest rate volatility and movements that may make obtaining financing more challenging or more expensive.

During the year ended December 31, 2021, the Company experienced the following key impacts related to COVID-19:

- a reduction in revenue, caused by volatility in demand for systems and one-time-use devices.
- customer payments delayed due to Profound's inability to install systems because of hospital restrictions, and
- a lower than anticipated number of TULSA-PRO procedures performed and related revenue being recognized.

The financial impacts from COVID-19 during the year ended December 31, 2021 have impacted Profound's ability to collect certain payments due to continuous lockdowns and hospital restrictions, which have impeded our efforts to install our systems and has delayed our collections. Profound continues to work with local authorities and team members located within these countries to help expedite the process. The COVID-19 pandemic remains uncertain in terms of its magnitude, outcome and duration, as well as further social distancing restrictions. Despite the challenging and uncertain economic environment created by the ongoing impact of the COVID-19 pandemic, our business continues to operate normally and we believe our business demonstrates resilience because of our preparation and strong relationships. Through the implementation of our detailed business continuity plan, we transitioned a significant portion of the Company's employee base to work from home. Throughout these challenging circumstances, the Company has continued to serve its customers, quickly adapting to the current environment.

Profound initiated its launch of the TULSA-PRO® system in the United States in Q4 2019 and the first patient was treated in the United States in a non-clinical trial setting in January 2020. Since then, Profound's business model has evolved to a pay per patient treated model that bundles durable hardware usage, one-time-use devices and Profound's Genius services, which includes necessary clinical support for a productive start-up of the practice.

Profound has generated revenues from capital sales, one-time-use devices and related services, in the EU (principally in Germany) and Asia. For the year ended December 31, 2021, approximately 39%, 30% and 31% of revenues were generated in the EU, United States and Asia, respectively, compared to approximately 38%,16% and 48% of revenues which were generated in the EU, United States and Asia, respectively for the year ended December 31, 2020. Revenue on a quarter over quarter basis is expected to fluctuate given the Company maintaining a limited European commercial effort and remains primarily focused on the U.S. market.

On January 10, 2020, Profound announced the signing of its first-ever US multi-site imaging center agreement for TULSA-PRO® with RadNet, an owner and operator of outpatient imaging centers, pursuant to which Profound will install TULSA-PRO® systems at three RadNet imaging centers in the greater Los Angeles area. The installation of these systems and initiation of patient treatments at these sites have been delayed as a result of the COVID-19 pandemic.

Profound's TULSA-PRO system is primarily marketed to early adopter physicians who specialize in treatment of prostate disease including urologists and radiologists at opinion leading hospitals. TULSA-PRO services are available at either independent imaging centers or at hospital-based imaging centers.

Historically, treatment of conditions such as localized prostate disease and uterine fibroids have included surgical intervention. Over time, surgery has evolved from an 'open' technique, to laparoscopic, to robotic surgery. The motivation of surgeons behind this evolution has been to perform procedures that reduce invasiveness, improve clinical outcomes and reduce recovery times. Profound is now taking this concept to the next level by enabling customizable, incision-free therapies for the MRI-guided ablation of diseased tissue with the TULSA-PRO® and Sonalleve® systems. These incision-free and radiation-free procedures offer surgeons the option of providing predictable and customizable procedures that eliminate invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

Profound is establishing its own direct sales and marketing teams for sales of TULSA-PRO ® systems and the one-time-use devices related thereto, as well as for Sonalleve® systems in the jurisdictions where it is approved. The primary focus of Profound's 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 one-time-use devices. Profound expects to generate recurring revenues from the use of the system, one-time-use devices, clinical support and service maintenance.
Profound also collaborates with its strategic partners Philips and Siemens for lead generation and distribution of durable equipment, which are currently available through the Philips and Siemens sales catalogs.

Under the agreement with Siemens (the "**Siemens Agreement**"), there is a one-time fixed license fee and per annum payments calculated based on annual volume of Profound's systems that are interfaced to a Siemens MRI scanner. The initial term of the Siemens Agreement is five years and will be automatically extended for successive one-year terms thereafter unless terminated earlier. The Company also obtained a non-exclusive license to Siemens Access I interface software and reasonable support for the term of the Siemens Agreement.

On December 21, 2020, Profound signed the GE Agreement to expand provider access to TULSA-PRO ®. Pursuant to the terms of the GE Agreement, Profound will be supplied with additional information to utilize the ExSI interface, which will allow Profound to interface with GE MRI scanners and GE will help support the development efforts of Profound to achieve compatibility with its GE MRI scanners.

On May 6, 2021, Profound signed the Akumin Agreement. Pursuant to the Akumin Agreement, Profound expects to install TULSA-PRO® systems at up to 10 Akumin centers to be outfitted with diagnostic and therapeutic imaging services specifically dedicated towards men's health. The initial geographic focus of the relationship will be in the State of Florida, with Texas and Pennsylvania expected to follow.

Competition

TULSA-PRO®

The TULSA-PRO® system is intended to ablate benign and malignant prostate tissue, however there are other treatment options for prostate disease. There are currently no marketed devices indicated for the treatment of prostate diseases or prostate cancer and our FDA indication and CE mark in the EU also do not include treatment of any particular disease or condition. However, there are a number of devices indicated for the destruction or removal of prostate tissue and devices indicated for use in performing surgical procedures that physicians and surgeons currently utilize when treating patients with prostate disease, including prostate cancer. Approaches that physicians and surgeons currently use to address prostate disease include: (1) watchful waiting/active surveillance; (2) simple prostectomy; (3) radical prostatectomy (includes open, laparoscopic and robotic procedures); (4) radiation therapies including, external beam radiation therapy, brachytherapy and high dose radiation; (5) cryoablation; and (6) trans-rectal high intensity focused ultrasound ("**HIFU**"). In addition, certain adjunct or less common procedures are used or are under development to address prostate disease, such as androgen deprivation therapy and proton beam therapy.

Each of the foregoing competing options have their own limitations and benefits and may only be appropriate for limited patient populations. For example, 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 options of surgery or radiation therapy imposes the possibility of substantial side effects, creating a need for a less invasive methodology to remove diseased prostate tissue that is both radiation and incision-free and provides a more favorable side-effect profile.

Profound believes that the flexibility of the TULSA-PRO ® system may allow the Company to demonstrate its use as a tool for ablating benign and malignant diseased prostate tissue with greater speed and precision than current options while minimizing potential side effects. Profound believes that the TULSA-PRO® system may overcome certain limitations of other devices and methodologies for removing or addressing diseased prostate tissue including HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. Profound believes that a transurethral (inside out) ablation approach with millimeter accuracy has advantages over HIFU in ablating 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. The most common treatment options for uterine fibroids include: (1) hormonal medications including gonadotrophin releasing hormone agonists; (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 fewer side effects than hormonal medications or surgical procedures, such as hysterectomy or myomectomy.

Reimbursement

Profound's ability to successfully commercialize the Company's products depends in large part on the extent to which coverage and adequate 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 payors. Pricing and reimbursement procedures and decisions vary from country to country. Many government health authorities and private payors condition payment on the cost-effectiveness of the product. Even if a device is FDA cleared or CE marked or has received other regulatory clearance or approval, there is no guarantee that third-party payors will reimburse providers or patients for the cost of the device and related procedures or that the amount of such reimbursement will be adequate to cover the cost of the device. The availability of coverage and adequate reimbursement to hospitals and clinicians using our products therefore is important to our ability to generate revenue and Profound plans to pursue coverage and reimbursement for the Company's products in the key markets where the Company has regulatory approvals. Successful commercialization of the Company's approved products will also depend on the cost of the system and the availability of coverage and adequate reimbursement from third-party payors.

Although we expect there to be an out-of-pocket market for our approved products, an out-of-pocket market alone is unlikely to be sufficient to support successful commercialization of our products. To date, our products do not have significant coverage or reimbursement from government or third-party payers in the jurisdictions where they are approved. A C-Code is a unique temporary product code established by CMS for the Hospital Outpatient Prospective Payment System ("OPPS") to promote the adoption of new medical technology that otherwise had no codes to facilitate payment. C-Codes are used on Medicare OPPS claims but may also be recognized on claims from other providers or by other payment systems.

HIGHLIGHTS

- On March 3, 2021, Profound announced the appointment of Cynthia Lavoie to its board of directors.
- On May 6, 2021, Profound announced a multi-site imaging center agreement for TULSA-PRO® with Akumin Inc. (NASDAQ/TSX:AKU), a leading provider of freestanding, fixed-site outpatient diagnostic imaging services in the United States.
- On May 6, 2021, Profound announced that it had entered into the Akumin Agreement.
- On January 5, 2022, Profound announced the joining of Kenneth Knudson as Chief Commercial Officer.
- On January 18, 2022, Profound announced that the first patients have been treated in the Level 1 "CAPTAIN" trial.
- On March 1, 2022, Profound confirmed that the TULSA-PRO® system's new compatibility with GE Healthcare's 3T MRI scanners.

SELECTED FINANCIAL INFORMATION

The following selected financial information as at and for the years ended December 31, 2021 and 2020, have been derived from the audited consolidated financial statements and should be read in conjunction with those audited consolidated financial statements and related notes.

	For year ended December 31,	
	2021	2020
	$	$
Revenue	6,873	7,304
Operating expenses	33,243	22,337
Finance costs	303	2,714
Net loss for the year	30,699	21,622
Basic and diluted loss per share	1.50	1.25
Total assets	86,775	104,601
Total non-current liabilities	2,002	2,442

Revenue has decreased due to lower capital sales during the year ended December 31, 2021 which is partially offset by increased US sales as new sites are enrolled and patient procedures increased.

Operating expenses increased significantly as at December 31, 2021 compared to the year ended December 31, 2020 because of increased personnel, R&D material expenditures, marketing expenditures and stock-based compensation. The increase in operating expenses is correlated to the US market launch, as the Company was required to deploy more resources and continues to expand. The other factor was the lockdowns in 2020 due to COVID-19 which led to a substantial decrease in our expenditures.

The significant decrease in net finance costs as at December 31, 2021 compared to the year ended December 31, 2020 was primarily the impact of the change in the foreign exchange rates for our foreign currency denominated cash, the change in the fair value of the of the derivative financial instrument and the change in amortized cost of trade and other receivables.

The Company reported total assets of $86,775 as at December 31, 2021 as compared to $104,601 as at December 31, 2020. The decrease in 2021 was a result of expenditures throughout the year.

