**PROFOUND MEDICAL CORP.**

# MANAGEMENT'S DISCUSSION AND ANALYSIS

## SEPTEMBER 30, 2024

## PRESENTED IN US DOLLARS (000s)

**Notice to Reader**

Profound Medical Corp. (the "Company", "Profound" or the "Group") now prepares its financial statements filed with the Canadian Securities Administrators and with the Securities and Exchange Commission in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). As required pursuant to section 4.3(4) of National Instrument 51-102 - Continuous Disclosure Obligations, the Company must restate its condensed consolidated interim financial statements for the three and nine months ended September 30, 2024 and 2023 in accordance with U.S. GAAP (the "Interim Financial Statements"), such Interim Financial Statements having previously been prepared in accordance with the International Financial Reporting Standards as issued by the International Accounting Standards Board. This restated management's discussion and analysis (this "MD&A") for the three and nine months ended September 30, 2024 and 2023 is current as of September 30, 2024 and provides financial information for the three and nine months ended September 30, 2024 and 2023, except that:

- changes were made throughout this MD&A to reflect the fact that the Interim Financial Statements are now prepared in accordance with U.S. GAAP; and

- in conjunction with the Company's transition to U.S. GAAP, the Audit Committee of Profound's Board of Directors identified an error which overstated revenue by $472,000 and resulted in an increase in net loss before tax and net loss attributed to shareholders by $386,000 in the previously reported first quarter of 2024 financial statements under IFRS Accounting Standards. Such financial information has been adjusted in the Interim Financial Statements and corresponding changes were made throughout this MD&A to reflect this correction.

Other than as expressly set forth above, this MD&A does not, and does not purport to, update or restate the information in the original MD&A or reflect any events that occurred after the date of the filing of the original MD&A.

The Company's Interim Financial Statements are available under the Company's profile on SEDAR+ at www.sedarplus.com and on EDGAR at www.sec.gov. Readers are cautioned that this MD&A should be read in conjunction with the Interim Financial Statements, including the related notes thereto.

The following Management's Discussion and Analysis (this "**MD&A**") prepared as of November 7, 2024, as restated on March 7, 2025, to reflect the filing of the restated unaudited interim condensed consolidated financial statements of Profound for the three and nine months ended September 30, 2024 and 2023 (the "**Interim Financial Statements**") described above. Other than as expressly set forth above, this MD&A does not purport to, update or restate the information in the original MD&A or reflect any events that occurred after the date of the filing of the original MD&A. It is supplemental to, and should be read in conjunction with, the Company's Interim Financial Statements and the accompanying notes for the three and nine months ended September 30, 2024 and 2023. The Interim Financial Statements and related notes were prepared in accordance with U.S. generally accepted accounting principles ("**US GAAP**") applicable to the preparation of interim financial statements. 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 US Securities Act and Section 21E of the U.S. Securities Exchange Act of 1934, as amended (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 the commercialization and adoption of our approved products (particularly the TULSA-PRO® system following US 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. ("**Philips**"), 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 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 changes to existing regulatory frameworks;
- our expectations regarding obtaining regulatory approvals;
- 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 ability to manage our working capital and our ongoing ability to satisfy our cash requirements and any future commitments, financial obligations, covenants and contingencies;
- our ability to raise debt and equity capital to fund future product development, pursue regulatory approvals and commercialize our approved products; 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 7, 2024 for the year ended December 31, 2023 (the "**AIF**"), available on SEDAR+ at www.sedarplus.ca and filed as an exhibit to the Company's annual report on Form 40-F, filed on March 7, 2024 (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 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;
- risks related to product liability; 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.

## 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 whole gland ablation pivotal clinical study ("**TACT**"). 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 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 2024 is estimated to reach 299,010 in the United States according to the American Cancer Society and in 2020 there were approximately 475,000 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 approximately 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. On June 2, 2023, Profound Medical announced new Current Procedural Terminology ("**CPT**") Category 1 Codes from the American Medical Association ("**AMA**") for TULSA to treat prostate diseases, which will be effective January 1, 2025. 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 adenomyotic tissue, palliative pain relief associated with bone metastases, treatment of osteoid osteoma, and management of benign desmoid tumors and has also been approved by the regulatory bodies in China and South Korea 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 MRIs.

Profound deploys a recurring revenue business model in the United States to market TULSA-PRO®, charging a one-time payment that includes a 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. 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.