RESULTS OF OPERATIONS

	Three months ended December 31,				Year ended December 31,			
	2021	2020	Change		2021	2020	Change	
	$	$	$	%	$	$	$	%
Revenue	998	2,880	(1,882)	(65)%	6,873	7,304	(431)	(6)%
Cost of sales	501	1,737	(1,236)	(71)%	3,921	3,830	91	2%
Gross profit	497	1,143	(646)	(57)%	2,952	3,474	(522)	(15)%
Expenses								
Research and development	4,699	2,514	2,185	87%	15,277	9,912	5,365	54%
General and administrative	3,223	1,789	1,434	80%	10,314	7,565	2,749	36%
Selling and distribution	2,303	1,748	555	32%	7,652	4,860	2,792	57%
Total operating expenses	10,225	6,051	4,174	69%	33,243	22,337	10,906	49%
Net finance (income)/costs	464	2,987	(2,523)	(84)%	303	2,714	(2,411)	(89)%
Loss before income taxes	10,192	7,895	2,297	29%	30,594	21,577	9,017	42%
Income taxes	(31)	(368)	337	(92)%	105	45	60	133%
Net loss attributed to shareholders for the period	10,161	7,527	2,634	35%	30,699	21,622	9,077	42%
Other comprehensive loss (income)								
Item that may be reclassified to profit or loss								
Foreign currency translation adjustment - net of tax	838	5,450	(4,612)	(85)%	(179)	2,802	(2,981)	(106)%
Net loss and comprehensive loss for the period	10,999	12,977	(1,978)	(15)%	30,520	24,424	6,096	25%
Loss per share								
Basic and diluted net loss per common share	0.49	0.38	0.11	29%	1.50	1.25	0.25	20%

Revenue

Profound deploys a recurring revenue business model in the United States to market TULSA-PRO ®, charging a one-time bundled payment per patient that includes the supply of its one-time-use device, use of the system as well as Company's Genius services that support each TULSA center with clinical and patient recruitment. The Sonalleve® product is marketed primarily outside North America in European and Asian countries deploying a capital model. Outside of North America, Profound generates most of its revenues from its system sales (both TULSA-PRO® and Sonalleve®) in Europe and Asia where the Company deploys a more traditional hybrid business model, charging for the system separately as capital and an additional per patient charge for the one-time-use devices and associated Genius services.

Sales of Sonalleve® systems are primarily one-time capital sale with limited recurring service revenue. For the historical financial periods presented herein, Profound has generated revenues primarily from sales of systems and one-time-use devices through its partnerships with Siemens and Philips in the EU and Asia. As the Company expands its

commercialization efforts, it anticipates generating revenues through in-house sales and marketing efforts, as well as from collaborative partnerships. In August 2019, the Company received FDA clearance for the TULSA-PRO® system in the United States, and accordingly the Company anticipates generating future revenues in that market.

For the three months ended December 31, 2021, the Company recorded revenue totaling $998 with the full amount of $998 from non-capital – recurring revenue, which consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. For the three months ended December 31, 2020, the Company recorded revenue totaling $2,880 with $2,280 from the one-time sale of capital equipment and $600 from non-capital – recurring revenue. The decrease in revenue for the three months ended December 31, 2021, was primarily the result of higher one-time sales of capital equipment.

For the year ended December 31, 2021, the Company recorded revenue totaling $6,873, with $3,150 from the one-time sale of capital equipment and $3,723 from non-capital – recurring revenue. For the year ended December 31, 2020, the Company recorded revenue totaling $7,304 with $4,581 from the one-time sale of capital equipment and $2,723 from non-capital – recurring revenue. The decrease in revenue for the year ended December 31, 2021, was the result of lower one-time sales of capital equipment.

Revenue on a quarter over quarter basis is expected to fluctuate in the near term given the Company is maintaining a limited European commercial effort and remains focused primarily on the U.S. market. The economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for the TULSA-PRO® systems and the one-time-use devices related thereto. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new TULSA-PRO® user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing and Profound continues to identify potential new TULSA-PRO® user sites. It continues to be very challenging to gauge the magnitude of the impact expected from the virus' outbreak on our future sales.

Cost of sales

Cost of sales include cost of finished goods, inventory provisions, warranty, freight and manufacturing overhead expenses.

For the three months ended December 31, 2021, the Company recorded a cost of sales of $501, related to the sale of medical devices, capital and non-capital, which reflects a 50% gross margin. For the three months ended December 31, 2020, the Company recorded a cost of sales of $1,737, related to the sale of medical devices, capital and non-capital, which reflects a 40% gross margin. The gross margin was higher in Q4 2021 due to the revenue product mix and greater recurring revenue.

For the year ended December 31, 2021, the Company recorded a cost of sales of $3,921, related to the sale of medical devices, capital and non-capital, which reflects a 43% gross margin. For the year ended December 31, 2020, the Company recorded a cost of sales of $3,830, related to the sale of medical devices, capital and non-capital, which reflects a 48% gross margin. The gross margin was lower in 2021 due to the revenue product mix.

Operating Expenses

Operating expenses consist of three components: research and development (" **R&D**"), general and administrative ("**G&A**") and selling and distribution expenses. Historically, R&D expenses have exceeded selling and distribution expenses; however, in the future Profound expects selling and distribution expenses to increase as the Company commercializes the TULSA-PRO® system in the United States.

R&D Expenses

R&D expenses are comprised of costs incurred in performing R&D activities, including new product development, continuous product improvement, investment in clinical trials and related clinical manufacturing costs, materials and supplies, salaries and benefits, consulting fees, patent procurement costs, and occupancy costs related to R&D activity.

For the three months ended December 31, 2021, R&D expenses were higher by $2,185 compared to the three months ended December 31, 2020. Materials, share based compensation, salaries and benefits and travel increased by $948, $435, $699 and $89, respectively. The increases were due to increased spending on R&D initiatives for new designs, technology improvements and different magnet compatibility, options awarded to employees, additional headcount and increased travel for off-site MRI testing.

For the year ended December 31, 2021, R&D expenses were higher by $5,365 compared to the year ended December 31, 2020. Materials, consulting fees, share based compensation, salaries and benefits, travel, rent and other expenses increased by $1,228, $173, $1,242, $2,296, $218, $27 and $179, respectively. These increases were due to increased spending on materials and R&D projects for technology improvements and upgrades, new system designs and MRI usage related to different magnet compatibility. In addition, the increases were also driven by options awarded to employees, additional headcount, increased travel due to restrictions being lifted, additional lab area rentals in Germany for design improvements, and overall increase to general expenses.

G&A expenses

G&A expenses are comprised of management costs, including salaries and benefits, various management and administrative support functions, insurance and other operating and occupancy costs.

G&A expenses for the three months ended December 31, 2021 increased by $1,434 compared to the three months ended December 31, 2020. Consulting fees, share based compensation, software and other expenses increased by $240, $806, $167 and $97, respectively, due to increased legal and accounting fees, options awarded to employees, increased license costs for the enterprise resource planning ("**ERP**") and customer relationship management ("**CRM**") software and an overall increase to general expenses as offices continue to reopen from COVID-19 restrictions. In addition, amortization expense increased by $46 due to the capitalization of ERP costs. Offsetting these amounts were a decrease to salaries and benefits of $42 which were due to salary adjustments and lower bonuses awarded to management in 2021. Depreciation expenses increased by $107 due to depreciation related to leasehold improvement assets and right of use assets.

G&A expenses for the year ended December 31, 2021 increased by $2,749 compared to the year ended December 31, 2020. Consulting fees, share based compensation, insurance, software and office expenses increased by $504, $1,690, $119, $193 and $204, respectively, due to increased legal and accounting fees, options awarded to employees, increased license costs for the ERP and CRM software and an overall increase to general expenses as offices continue to reopen from COVID-19 restrictions. In addition, amortization expense increased by $118 due to the capitalization of ERP costs. Offsetting these amounts were a decrease to salaries and benefits of $117 which were due to salary adjustments and lower bonuses awarded to management in 2021. Depreciation expenses increased by $49 due to depreciation related to leasehold improvement assets and right of use assets.

Selling and distribution expenses

Selling and distribution expenses are comprised of business development costs related to the market development activities and commercialization of the Company's systems, including salaries and benefits, marketing support functions, occupancy costs related to marketing activity and other miscellaneous marketing costs.

Selling and distribution expenses for the three months ended December 31, 2021 were higher by $555 compared to the three months ended December 31, 2020. Salaries and benefits and share based compensation increased by $334 and $212, respectively, due to increased salesforce hired in the US and China and options awarded to employees.

Selling and distribution expenses for the year ended December 31, 2021 increased by $2,792 compared to the year ended December 31, 2020. Salaries and benefits, share based compensation, marketing and travel increased by $1,207, $1,163, $328 and $82, respectively, due to increased salesforce hired in the US and China, options awarded to employees, increased marketing campaigns and conferences in the US and travel restrictions being removed.

Finance costs

Net finance costs are primarily comprised of the following: (i) the change in fair value of the contingent consideration payable to Phillips; (ii) the CIBC Loan (as defined herein) accreting to the principal amount repayable and its related interest expense; (iii) the change in the fair value of the derivative liability warrants; (iv) the lease liability interest expense; (v) foreign exchange gain or losses; (vi) interest income; and (vii) the change in amortized cost of trade and other receivables. The Company repaid the CIBC Loan on February 4, 2020.

Net finance costs for the three months ended December 31, 2021 were lower by $2,523 compared to the three months ended December 31, 2020 primarily due to a lower foreign exchange loss. During the three months ended December 31, 2021, the Company recognized $197 of foreign exchange loss, $448 change in amortized cost of trade and other receivables and a $110 gain on the change in fair value of the derivative liability warrants. The Company recognized interest income of $89 and lease liability interest expense of $18.

Net finance costs for the year ended December 31, 2021 were lower by $2,411 compared to the year ended December 31, 2020 primarily due to a lower foreign exchange loss. During the year ended December 31, 2021, the Company recognized $286 of foreign exchange loss primarily related to cash held in foreign currencies, $448 change in amortized cost of trade and other receivables and a $293 gain on the change in fair value of the derivative liability warrants. The Company recognized interest income of $205 and lease liability interest expense of $67.

Net loss

Net loss for the three months ended December 31, 2021 was $10,161 or $0.49 per Common Share, compared to a net loss of $7,527 or $0.38 per Common Share for the three months ended December 31, 2020. The increase in net loss was primarily attributed to an increase in R&D expense of $2,185, an increase in G&A expenses of $1,434, an increase in selling and distribution expenses of $555 and a decrease in gross profits of $646. This was offset by a decrease in net finance costs of $2,523.

Net loss for the year ended December 31, 2021 was $30,699 or $1.50 per Common Share, compared to a net loss of $21,622 or $1.25 per Common Share for the year ended December 31, 2020. The increase in net loss was primarily attributed to an increase in R&D expenses of $5,365, increase in G&A expenses of $2,749, increase in selling and distribution expenses of $2,792 and a decrease in gross profits of $522. This was offset by a decrease in net finance cost of $2,411.

SUMMARY OF QUARTERLY FINANCIAL RESULTS

The summary financial information provided below is derived from the Company's interim financial statements for each of the last eight quarters that are prepared under IFRS in US dollars.

	2021				2020			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
	$	$	$	$	$	$	$	$
Revenue	998	2,537	2,627	711	2,880	2,238	1,026	1,160
Cost of sales	501	1,550	1,411	459	1,737	765	610	718
Gross profit	497	987	1,216	252	1,143	1,473	416	442
Operating expenses	10,225	8,594	7,600	6,824	6,051	6,615	4,356	5,314
Net finance costs	464	(1,663)	602	900	2,987	784	1,224	(2,281)
Loss before income taxes	10,192	5,944	6,986	7,472	7,895	5,926	5,164	2,591
Income taxes	(31)	52	57	27	(368)	183	139	92
Net loss for the period	10,161	5,996	7,043	7,499	7,527	6,109	5,303	2,683
Loss per Common Share								
Basic and diluted	0.49	0.29	0.35	0.37	0.38	0.33	0.33	0.21

The first quarter of 2020 was impacted by the increase in the US dollar and Euro foreign currency rates, triggering an unrealized foreign exchange gain. Net loss for the period was lower due to these gains.
The second quarter of 2020 experienced a partial reversal of the Q1 2020 foreign exchange gains resulting in higher net finance costs. Net loss for the period was higher due to these losses.

The third quarter of 2020 operating expenses increased because of the personnel hired, share based compensation awards and increased spending on R&D projects coupled with technology improvements.

The fourth quarter of 2020 was impacted by the decrease in the foreign exchange currency rate, triggering an unrealized foreign exchange loss. Net loss for the period was higher due to these losses.

The first quarter of 2021 was impacted by lower sales and higher operating costs. These changes were mainly attributed to the impact of COVID-19 and an increase in R&D projects.

The second quarter of 2021 operating expenses were higher due to increased headcount, material expenditures and stock-based compensation.

The third quarter of 2021 operating expenses were higher due to increased headcount, increased travel due to travel restrictions being removed and increased share-based compensation. In addition, there was also a decrease in finance costs due to the US dollar and Euro foreign currency rate, triggering an unrealized foreign exchange gain.

The fourth quarter of 2021 revenue was lower due to decreased one-time capital sales. Operating expenses were higher due to the increase in headcount and increased share-based compensation. In addition, there were minimal financing costs due to the US dollar and Euro foreign currency rate, triggering an unrealized foreign exchange loss offset by gain on the fair value of the derivative financial instrument.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2021, the Company had cash of $67,152 compared to $83,913 at December 31, 2020.

CIBC Loan

Profound Medical Inc. ("**PMI**") entered into a loan agreement with Canadian Imperial Bank of Commerce (" **CIBC**") on July 30, 2018 (the "**CIBC Loan Agreement**"), for initial gross proceeds of C$12,500, maturing on July 29, 2022, with an interest rate based on prime plus 2.5% (the "**CIBC Loan**"). All obligations of the Company under the CIBC Loan Agreement were guaranteed by current and future subsidiaries of the Company and included security of first priority interests in the assets of the Company and its subsidiaries. On February 4, 2020, the full outstanding amount of the CIBC Loan at that date, plus accrued interest, was repaid for a total payment of $9,317.

In connection with this term loan agreement on July 31, 2018, the Company also issued 32,171 Common Share purchase warrants to CIBC, with each warrant entitling the holder to acquire one Common Share at a price of C$9.70 per Common Share until the date that is 60 months from the closing of the CIBC Loan Agreement, with a cashless exercise feature. The cashless exercise feature causes the conversion ratio to be variable and the warrants are therefore classified as a financial liability. Gains and losses on the warrants are recorded within finance costs on the consolidated statements of loss and comprehensive loss. A pricing model with observable market based inputs was used to estimate the fair value of the warrants issued. The estimated fair value of the warrants as at December 31, 2021 and December 31, 2020 was $161 and $450, respectively.

Cash Flow

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

The Company may require additional capital to fund R&D activities and any significant expansion of operations. Potential sources of capital could include equity and/or debt financings, development agreements or marketing agreements, the collection of revenue resulting from future commercialization activities and/or new strategic partnership agreements to fund some or all costs of development. There can be no assurance that the Company will be able to obtain the capital sufficient to meet any or all of the Company's needs. The availability of equity or debt financing will be affected by, among other things, the results of R&D, the Company's ability to obtain regulatory approvals, the market acceptance of the Company's products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raises additional funds by issuing equity securities, existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require the Company to agree to operating and financial covenants that would restrict operations. Any failure on the Company's part to raise additional funds on terms favourable to the Company or at all may require the Company 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 the Company not being in a position to take advantage of business opportunities, in the termination or delay of clinical trials for our products, in curtailment of product development programs designed to identify new products, in the sale or assignment of rights to technologies, product and/or an inability to file market approval applications at all or in time to competitively market products.

	Three months ended		Year ended	
	December 31, 2021 $	December 31, 2020 $	December 31, 2021 $	December 31, 2020 $
Cash provided by (used in) operating activities	(5,053)	(7,458)	(22,360)	(20,574)
Cash provided by (used in) investing activities	(127)	(350)	(593)	(350)
Cash provided by (used in) financing activities	(88)	4,246	5,948	87,433
Foreign exchange on cash	202	4,596	244	2,604
Net increase (decrease) in cash	(5,066)	1,034	(16,761)	69,113

Operating Activities

Net cash provided by (used in) operating activities for the three months ended December 31, 2021 was $(5,503) versus $(7,458) for the three months ended December 31, 2020. The principal use of the operating cash flows during this period related to increased employee headcount, increased travel expenditures and increased spending on R&D initiatives which was offset by the foreign exchange loss during the quarter.

Net cash provided by (used in) operating activities for the year ended December 31, 2021 was $(22,360) versus $(20,574) for the year ended December 31, 2020. The principal use of the operating cash flows during this period related to increased employee headcount, increased manufacturing costs, increased spending for R&D initiatives and projects as well as increased legal and accounting costs.

Investing Activities

Net cash provided by (used in) investing activities for the three months ended December 31, 2021 were $(127) versus $(350) for the three months ended December 31, 2020. These cash flows related to ERP implementation costs.

Net cash provided by (used in) investing activities for the year ended December 31, 2021 were $(593) versus $(350) for the year ended December 31, 2020. These cash flows related to ERP implementation costs and the construction of a new manufacturing and radio frequency room.

Financing Activities

Net cash provided by (used in) financing activities for the three months ended December 31, 2021 were $(88) versus $4,246 for the three months ended December 31, 2020. These cash flows related to the exercise of options and warrants in 2020 while in 2021 there were no warrants exercised during the period.

Net cash provided by (used in) financing activities for the year ended December 31, 2021 were $5,948 versus $87,433 for the year ended December 31, 2020. These cash flows related to the options and warrants exercised while in Q1 2020, Profound completed a public offering of 3,392,500 Common Shares at a price of $11.65 per Common Share for gross proceeds of $39,523 and in Q3 2020 Profound completed a public offering of 3,172,414 Common Shares for gross proceeds of $46,000.

Foreign Exchange on Cash

Cash was impacted by the change in the foreign exchange rates for our foreign currency denominated cash. The value of our currencies increased, resulting in an increase in the Company's cash holdings.

The Company's cash requirements depend on numerous factors, including market acceptance of the Company's products, the resources devoted to developing and supporting the products and other factors. Profound expects to continue to devote substantial resources to expand procedure adoption and acceptance of the Company's products.

Contractual obligations

The following table summarizes the Company's significant contractual obligations:

	December 31, 2021				
	Carrying amount $	Future cash flows $	Less than 1 Year $	Between 1 year and 5 years $	Greater than 5 years $
Accounts payables and accrued liabilities	3,180	3,180	3,180	—	—
Lease liability[1]	1,377	1,575	321	1,254	—
Total	4,557	4,755	3,501	1,254	—

1 Present value of the lease payments that are not paid, discounted using the interest rate implicit in the lease.

Non-IFRS Financial Measures

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

The Company's working capital (defined as current assets less current liabilities) is a non-IFRS financial measure. Working capital is used to fund operations and meet short-term obligations. If the Company has enough working capital, it can continue to pay its employees and suppliers and meet other obligations, such as interest payments and taxes, even if it runs into cash flow challenges. The working capital as at December 31, 2021 and 2020 is set forth in the table below.

	2021 $	2020 $
Current assets	77,125	97,742
Less: Current liabilities	4,155	4,809
Working capital	72,970	92,933

Working capital has decreased by $19,963 with a surplus of $72,970 at December 31, 2021 compared to the surplus of $92,933 at December 31, 2020. The change in working capital is due to a decrease in current assets of $20,617, which was primarily the result of the decreased cash balance of $16,761 and the reclassification of certain receivables to long term. Current liabilities decreased by $654 due to the timing of accruals and payments.

COMMITMENTS & CONTINGENCIES

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

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

FINANCIAL INSTRUMENTS

The Company's financial instruments consist of cash, trade and other receivables, accounts payable and accrued liabilities, lease liabilities and other liabilities. The fair values of these financial instruments and other liabilities, approximate carrying value because of their short-term nature. For the non-current trade and other receivables, the fair value is also not significantly different form the carrying amount. Financial assets measured at amortized cost include cash and trade and other receivables.

The fair value of the Company's derivative financial instruments is based on the valuation techniques described and is considered level 2 in the fair value hierarchy.

Financial liabilities measured at amortized cost include accounts payable and accrued liabilities, lease liabilities and other liabilities.

The Company's financial instruments are exposed to certain financial risks including credit risk, liquidity risk, currency risk and interest rate risk. There have been no significant changes to those risks impacting the Company since December 31, 2020, nor has there been a significant change in the composition of its financial instruments since December 31, 2020.

RELATED PARTY TRANSACTIONS

Key management includes the Company's directors and senior management team. Additional information on the senior management team can be found in the Company's AIF. The remuneration of directors and the senior management team were as follows:

	Three months ended		Year ended	
	December 31, 2021 $	December 31, 2020 $	December 31, 2021 $	December 31, 2020 $
Salaries and employee benefits	554	284	1,989	1,418
Directors' fees	62	29	233	99
Share-based compensation	1,162	404	3,182	1,594
Total	1,778	717	5,404	3,111

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

OUTSTANDING SHARES

As at March 3, 2022, the date of this MD&A, the Company had the following securities outstanding:

	Number
Common Shares	20,776,217
Share purchase options	2,087,146
Warrants	724,983
RSU	232,317

OFF-BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of consolidated financial statements in conformity with IFRS requires management to make estimates and judgements that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the period. Actual results could differ from these estimates. As additional information becomes available or actual amounts are determinable, the recorded estimates are revised and reflected in operating results in the period in which they are determined.

Critical accounting policies

Revenue

To determine revenue recognition for arrangements the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company derives its revenues primarily from the lease and sale of medical devices and the sale of certain one-time-use devices. Capital equipment consists of one-time revenue for the sale of capital equipment including installation fees. Non-capital – recurring revenue consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. Revenue is recognized when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over the promised goods or services, generally at the point in time of shipment to or receipt of the products by the customer or when the services are performed. When contracts contain customer acceptance provisions, revenue is recognized on the satisfaction of the specific acceptance criteria.

The amount of revenue to be recognized is based on the consideration the Company expects to receive in exchange for its goods and services. For contracts that contain multiple performance obligations, the Company allocates the consideration to which it expects to be entitled to each performance obligation based on relative standalone selling prices and recognizes the related revenue when or as control of each individual performance obligation is transferred to customers.

Service revenue related to installation and training is recognized over the period in which the services are performed. Service revenue related to extended warranty service is deferred and recognized on a straight-line basis over the extended warranty period covered by the respective customer contract.

Critical accounting estimates

Impairment of non-financial assets

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

Trade and other receivables

The key judgements and estimates used in determining the amortized cost for trade and other receivables are the estimated collection period and the discount rate applied to the cash flow projections.

DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

Disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure.

The Chief Executive Officer and the Chief Financial Officer of the Company (collectively the " **Certifying Officers**") are responsible for establishing and maintaining disclosure controls and procedures ("**DC&P**") and internal control over financial reporting ("**ICFR**"), as those terms are defined in *National Instrument 52-109 Certification of Disclosure in Issuer's Annual and Interim Filings*, and in applicable SEC rules and regulations, for the Company.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. These inherent limitations include, but are not limited to, human error and circumvention of controls and as such, there can be no assurance that the controls will prevent or detect all misstatements due to errors or fraud, if any.

Management concluded that internal control over financial reporting was not effective as of December 31, 2021 as a result of a material weakness in internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the assessment of the effectiveness of our internal control over financial reporting, management identified a material weakness that existed as of December 31, 2021 in the control environment.

Control Environment

The Company did not design or implement adequate oversight processes and structures, or an organizational design to support the achievement of the Company's objectives in relation to internal controls. The Company identified a deficiency in internal controls, primarily due to the control environment not supporting the increasing complexity of the share based compensation arrangements for employees and directors and review of third-party calculations. As a result, an issue existed within the control environment that impacted the ability of the Company to maintain effective internal control over financial reporting. This material weakness contributed to the following:

- The Company did not design and maintain effective controls over the review of inputs utilized in the calculation of the share based compensation expense. Specifically, the Company did not design appropriate controls over the valuation and review of third party calculations.

This material weakness resulted in audit adjustments to the share based compensation expense, contributed surplus and related financial statement disclosures, which were recorded prior to the issuance of the consolidated financial statements as of and for the year ended December 31, 2021.

While there was a material weakness, no restatement for any previous periods were required as the impact was immaterial in the aggregate and did not have a pervasive impact on ICFR.

Status of Remediation Plan

Management, with the assistance of external consultants, is reviewing and revising our internal control over financial reporting. Management is committed to implementing changes to our internal control over financial reporting to ensure that the control deficiencies that contributed to the material weaknesses are remediated. The following remedial activities are in process:

- We are increasing the number of finance and accounting personnel and have redesigned financial reporting structures within the organization to establish clear responsibility and accountability for key financial reporting processes and controls. We have identified the need for additional financial reporting personnel with an appropriate level of internal controls and accounting knowledge, training and experience commensurate with our financial reporting requirements, and are actively working to identify additional resources.

- We are continuing to establish an internal audit function and we have engaged external consultants to assist management with designing and implementing internal controls. As a result, a project was commenced to reassess risks related to financial reporting, understand and document significant financial reporting processes, and to re-assess the design and operation of key controls. This project is expected to continue until management has determined that deficiencies have been remediated and our internal control over financial reporting are operating effectively.

Management believes these actions will remediate the material weaknesses and have not completed all the corrective processes, procedures and related evaluation or remediation that we believe are necessary. As we continue to evaluate and work to remediate the material weaknesses, we may need to take additional measures to address the control deficiencies. Until the remediation steps set forth above, including the efforts to implement any additional control activities identified through our remediation processes, are fully implemented and concluded to be operating effectively, the material weaknesses described above will not be considered fully remediated.

Other than disclosed above, there have been no significant changes to the Company's ICFR for the year ended December 31, 2021, which have materially affected, or are reasonably likely to materially affect the Company's ICFR.

RISK FACTORS

For a detailed description of risk factors associated with the Company, refer to the "Risk Factors" section of the AIF, which is available on SEDAR at www.sedar.com and filed as an exhibit to the 40-F, available on EDGAR at www.sec.gov.

In addition, the Company is exposed to a variety of financial risks in the normal course of operations, including risks relating to cash flows from operations, liquidity, capital reserves, market rate fluctuations and internal controls over financial reporting. Our overall risk management program and business practices seek to minimize any potential adverse effects on our consolidated financial performance. Financial risk management is carried out under practices approved by our audit committee. This includes reviewing and making recommendations to the board of directors regarding the adequacy of our risk management policies and procedures with regard to identification of the Company's principal risks, and implementation of appropriate systems and controls to manage these risks.

ADDITIONAL INFORMATION

Additional information relating to the Company, including the AIF the other exhibits to the 40-F, is available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov. The Common Shares are listed for trading on the TSX under the symbol "PRN" and on Nasdaq under the symbol "PROF".

Exhibit 99.3

PROFOUND MEDICAL CORP.

CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020

PRESENTED IN US DOLLARS (000s)

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Profound Medical Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Profound Medical Corp. and its subsidiaries (together, the Company) as of December 31, 2021 and 2020, and the related consolidated statements of loss and comprehensive loss, changes in shareholders' equity and cash flows for the years then ended, including the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and its financial performance and its cash flows for the years then ended in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

PricewaterhouseCoopers LLP
PwC Centre, 354 Davis Road, Suite 600, Oakville, Ontario, Canada L6J 0C5
T: +1 905 815 6300, F: +1 905 815 6499

"PwC" refers to PricewaterhouseCoopers LLP, an Ontario limited liability partnership.



Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Chartered Professional Accountants, Licensed Public Accountants

Oakville, Ontario, Canada
March 3, 2022

We have served as the Company's auditor since 2013.

Profound Medical Corp.
Consolidated Balance Sheets
As at December 31, 2021 and 2020
In USD (000s)

	2021 $	2020 $
Assets		
Current assets		
Cash	67,152	83,913
Trade and other receivables (note 4)	1,412	7,431
Inventory (note 5)	7,413	5,331
Prepaid expenses and deposits	1,148	1,067
Total current assets	77,125	97,742
Trade and other receivables (note 4)	3,622	—
Property and equipment (note 6)	788	859
Intangible assets (note 7)	1,435	1,898
Right-of-use assets (note 8)	1,116	1,424
Goodwill (note 7)	2,689	2,678
Total assets	86,775	104,601
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	3,180	3,382
Deferred revenue	477	358
Provisions	87	195
Other liabilities (note 10)	—	99
Derivative financial instrument	161	450
Lease liabilities (note 11)	250	312
Income taxes payable	—	13
Total current liabilities	4,155	4,809
Deferred revenue	875	1,078
Lease liabilities (note 11)	1,127	1,364
Total liabilities	6,157	7,251
Shareholders' Equity		
Share capital (note 12)	219,579	211,527
Contributed surplus	16,986	11,250
Accumulated other comprehensive loss	4,746	4,567
Deficit	(160,693)	(129,994)
Total Shareholders' Equity	80,618	97,350
Total Liabilities and Shareholders' Equity	86,775	104,601

The accompanying notes are an integral part of these consolidated financial statements.

Profound Medical Corp.
Consolidated Statements of Loss and Comprehensive Loss
For the years ended December 31, 2021 and 2020
In USD (000s)

	2021 $	2020 $
Revenue (note 14)		
Capital equipment	3,150	4,581
Recurring - non-capital	3,723	2,723
	6,873	7,304
Cost of sales (note 15)	3,921	3,830
Gross profit	2,952	3,474
Operating expenses (note 15)		
Research and development	15,277	9,912
General and administrative	10,314	7,565
Selling and distribution	7,652	4,860
Total operating expenses	33,243	22,337
Operating Loss	30,291	18,863
Net finance costs (note 16)	303	2,714
Loss before taxes	30,594	21,577
Income taxes (note 17)	105	45
Net loss attributed to shareholders for the year	30,699	21,622
Other comprehensive loss		
Item that may be reclassified to loss		
Foreign currency translation adjustment - net of tax	(179)	2,802
Net loss and comprehensive loss for the year	30,520	24,424
Loss per share (note 18)		
Basic and diluted loss per common share	1.50	1.25

The accompanying notes are an integral part of these consolidated financial statements.

Profound Medical Corp.
Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2021 and 2020
In USD (000s)

	Number of shares	Share capital $	Contributed surplus $	Accumulated other comprehensive income (loss) $	Deficit $	Total $
Balance – January 1, 2020	11,852,749	100,298	15,076	7,369	(108,372)	14,371
Net loss for the year	—	—	—	—	(21,622)	(21,622)
Cumulative translation adjustment - net of tax of $nil	—	7,040	94	(2,802)	—	4,332
Exercise of share options	235,131	3,025	(1,199)	—	—	1,826
Exercise of warrants	1,556,154	22,070	(5,739)	—	—	16,331
Share-based compensation (note 13)	—	—	3,018	—	—	3,018
Issuance of units from offering (note 12)	6,564,914	79,094	—	—	—	79,094
Balance - December 31, 2020	20,208,948	211,527	11,250	4,567	(129,994)	97,350
Net loss for the year	—	—	—	—	(30,699)	(30,699)
Cumulative translation adjustment - net of tax of $nil	—	168	(18)	179	—	329
Exercise of share options	79,208	992	(397)	—	—	595
Exercise of warrants	485,161	6,836	(998)	—	—	5,838
Vesting of RSUs	2,900	56	(56)	—	—	—
Share-based compensation (note 13)	—	—	7,205	—	—	7,205
Balance - December 31, 2021	20,776,217	219,579	16,986	4,746	(160,693)	80,618

The accompanying notes are an integral part of these consolidated financial statements.

Profound Medical Corp.
Consolidated Statements of Cash Flows
For the years ended December 31, 2021 and 2020
In USD (000s)

	2021 $	2020 $
Operating activities		
Net loss for the year	(30,699)	(21,622)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation of property and equipment (note 6)	518	352
Amortization of intangible assets (note 7)	1,029	881
Depreciation of right-of-use assets (note 8)	332	305
Share-based compensation (note 13)	7,205	3,018
Interest and accretion expense (note 16)	67	543
Deferred revenue	(90)	257
Change in fair value of derivative financial instrument(note 9)	(293)	237
Change in amortized cost of trade and other receivables (note 4)	448	—
Change in fair value of contingent consideration (note 10)	—	90
Changes in non-cash working capital balances		
Investment tax credits receivable	—	179
Trade and other receivables	1,996	(4,028)
Prepaid expenses and deposits	(78)	(17)
Inventory	(2,491)	(2,141)
Accounts payable and accrued liabilities	(356)	102
Provisions	(110)	71
Income taxes payable	(13)	1
Foreign exchange on cash	175	1,198
Net cash flow used in operating activities	(22,360)	(20,574)
Investing activities		
Purchase of property and equipment	(32)	—
Purchase of intangible assets	(561)	(350)
Total cash used in investing activities	(593)	(350)
Financing activities		
Issuance of common shares	—	85,523
Transaction costs paid	—	(6,429)
Payment of other liabilities	(99)	(212)
Payment of long-term debt and interest	—	(9,317)
Proceeds from share options exercised	595	1,826
Proceeds from warrants exercised	5,838	16,331
Payment of lease liabilities	(386)	(289)
Total cash from financing activities	5,948	87,433
Net change in cash during the year	(17,005)	66,509
Foreign exchange on cash	244	2,604
Cash – Beginning of year	83,913	14,800
Cash – End of year	67,152	83,913

The accompanying notes are an integral part of these consolidated financial statements.

1 Description of business

Profound Medical Corp. (Profound) and its subsidiaries (together, the Company) were incorporated under the Ontario Business Corporations Act on July 16, 2014. The Company is a medical technology Company developing treatments to ablate the prostate gland, uterine fibroids, osteoid osteoma and nerves for palliative pain relief for patients with metastatic bone disease.

The Company's registered address is 2400 Skymark Avenue, Unit 6, Mississauga, Ontario, L4W 5K5, Canada.

2 Summary of significant accounting policies and basis of preparation

Basis of preparation

The Company prepares its consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS). The Board of Directors approved these consolidated financial statements on March 3, 2022. These consolidated financial statements comply with IFRS.

Accounting policies

Use of estimates and judgments

The preparation of consolidated financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 3.

Consolidation

Subsidiaries are all entities over which the Company has control. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The wholly owned subsidiaries of Profound are consolidated from the date control is obtained. All intercompany transactions, balances, income and expenses on transactions with the subsidiaries are fully eliminated.

These consolidated financial statements include the following wholly owned subsidiaries of the Company: Profound Medical Inc. (Canada), Profound Medical Oy (Finland), Profound Medical GmbH (Germany), Profound Medical (U.S.) Inc. (United States), Profound Medical Technology Services (Beijing) Co., Ltd. (China) and 2753079 Ontario Inc. (Canada).

Business combinations

The acquisition method of accounting is used to account for business combinations. The consideration transferred in a business combination is measured at fair value at the date of acquisition. Acquisition-related transaction costs are recognized in the consolidated statements of loss and comprehensive loss as incurred. At the acquisition date, the identifiable assets acquired and the liabilities assumed are initially recognized at their fair value. Goodwill is measured as the excess of the sum of the consideration transferred and the fair value of the acquirer's previously held equity interest in the acquiree (if any) over the net of the acquisition date amounts of the identifiable assets acquired and liabilities assumed. When the consideration transferred by the Company in a business combination includes assets or liabilities resulting from a contingent consideration arrangement, the contingent consideration is measured at its acquisition date fair value and is included as part of the consideration transferred in a business combination. Changes in the acquisition date fair values of the identifiable assets, liabilities and contingent consideration that qualify as measurement period adjustments are adjusted retrospectively, with corresponding adjustments against goodwill. Measurement period adjustments are adjustments that arise from additional information obtained during the measurement period (which cannot exceed one year from the acquisition date) about facts and circumstances that existed at the acquisition date.

Other than measurement period adjustments, contingent consideration that is classified as a financial liability is remeasured at subsequent reporting dates, with the corresponding gain or loss recognized in the consolidated statements of loss and comprehensive loss.

Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision maker. The chief operating decision maker has been identified as the chief executive officer.

Foreign currency translation

The Company has a functional currency of Canadian dollars and the functional currency of each subsidiary is determined based on facts and circumstances relevant for each subsidiary. Where the Company's presentation currency of US dollars differs from the functional currency of a subsidiary, the assets and liabilities of the subsidiary are translated from the functional currency into the presentation currency at the exchange rates as at the reporting date. The income and expenses of the subsidiaries are translated at rates approximating the exchange rates at the dates of the transactions. Exchange differences arising on the translation of the financial statements of the Company's subsidiaries are recognized in other comprehensive loss (income).

Foreign currency transactions are translated into the functional currency of the Company or its subsidiaries, using the exchange rates prevailing at the dates of these transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in currencies other than an entity's functional currency are recognized in the consolidated statements of loss and comprehensive loss, within finance costs.

Financial assets

The Company classifies its financial assets in the following measurement categories:

- those to be measured subsequently at fair value (either through other comprehensive income, or through profit or loss); and
- those to be measured at amortized cost.

The classification depends on the Company's business model for managing the financial assets and the contractual terms of the cash flows. The Company does not currently have any assets measured subsequently at fair value.

At initial recognition, the Company measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset.

Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Company has transferred substantially all the risks and rewards of ownership.

Trade and other receivables are amounts due from customers for goods sold or services performed in the ordinary course of business. They are generally due for settlement within 12 months and are therefore generally classified as current. Trade and other receivables are recognized initially at the amount of consideration that is unconditional, unless they contain significant financing components, when they are recognized at fair value. The Company holds the trade and other receivables with the objective of collecting the contractual cash flows and therefore measures them subsequently at amortized cost using the effective interest rate method.

The Company reviews its expected cash flows from trade and other receivables and when the receivable extends beyond one year, the amortized cost is calculated using management's estimate of the cash flow timing and amounts. These amounts are continually re-assessed and adjustments are made when necessary.

The Company assesses on a forward-looking basis the expected credit losses associated with its financial assets carried at amortized cost. For trade and other receivables, the Company applies the simplified approach permitted by IFRS 9, Financial Instruments (IFRS 9), which requires lifetime expected credit losses to be recognized at the time of initial recognition of the receivables.

Inventories

Inventories are valued at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale. Cost is determined using the first-in, first-out method for finished goods and weighted average cost for raw materials.

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and accumulated impairment losses. Cost includes expenditures that are directly attributable to the acquisition of the asset. The carrying amount of a replaced asset is derecognized when replaced. Repairs and maintenance costs are charged to the consolidated statements of loss and comprehensive loss during the year in which they are incurred.

The major categories of property and equipment are depreciated on a straight-line basis as follows:

Furniture and fittings	20 % per year
Research and manufacturing equipment	30 % per year
Computer equipment	45 % per year
Equipment under lease	50 % per year
Leasehold improvements	over the term of the lease

Residual values, methods of depreciation and useful lives of the assets are reviewed annually and adjusted if appropriate.

Goodwill

Goodwill represents the excess fair value of the consideration transferred over the fair value of the underlying net assets in a business combination and is measured at cost less accumulated impairment losses. Goodwill is not amortized but is tested for impairment on an annual basis or more frequently if there are indications the goodwill may be impaired. For the purposes of impairment testing, goodwill is allocated to each of the Company's cash generating units (CGUs) or group of CGUs that are expected to benefit from the synergies of the acquisition. If the recoverable amount of the CGU or group of CGUs is less than the carrying amount, the impairment loss is allocated first to reduce the carrying amount of any goodwill and then to other assets of the CGU or group of CGUs.

Identifiable intangible assets

The Company's intangible assets are stated at cost, less accumulated amortization and are amortized on a straight-line basis in the consolidated statements of loss and comprehensive loss over their estimated useful lives.

The major categories of intangible assets are amortized as follows:

Exclusive licence agreement	20 years
Software	5 years
Brand	5 years
Proprietary technology	5 years

Impairment of non-financial assets

Property and equipment and intangible assets are tested for impairment when events or changes in circumstances indicate the carrying amount may not be recoverable. For the purpose of measuring recoverable amounts, assets are grouped at the lowest levels for which there are separately identifiable cash flow CGUs.

The recoverable amount is the higher of an asset's fair value, less costs of disposal and value in use (which is the present value of the expected future cash flows of the relevant asset or CGU). An impairment loss is recognized as the amount by which the asset's carrying amount exceeds its recoverable amount. The Company evaluates impairment losses for potential reversals when events or circumstances warrant such consideration.

Accounts payable and accrued liabilities

These amounts represent liabilities for goods and services provided to the Company before the end of the financial year, which are unpaid. Accounts payable and accrued liabilities are presented as current liabilities unless payment is not due within 12 months after the reporting period. They are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

Long-term debt

Long-term debt is initially recognized at fair value, net of transaction costs incurred. Long-term debt is subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in the consolidated statements of loss and comprehensive loss over the period of the long-term debt using the effective interest method.

Long-term debt is removed from the consolidated balance sheets when the obligation specified in the contract is discharged, cancelled or expired. The difference between the carrying amount of a financial liability that has been extinguished and the consideration paid is recognized in the consolidated statements of loss and comprehensive loss within finance costs.

Provisions

A provision is recognized when the Company has a legal or constructive obligation as result of a past event, it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. If the effect is material, provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and, where appropriate, the risks specific to the liability.

Leases

At inception of a contract, the Company assesses whether a contract is, or contains, a lease based on whether the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured based on the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received. The assets are depreciated to the earlier of the end of the useful life of the right-of-use asset or the lease term using the straight-line method as this most closely reflects the expected pattern of consumption of the future economic benefits. The lease term includes periods covered by an option to extend if the Company is reasonably certain to exercise that option. Lease terms range from four to ten years for offices. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate.

The lease liability is measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Company's estimate of the amount expected to be payable under a residual value guarantee, or if the Company changes its assessment of whether it will exercise a purchase, extension or termination option.

When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

Revenue

To determine revenue recognition for arrangements the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company derives its revenues primarily from the lease and sale of medical devices and the sale of certain one-time-use devices. Capital equipment consists of one-time revenue for the sale of capital equipment including installation fees. Recurring - non-capital revenue consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. Revenue is recognized when a contractual promise to a customer (performance obligation) has been fulfilled by transferring control over the promised goods or services, generally at the point in time of shipment to or receipt of the products by the customer or when the services are performed. When contracts contain customer acceptance provisions, revenue is recognized on the satisfaction of the specific acceptance criteria.

The amount of revenue to be recognized is based on the consideration the Company expects to receive in exchange for its goods and services. For contracts that contain multiple performance obligations, the Company allocates the consideration to which it expects to be entitled to each performance obligation based on relative standalone selling prices and recognizes the related revenue when or as control of each individual performance obligation is transferred to customers.

Service revenue related to installation and training is recognized over the period in which the services are performed. Service revenue related to extended warranty service is deferred and recognized on a straight-line basis over the extended warranty period covered by the respective customer contract.

Cost of sales

Cost of sales primarily includes the cost of finished goods, depreciation of equipment under lease, inventory provisions, royalties, warranty expense, freight and direct overhead expenses necessary to acquire or manufacture the finished goods.

Income taxes

Income taxes are accounted for using the liability method. Deferred tax assets and liabilities are recognized for the differences between the tax basis and carrying amounts of assets and liabilities, for operating losses and for tax credit carry-forwards. Deferred tax assets are recognized to the extent that it is probable that future taxable income will be available against which temporary differences can be utilized. Deferred tax assets and liabilities are measured using enacted or substantively enacted tax rates and laws.

Share-based compensation

The Company grants share options periodically to certain employees, directors, officers and advisers.

Options currently outstanding vest over four years and have a contractual life of ten years. Each tranche in an award is considered a separate award with its own vesting period and grant date fair value. The fair value of each tranche is measured at the date of grant using the Black-Scholes option pricing model. Compensation expense is recognized over the tranche's vesting period using the graded vesting method by increasing contributed surplus based on the number of awards expected to vest.

The Company has a long-term incentive plan (LTIP). For each Restricted Share Unit (RSU) or Deferred Share Unit (DSU) granted under the long-term incentive plan, the Company recognizes an expense equal to the market value of a Profound common share at the date of grant based on the number of RSUs and DSUs expected to vest, recognized over the term of the vesting period, with a corresponding credit to contributed surplus for share-based compensation anticipated to be equity settled or a corresponding credit to a liability for those anticipated to be cash settled. Share-based compensation expense is adjusted for subsequent changes in management's estimate of the number of RSUs or DSUs that are expected to vest, for RSUs or DSUs anticipated to be cash settled and changes in the market value of Profound common shares. The effect of these changes is recognized in the period of the change. Vested RSUs and DSUs are settled either in Profound common shares or in cash or a combination thereof at the discretion of the Company.

Research and development costs

Research costs are charged to expense as incurred. Development costs are capitalized and amortized when the criteria for capitalization are met, otherwise they are expensed as incurred. No development costs have been capitalized to date.

Clinical trial expenses result from obligations under contracts with vendors, consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company. The appropriate level of clinical trial expenses is reflected in the Company's consolidated financial statements by matching period expenses with period services and efforts expended. These expenses are recorded according to the progress of the clinical trial as measured by patient progression and the timing of various aspects of the clinical trial. Clinical trial accrual estimates are determined through discussions with internal clinical personnel and outside service providers as to the progress or state of completion of clinical trials, or the services completed. Service provider status is then compared to the contractually obligated fees to be paid for such services. During the course of a clinical trial, the Company may adjust the rate of clinical expense recognized if actual results differ from management's estimates.

Government grants

The Company recognizes government grants when there is reasonable assurance that the Company will comply with the conditions of the grant and the grant will be received. Government grants receivable are recorded in accounts receivable on the consolidated statements of financial position. The Company recognizes government grants in the consolidated statements of loss and comprehensive loss in the same period as the expenses for which the grant is intended to compensate and nets the amount off the related expenses. In cases where a government grant becomes receivable as compensation for expenses already incurred in prior periods, the grant is recognized in profit or loss in the period in which it becomes receivable.

Loss per share

Basic loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the year. Diluted loss per share is calculated by dividing the applicable net loss by the sum of the weighted average number of shares outstanding during the year and all additional common shares that would have been outstanding if potentially dilutive common shares had been issued during the year. The computation of diluted loss per share is equal to the basic loss per share due to the anti-dilutive effect of the share options, RSUs, DSUs and warrants.

COVID-19

The COVID-19 outbreak has been declared a pandemic by the World Health Organization. COVID-19 is altering business and consumer activity in affected areas and beyond. The global response to the COVID-19 pandemic has resulted in, among other things, border closures, severe travel restrictions, the temporary shut-down of non-essential services and extreme fluctuations in financial and commodity markets. Additional measures may be implemented by one or more governments in jurisdictions where the Company operates. These measures have caused material disruption to businesses globally, resulting in an economic slowdown. The extent to which COVID-19 and any other pandemic or public health crisis impacts the Company's business, affairs, operations, financial condition, liquidity, availability of credit and results of operations will depend on future developments that are highly uncertain and cannot be predicted with any meaningful precision, including new information which may emerge concerning the severity of the COVID-19 virus and the actions required to contain the COVID-19 virus or remedy its impact, among others.

Further, from an operational perspective, the Company's employees, direct sales and marketing teams and distribution partners, as well as the workforce of vendors, services providers and counterparties with which the Company does business, may also be adversely affected by the COVID-19 pandemic or efforts to mitigate the pandemic, including government-mandated shutdowns, requests or orders for employees to work remotely, and other physical distancing measures, which could result in an adverse impact on the Company' ability to conduct its businesses, including its ability to cultivate adoption of the TULSA-PRO® technology, support clinical trials, support clinical customers with the TULSA-PRO ® procedures and increase the utilization of the systems and one-time-use devices.

To date, the economic downturn and uncertainty caused by the COVID-19 pandemic and global measures undertaken to contain its spread have affected all of the Company's operations to some extent and, in particular, have caused volatility in demand for the TULSA-PRO® and SONALLEVE® systems and the one-time-use devices related thereto. This has resulted in a reduction in anticipated sales and led to delays in the Company's expectations regarding the rate at which agreements for new system user sites will be entered into and when user sites will become operational for the initiation of patient treatments. Despite the COVID-19 pandemic, patient treatments are continuing and Profound continues to identify potential new system user sites. The Company continues to evaluate the current and potential impact of the COVID-19 pandemic on its business, affairs, operations, financial condition, liquidity, availability of credit and results of operations.

The financial impacts from COVID-19 during the year has affected Profound's ability to collect payments due to continuous lockdowns and hospital restrictions, which have impeded our efforts to install our systems and has delayed corresponding collections. Profound continues to work with local authorities and team members located within these countries to help expedite the process.

3 Critical accounting estimates and judgments

Critical accounting estimates

The Company makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed as follows:

- Impairment of non-financial assets

  The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

- Trade and other receivables

The key judgements and estimates used in determining the amortized cost for trade and other receivables are the estimated collection period and the discount rate applied to the cash flow projections (note 4).

4 Trade and other receivables

The trade and other receivables balance comprises the following:

	2021 $	2020 $
Trade receivables	4,592	6,446
Tax receivables	407	774
Other receivables	35	211
Total trade and other receivables	5,034	7,431
Less: Current portion	1,412	7,431
Long-term portion	3,622	—

Trade receivables past due represents amounts not collected beyond the customer's contractual terms. The Company applies the simplified approach to provide for expected credit losses prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. At December 31, 2021 there were no trade receivables that were past due (2020 - $695 of trade receivables that were past due but still collectible).

Management continually reviews the future cash flows used in the calculation of the amortized cost of its trade and other receivables. Due to the ongoing COVID-19 pandemic and access to customer locations, certain trade and other receivables are expected to have a longer repayment term due to the payment term being based on installation of the device. The revised future cash flows have been used to calculate amortized cost. The key assumptions and estimates used in determining the revised amortized cost are based on a two year collection period and a discount rate of 6%, both of which required the application of significant judgement. The collection period and the significant judgement applied does not impact the credit risk of the associated trade and other receivables. The Company recognized $448 interest expense for the year ended December 31, 2021 (2020 – $nil) as a result of this adjustment. Those trade and other receivables that are anticipated to be collected after one year are classified as non-current.

5 Inventory

	2021 $	2020 $
Finished goods	5,114	3,573
Raw materials	2,306	1,774
Inventory provision	(7)	(16)
Total inventory	7,413	5,331

During the year ended December 31, 2021, $3,547 (2020 - $3,610) of inventory was recognized in cost of sales. The Company decreased its inventory provision by $9 during the year ended December 31, 2021 (2020 – $2). There were no other inventory writedowns charged to cost of sales during the year ended December 31, 2021.

6 Property and equipment

Property and equipment consist of the following:

	Furniture and fittings $	Research and manufacturing equipment $	Leasehold improvements $	Equipment under lease $	Total $
Year ended December 31, 2020					
Opening net book value	45	122	360	—	527
Additions	—	—	—	633	633
Foreign exchange	1	14	12	24	51
Depreciation	(34)	(136)	(59)	(123)	(352)
Closing net book value	12	—	313	534	859
At December 31, 2020					
Cost	127	1,068	553	633	2,381
Accumulated depreciation	(115)	(1,068)	(240)	(99)	(1,522)
Net book value	12	—	313	534	859
Year ended December 31, 2021					
Opening net book value	12	—	313	534	859
Additions	—	—	32	408	440
Foreign exchange	(2)	—	1	8	7
Depreciation	(10)	—	(60)	(448)	(518)
Closing net book value	—	—	286	502	788
At December 31, 2021					
Cost	127	1,068	578	1,077	2,850
Accumulated depreciation	(127)	(1,068)	(292)	(575)	(2,062)
Net book value	—	—	286	502	788

7 Intangible assets

Intangible assets consist of the following:

	Exclusive licence agreement $	Software $	Proprietary technology $	Brand $	Total $
Year ended December 31, 2020					
Opening net book value	205	67	1,785	352	2,409
Additions	—	350	—	—	350
Foreign exchange	2	4	12	2	20
Amortization	(21)	(59)	(669)	(132)	(881)
Closing net book value	186	362	1,128	222	1,898
As at December 31, 2020					
Cost	231	421	3,456	681	4,789
Accumulated amortization	(45)	(59)	(2,328)	(459)	(2,891)
Net book value	186	362	1,128	222	1,898

	Exclusive licence agreement $	Software $	Proprietary technology $	Brand $	Total $
Year ended December 31, 2021					
Opening net book value	186	362	1,128	222	1,898
Additions	—	561	—	—	561
Foreign exchange	1	(5)	7	2	5
Amortization	(22)	(148)	(718)	(141)	(1,029)
Closing net book value	165	770	417	83	1,435
As at December 31, 2021					
Cost	231	978	3,456	681	5,346
Accumulated amortization	(66)	(208)	(3,039)	(598)	(3,911)
Net book value	165	770	417	83	1,435

The Company has a licence agreement (the licence) with Sunnybrook Health Sciences Centre (Sunnybrook), pursuant to which Sunnybrook licenses to the Company certain intellectual property. Pursuant to the licence, the Company has exclusively licenced-in rights that enable the Company to use Sunnybrook's technology for MRI-guided trans-urethral ultrasound therapy. Under the licence, the Company is subject to various obligations, including a milestone payment of C$250,000, which was paid on August 16, 2019 upon FDA approval. In addition, the Company has a further option to acquire rights to improvements to the relevant technology and intellectual property. If the Company fails to comply with any of its obligations or otherwise breaches this agreement, Sunnybrook may have the right to terminate the licence.

In accordance with the Company's accounting policy, the carrying value of goodwill is assessed annually as well as assessed for impairment triggers at each reporting date to determine whether there exists any indicators of impairment. When there is an indicator of impairment of non-current assets within a CGU or group of CGUs containing goodwill, the Company tests the non-current assets for impairment first and recognizes any impairment loss on goodwill before applying any remaining impairment loss against the non-current assets within the CGU.

The Company completed its annual goodwill impairment testing on the goodwill related to the Sonalleve MR-HIFU CGU, which comprises all of the goodwill of the Company, on December 31, 2021. The recoverable amount of the Sonalleve MR-HIFU CGU was calculated using fair value less costs of disposal (FVLCD).

The calculation of the recoverable amount of the Sonalleve MR-HIFU CGU was determined using discounted cash flow projections based on financial forecasts approved by management covering a four-year period (Level 3 of the fair value hierarchy) and a terminal growth assumption of 4%. The key assumptions and estimates used in determining the FVLCD are related to revenue and EBITDA assumptions, which are based on the financial forecast and assumed growth rates and the discount rate of 16% applied to the cash flow projections. As a result of the impairment testing performed, it was determined that the recoverable amount of the Sonalleve MR-HIFU CGU exceeded the carrying value of $3,464 and no impairment writedown was required.

8 Right-of-use assets

	Leased premises $
Year ended December 31, 2020	
Opening net book value	1,693
Foreign exchange	36
Depreciation	(305)
Closing net book value	1,424
As at December 31, 2020	
Cost	1,918
Accumulated depreciation	(494)
Net book value	1,424
Year ended December 31, 2021	
Opening net book value	1,424
Addition	18
Foreign exchange	6
Depreciation	(332)
Closing net book value	1,116
As at December 31, 2021	
Cost	1,918
Accumulated depreciation	(802)
Net book value	1,116

The Company leases office premises in Mississauga, Canada, China, Beijing and Vantaa, Finland. These lease agreements are typically entered into for three to ten-year periods.

9 Long-term debt

On July 30, 2018, the Company signed a term loan agreement with CIBC Innovation Banking (CIBC) to provide a secured loan for total gross proceeds of C$12,500 maturing on July 29, 2022 with an interest rate based on prime plus 2.5%. All obligations of the Company under the term loan agreement were guaranteed by current and future subsidiaries of the Company and included

security of first priority interests in the assets of the Company and its subsidiaries. On February 4, 2020, the full outstanding amount of the CIBC loan at that date, plus accrued interest, was repaid for a total payment of $9,317.

	2021 $	2020 $
Balance - Beginning of period	—	9,135
Interest and accretion expense	—	472
Foreign exchange	—	(290)
Repayment	—	(9,317)
Balance - End of period	—	—

In connection with this term loan agreement on July 31, 2018, the Company also issued 32,171 common share purchase warrants to CIBC, with each warrant entitling the holder to acquire one common share at a price of C$ 9.70 per common share until the date that is 60 months from the closing of the term loan agreement, with a cashless exercise feature (note 12). The cashless exercise feature causes the conversion ratio to be variable and the warrants are therefore classified as a financial liability. Gains and losses on the warrants are recorded within finance costs on the consolidated statements of loss and comprehensive loss. A pricing model with observable market based inputs was used to estimate the fair value of the warrants issued. The estimated fair value of the warrants as at December 31, 2021 and December 31, 2021 was $161 and $450, respectively. The variables used to determine the fair values are as follows:

	2021	2020
Share price	C$14.26	C$26.19
Volatility	61 %	63 %
Expected life of warrants	1.6 years	2.6 years
Risk free interest rate	0.94%	0.20%
Dividend yield	—	—

10 Other liabilities

	Contingent consideration $
As at January 1, 2020	221
Amounts paid	(212)
Change in fair value	90
As at December 31, 2020	99
Amounts paid	(99)
As at December 31, 2021	—

Contingent consideration

The final payment in relation to the contingent consideration was made during the period and no further amounts are owing.

On July 31, 2017, the Company entered into an Asset and Share Purchase Agreement (the agreement) to acquire all of the issued and outstanding shares and certain assets of Royal Philips' (Philips) Sonalleve MR-HIFU business (Sonalleve). The agreement includes certain contingent consideration payments payable monthly in euro tied to revenue levels of the Sonalleve business summarized as follows:

- 5% of revenue between the date of acquisition and December 31, 2017;
- 6% of revenue during the year ending December 31, 2018;

- 7% of revenue during the years ending December 31, 2019 and 2020; and
- if total revenues are in excess of a defined amount from the date of acquisition to December 31, 2020, then the Company will be required to pay 7% of revenue from the date of acquisition to December 31, 2019.

11 Lease liabilities

	$
As at January 1, 2020	1,836
Repayments	(289)
Foreign exchange	58
Interest and accretion expense	71
As at December 31, 2020	1,676
Repayments	(386)
Foreign exchange	2
Addition	18
Interest and accretion expense	67
As at December 31, 2021	1,377
Less: Current portion	250
Long-term portion	1,127

12 Share capital

Common shares

The Company is authorized to issue an unlimited number of common shares.
Issued and outstanding (with no par value)

	2021 $	2020 $
20,776,217 (2020 – 20,208,948) common shares	219,579	211,527

On July 21, 2020, the Company closed an offering, resulting in the issuance of 3,172,414 common shares at a price of $14.50, for gross proceeds of $46,000 ($42,721, net of transaction costs).

On January 27, 2020, the Company closed an offering, resulting in the issuance of 3,392,500 common shares at a price of $11.65, for gross proceeds of $39,523 ($36,373, net of transaction costs).

Warrants

A summary of warrants outstanding is shown below:

	Number of warrants	Weighted average exercise price C$	Weighted average remaining contractual life (years)
Balance - January 1, 2020	2,779,898	14.20	2.49
Granted	(1,556,154)	14.08	1.82
Balance - December 31, 2020	1,223,744	14.35	1.68
Expired	(13,600)	15.50	—
Exercised	(485,161)	15.33	0.32
Balance - December 31, 2021	724,983	13.81	1.23

13 Share-based payments

Share options

Effective May 20, 2020, the Company adopted amendments to the share option plan (the Share Option Plan). The maximum number of common shares reserved for issuance under this plan is 2,700,908 common shares or such other number as may be approved by the holders of the voting shares of the Company. As at December 31, 2021, 2,092,596 (2020 – 1,522,362)options are outstanding. Each option granted allows the holder to purchase one common share, at an exercise price not less than the lesser of the closing trading price of the common shares on the TSX (or other exchange where the common shares are listed), on the date a share option is granted and the volume-weighted average price of the common shares for the five trading days immediately preceding the date the share option is granted. Share options granted under the Share Option Plan generally have a maximum term of ten years and vest over a period of up to four years.

A summary of the share option changes during the period presented and the total number of share options outstanding as at those dates are set forth below:

	Number of options	Weighted average exercise price C$
Balance - January 1, 2020	1,109,943	10.51
Granted	687,255	18.46
Exercised	(235,123)	10.42
Forfeited/expired	(39,713)	12.80
Balance - December 31, 2020	1,522,362	14.05
Granted	698,035	22.21
Exercised	(79,208)	9.72
Forfeited/expired	(48,593)	15.46
Balance - December 31, 2021	2,092,596	16.90

The Company estimated the fair value of the share options granted during the period using the Black-Scholes option pricing model with the weighted average assumptions below. Due to the absence of Company-specific volatility rates for the expected life of the share options, the Company chose comparable companies in the medical device industry.

	November 15, 2021	December 30, 2021
Exercise price	C$ 14.96	C$ 14.90
Expected volatility	84 %	84 %
Expected life of options	6 years	6 years
Risk-free interest rate	1.54 %	1.69 %
Dividend yield	—	—
Number of share options issued	24,500	105,071

	March 11, 2021	May 21, 2021	June 17, 2021
Exercise price	C$ 28.16	C$ 22.08	C$ 23.14
Expected volatility	84 %	85 %	85 %
Expected life of options	6 years	6 years	6 years
Risk-free interest rate	1.09 %	1.34 %	1.25 %
Dividend yield	—	—	—
Number of share options issued	12,000	555,464	1,000

	November 16, 2020	December 15, 2020	December 22, 2020
Exercise price	C$ 24.31	C$ 23.02	C$ 25.01
Expected volatility	85 %	85 %	85 %
Expected life of options	6 years	6 years	6 years
Risk-free interest rate	0.46 %	0.45 %	0.48 %
Dividend yield	—	—	—
Number of share options issued	84,900	10,000	11,500

	March 12, 2020	May 20, 2020	June 8, 2020	August 17, 2020
Exercise price	C$ 15.15	C$ 17.44	C$ 16.87	C$ 20.39
Expected volatility	82 %	84 %	84 %	83 %
Expected life of options	6 years	6 years	6 years	6 years
Risk-free interest rate	0.60 %	0.46 %	0.58 %	0.48 %
Dividend yield	—	—	—	—
Number of share options issued	16,550	481,405	80,000	2,900

The following table summarizes information about the share options outstanding as at December 31, 2021:

Exercise price C$	Number of options outstanding	Weighted average remaining contractual life (years)	Number of options exercisable
2.01 – 4.00	6,300	0.78	6,300
8.01 – 10.00	452,310	6.47	274,745
10.01 – 12.00	137,890	6.42	106,903
12.01 – 14.00	8,300	4.61	8,300
14.01 – 16.00	289,827	7.28	152,353
16.01 – 18.00	533,155	8.42	209,363
20.01 – 22.00	1,400	8.63	464
22.01 – 24.00	561,514	9.27	2,500
24.01 – 26.00	90,900	8.93	24,485
28.01 – 30.00	11,000	9.20	—
	2,092,596	7.95	785,413

Compensation expense related to share options for the year ended December 31, 2021 was $5,891 (2020 - $3,007).

Long-term incentive plan

Effective May 20, 2020, the Company adopted the long term incentive plan (the “LTIP”). The LTIP is an incentive-based equity compensation plan that provides for the grant of restricted share units (the “RSUs”) and deferred share units (the “DSUs”, together with the RSUs, the “Units”). The Company may grant Units to officers, directors, employees or consultants of the Company. Each Unit represents the right to receive one common share in accordance with the terms of the LTIP. The number of Units granted at any particular time will be calculated by dividing the dollar amount of such grant by the market value of a common share on the applicable grant date, which is equal to the volume weighted average trading price of all common shares traded on the TSX (or other exchange where the Common Shares are listed) for the five trading days immediately preceding such date. RSUs granted under the LTIP vest over a period of up to three years and DSUs vest on the date on which the participant ceases to be a director or employee of the Company.

Share-based compensation expense related to the LTIP for the year ended December 31, 2021 was $1,314 (2020 - $11). During the year ended December 31, 2021 the Company authorized for issuance under the LTIP a total of 241,500 RSUs with market prices between C$14.90 and C$23.14 with vesting terms over 3 years.

A summary of the RSUs changes during the period are set forth below:

	Number of RSUs	Weighted average remaining contractual life (years)
Balance - January 1, 2020	—	—
Granted	8,917	3.00
Forfeited	(200)	2.65
Balance - December 31, 2020	8,717	2.39
Granted	241,500	3.00
Vested	(2,900)	—
Forfeited	(15,000)	2.39
Balance - December 31, 2021	232,317	2.45

14 Revenue

	Year ended December 31,					
	2021 $			2020 $		
	Contracts with customers	Leasing	Total	Contracts with customers	Leasing	Total
Capital equipment	3,150	—	3,150	4,581	—	4,581
Recurring - non-capital	3,293	430	3,723	2,409	314	2,723
	6,443	430	6,873	6,990	314	7,304

15 Nature of expenses

	2021 $	2020 $
Production and manufacturing costs	2,738	3,063
Salaries and benefits	12,835	9,917
Consulting fees	4,076	3,395
Research and development expenses	3,433	2,318
Sales and marketing expenses	1,142	574
Amortization and depreciation	1,879	1,538
Share-based compensation	7,205	3,018
Rent	250	231
Software/hardware	619	424
Insurance	1,397	1,278
Other expenses	1,590	411
	37,164	26,167

Salaries and benefits are net of government assistance of $nil for the year ended December 31, 2021 (2020 - $376).

Research and development expenses are net of reimbursements of $nil for the year ended December 31, 2021 (2020 - $316).

16 Net finance costs

	2021 $	2020 $
Change in fair value of derivative financial instrument	(293)	237
Lease liability interest expense (note 11)	67	71
Interest income	(205)	(692)
Change in amortized cost of trade and other receivables (note 4)	448	—
CIBC loan	—	472
Change in fair value of contingent consideration (note 10)	—	90
Foreign exchange loss	286	2,536
	303	2,714

17 Income taxes

Income tax expense differs from the tax recovery amount that would be obtained by applying the statutory income tax rate to the respective year's loss before income taxes as follows:

	2021 $	2020 $
Loss before income taxes	30,594	21,577
Recovery based on combined federal and provincial statutory rate of 25.48% (2020 - 26.1%)	(7,795)	(5,632)
Permanent differences	1,608	(638)
Change in deferred tax assets not recognized	6,287	6,331
Effect of tax rates in foreign jurisdictions	5	(16)
Net income tax expense	105	45

Deferred tax assets are recognized for tax loss carry-forwards and unused tax credits to the extent that the realization of the related tax benefit through future taxable profits is probable. The Company has not recognized deferred tax assets that can be carried forward against future taxable income.

Permanent differences are primarily comprised of non-refundable tax credits and deductible finance fees not recorded in the consolidated statements of loss and comprehensive loss, offset by non-deductible share-based compensation and accretion expense.

The Company has non-capital loss carry-forwards of approximately $98,454 as at December 31, 2021 that expire in varying amounts from 2028 to 2041.

The Company has SR&ED expenditures of approximately $14,435 as at December 31, 2021, which can be carried forward indefinitely to reduce future years' taxable income.

The Company has approximately $2,992 of federal and provincial tax credits that are available to be applied against federal and provincial taxes otherwise payable in future years and that expire in varying amounts from 2028 to 2041.

18 Loss per share

The following table shows the calculation of basic and diluted loss per share:

	2021	2020
Net loss for the year	$ 30,699	$ 21,622
Weighted average number of common shares	20,464,168	17,294,653
Basic and diluted loss per share	$ 1.50	$ 1.25

Of the 2,092,596 (2020 – 1,522,362) share options, 232,317 (2020 – 8,717) RSUs and 724,983 (2020 – 1,223,744) warrants not included in the calculation of diluted loss per share for the period ended December 31, 2021, 1,510,396 (2020 – 1,678,431) were exercisable.

19 Financial assets and liabilities

Classification of financial instruments

	2021		
	Fair value through profit or loss $	Financial assets at amortized cost $	Financial liabilities at amortized cost $
Cash	—	67,152	—
Trade and other receivables	—	5,034	—
Accounts payable and accrued liabilities	—	—	3,180
Lease liabilities	—	—	1,377
Derivative financial instrument	161	—	—
	161	72,186	4,557

	2020		
	Fair value through profit or loss $	Financial assets at amortized cost $	Financial liabilities at amortized cost $
Cash	—	83,913	—
Trade and other receivables	—	7,431	—
Accounts payable and accrued liabilities	—	—	3,382
Other liabilities	99	—	—
Lease liabilities	—	—	1,676
Derivative financial instrument	450	—	—
	549	91,344	5,058

Credit risk

Credit risk is the risk of a financial loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligation. The Company is exposed to credit risk on its cash and trade and other receivable balances. The Company's cash management policies include ensuring cash is deposited in Canadian chartered banks.

The Company applies the IFRS 9 simplified approach to measuring expected credit losses, which uses a lifetime expected loss allowance for all trade and other receivables. To measure the expected credit losses, trade and other receivables are grouped based on shared credit risk characteristics and the days past due. On that basis, the loss allowance as at December 31, 2021 and 2020 is nominal as the Company only transacts with hospitals and private clinics and has not incurred a sustained trend of any credit losses since revenue began.

Trade and other receivables are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, failure to make contractual payments for a period of greater than 120 days past due.

Market risk

Market risk is the risk the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices, including interest rate risk and foreign currency risk.

- Interest rate price risk

  Interest rate price risk is the risk the cash flows of a financial instrument will fluctuate due to changes in market interest rates. The Company is not exposed to any significant interest rate price risk.

- Foreign currency risk

  Foreign currency risk occurs as a result of foreign exchange rate fluctuations between the time a transaction is recorded and the time it is settled.

  The Company purchases goods and services denominated in foreign currencies and, accordingly, is subject to foreign currency risk, primarily the US dollar and Euro. Foreign currency risk arises from future commercial transactions and recognized assets and liabilities denominated in a currency that is not the functional currency. The risk is measured through a forecast of highly probable US dollar and Euro expenditures. The Company's financial instruments denominated in foreign currencies are shown below in Canadian dollars.

					2021
	US dollars $	Euro $	Canadian dollars $	Chinese renminbi $	Total $
Cash	47,765	1,349	17,984	54	67,152
Trade and other receivables	4,310	421	303	—	5,034
Accounts payable and accrued liabilities	(372)	(1,030)	(1,759)	(19)	(3,180)
Lease liabilities	—	—	(1,368)	(9)	(1,377)

				2020
	US dollars $	Euro $	Canadian dollars $	Total $
Cash	61,644	1,899	20,370	83,913
Trade and other receivables	5,002	2,197	232	7,431
Accounts payable and accrued liabilities	(734)	(1,700)	(948)	(3,382)
Other liabilities	—	(99)	—	(99)
Lease liabilities	—	(95)	(1,581)	(1,676)

As at December 31, 2021, if foreign exchange rates had been 5% higher, with all other variables held constant, loss before income taxes would have been $2,623 (2020 – $3,406) higher, mainly as a result of the translation of foreign currency denominated cash, trade and other receivables, accounts payable and accrued liabilities, other liabilities and lease liabilities.

The Company does not use derivatives to reduce exposure to foreign currency risk.

Liquidity risk

Liquidity risk is the risk the Company may encounter difficulties in meeting its financial liability obligations as they come due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis.

The Company controls liquidity risk through management of working capital, cash flows and the availability and sourcing of financing. The Company's ability to accomplish all of its future strategic plans is dependent on obtaining additional financing or executing other strategic options; however, there is no assurance the Company will achieve these objectives.

The following table summarizes the Company's significant contractual, undiscounted cash flows related to its financial liabilities.

					2021
	Carrying amount $	Future cash flows $	Less than 1 year $	Between 1 year and 5 years $	Greater than 5 years $
Accounts payable and accrued liabilities	3,180	3,180	3,180	—	—
Lease liability	1,377	1,575	321	1,254	—
	4,557	4,755	3,501	1,254	—

					2020
	Carrying amount $	Future cash flows $	Less than 1 year $	Between 1 year and 5 years $	Greater than 5 years $
Accounts payable and accrued liabilities	3,382	3,382	3,382	—	—
Lease liability	1,676	1,958	398	1,240	320
Other liabilities	99	99	99	—	—
	5,157	5,439	3,879	1,240	320

Fair value

The fair values of cash, current trade and other receivables, accounts payable and accrued liabilities and lease liabilities approximate their carrying values, due to their relatively short periods to maturity.

For the non-current trade and other receivables, the fair value is also not significantly different from the carrying amount.

The fair value of the Company's derivative financial instrument is determined based on the valuation techniques described in note 9 and is considered level 2 in the fair value hierarchy.

20 Related party transactions

Key management includes the Company's directors and senior management team. The remuneration of directors and the senior management team was as follows:

	2021 $	2020 $
Salaries and employee benefits	1,989	1,418
Directors' fees	233	99
Share-based compensation	3,182	1,594
	5,404	3,111

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

21 Commitments and contingencies

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

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

22 Capital management

The Company's capital management objectives are to safeguard its ability to continue as a going concern and to provide returns for shareholders and benefits for other stakeholders by ensuring it has sufficient cash resources to fund its research and development activities, to pursue its commercialization efforts and to maintain its ongoing operations. The Company includes its share capital, deficit and long-term debt in the definition of capital.

A summary of the Company's capital structure is as follows:

	2021 $	2020 $
Common shares	219,579	211,527
Deficit	(160,693)	(129,994)
	58,886	81,533

23 Segment reporting

The Company's operations are categorized into one industry segment, which is medical technology focused on magnetic resonance guided ablation procedures for the treatments to ablate the prostate gland, uterine fibroids, osteoid osteoma and nerves for palliative pain relief for patients with metastatic bone disease. The Company is managed geographically in Canada, Germany, USA, China and Finland.

For the year ended December 31, 2021:

	Canada $	USA $	Germany $	Total $
Revenue				
Capital equipment	1,724	—	1,426	3,150
Recurring - non-capital	353	2,090	1,280	3,723
	2,077	2,090	2,706	6,873

For the year ended December 31, 2020:

	Canada $	Germany $	Total $
Revenue			
Capital equipment	4,031	550	4,581
Recurring - non-capital	2,454	269	2,723
	6,485	819	7,304

Other financial information by segment as at December 31, 2021:

	Canada $	USA $	Germany $	China $	Finland $	Total $
Total assets	81,529	2,068	1,445	81	1,652	86,775
Goodwill and intangible assets	4,124	—	—	—	—	4,124
Property and equipment	490	298	—	—	—	788
Right-of-use assets	1,106	—	—	10	—	1,116
Amortization of intangible assets	1,029	—	—	—	—	1,029
Depreciation of property and equipment	408	110	—	—	—	518
Depreciation of right-of-use assets	234	—	—	8	90	332

Other financial information by segment as at December 31, 2020:

	Canada $	USA $	Germany $	Finland $	Total $
Total assets	98,890	456	1,682	3,573	104,601
Goodwill and intangible assets	4,576	—	—	—	4,576
Property and equipment	859	—	—	—	859
Right-of-use assets	1,325	—	—	99	1,424
Amortization of intangible assets	881	—	—	—	881
Depreciation of property and equipment	236	—	—	116	352
Depreciation of right-of-use assets	212	—	—	93	305

Exhibit 99.4

CERTIFICATION

I, Arun Menawat, certify that:

1. I have reviewed this annual report on Form 40-F of Profound Medical Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: March 3, 2022

/s/Arun Menawat
Arun Menawat
Chief Executive Officer

CERTIFICATION

I, Rashed Dewan, certify that:

1. I have reviewed this annual report on Form 40-F of Profound Medical Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the issuer and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: March 3, 2022

/s/ Rashed Dewan
Rashed Dewan
Chief Financial Officer

Exhibit 99.5

Certification

pursuant to
18 U.S.C. Section 1350
as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 40-F of Profound Medical Corp. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies pursuant to 18 U.S.C.§ 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his respective knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 3, 2022

/s/Arun Menawat
Arun Menawat
Chief Executive Officer

Date: March 3, 2022

/s/ Rashed Dewan
Rashed Dewan
Chief Financial Officer

This certificate has not been, and shall not be deemed to be, "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934.

Exhibit 99.6

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Annual Report on Form 40-F for the year ended December 31, 2021 and in the Registration Statements on Form S-8 (333-234574 and 333-238528) of our report dated March 3, 2022 relating to the consolidated financial statements, which appears in this Form 40-F.

/s/ PricewaterhouseCoopers LLP

Chartered Professional Accountants, Licensed Public Accountants

Oakville, Ontario, Canada
March 3, 2022

PricewaterhouseCoopers LLP
PwC Centre, 354 Davis Road, Suite 600, Oakville, Ontario, Canada L6J 0C5
T: +1 905 815 6300, F: +1 905 815 6499, www.pwc.com/ca

"PwC" refers to PricewaterhouseCoopers LLP, an Ontario limited liability partnership.