**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 measures 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. The TULSA-PRO in conjunction with its Thermal Boost module, enables surgeons to temporarily increase the ablation target temperature in prostate regions where advanced stage cancer might reside, further increasing their confidence that aggressive cancer cells have been ablated. Profound believes that TULSA-PRO®'s controlled and relatively gentle heating process may result in lower post procedural pain and complications, 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®**

The TULSA-PRO® system is designed to provide precise, flexible and durable ablation of a surgeon defined region of the prostate while actively protecting the urethra and rectum to help preserve the patient's natural functional abilities. To date, over 3,000 global TULSA-PRO® procedures have been performed by more than 100 physicians at over 30 commercial and 20 clinical research sites.

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 its 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 and five years, 7% and 21%, respectively, 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 21% 5-year 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. By five years, the median PSA nadir further reduced to 0.26 ng/ml. PSA reduction was durable over the extended follow-up period, from 0.53 ng/ml at one year to 0.63 ng/ml at five years.

TULSA was associated with a high degree of safety and maintenance of quality-of-life, durable to five years, 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, with these rates remaining stable or further improving to five years. 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

[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
[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; Hatiboglu et al, "Durability of functional outcomes after MRI-guided transurethral ultrasound ablation of the prostate," JU Open Plus, 2023.

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 clinical studies showing improvements in IPSS comparable to modern minimally invasive surgical therapies[5]. A retrospective analysis of a sub-group of nine men from the Phase I 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 Phase I/II study of TULSA-PRO® for BPH has been conducted with early outcomes published in 2022[6]. All measures of urinary function and quality of life improved during the initial twelve-month follow up among the first ten patients treated, while no adverse effects were seen on sexual and bowel functions: average IPSS decreased from 17.5 to 4.0, IPSS QoL decreased from 4.0 to 0.5, and Qmax increased from 12.4 ml/s to 21.8 ml/s, among several other improved urinary measures. A single serious adverse event had occurred, abscess of the epididymis requiring drainage at two weeks post therapy. Enrollment of this study has been increased to 30 patients.

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 Phase I/II study of TULSA-PRO® with early outcomes published in 2020[7]. The report includes the first eleven patients from a 40-patient study, who were successfully treated, and discharged on the first postoperative day, with median catheterization time of seven days. Median PSA decreased from 7.6 ng/ml at baseline to a nadir of 0.2 ng/ml and was 0.23 ng/ml at 12 months. At 12 months, 10/11 patients were free of any PCa in the targeted ablation zone, confirmed with biopsy and imaging (MRI and PSMA-PET), and had low and stable PSA. 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[8]. 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

[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] Viitala et al, "Magnetic resonance imaging-guided transurethral ultrasound ablation for benign prostatic hyperplasia: 12-month clinical outcomes of a phase I study," BJU Int, 2022.

[7] Anttinen et al, "Salvage Magnetic Resonance Imaging–guided Transurethral Ultrasound Ablation for Localized Radiorecurrent Prostate Cancer: 12-Month Functional and Oncological Results," European Urology Open Science, 2020.

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

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.

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 takes place primarily in the United States, with an additional two sites in Canada and one in Europe. Of those, eighteen 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 the CAPTAIN trial is to demonstrate that the efficacy of the TULSA procedure is not inferior to RP, while demonstrating superior quality of life outcomes in patients receiving the TULSA procedure as compared to those patients receiving RP. 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, adenomyotic tissue, palliative pain treatment of bone metastases, osteoid osteoma and management of benign tumors. 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 and by the Ministry of Food and Drug Safety in South Korea. Philips Oy registered Sonalleve® in several Middle East, North African, and South Asian countries. In 2020, Sonalleve® also received HDE from the US 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), National Institutes of Health (Bethesda, MD, USA), St. Luke's Episcopal Hospital (Houston, TX, USA), 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), and Turku University Hospital (Turku, Finland), 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 and/or dosage of medication and increase in 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. A desmoid tumor, also called desmoid fibromatosis or aggressive fibromatosis, is a non-metastasizing but locally aggressive proliferation of myofibroblasts that affects children and adults, with a peak incidence in early adulthood. Traditional management of desmoid tumors includes observation, surgical resection, radiation, and/or chemotherapy. Observation allows assessment of the rate of tumor growth and may be acceptable in small, slow-growing, or asymptomatic lesions. Surgical resection is often a highly morbid procedure and has a high rate of recurrence even with negative margins. Radiotherapy provides somewhat improved local control rates but the morbidity from radiation, including burns, fibrosis, chronic edema, and pathologic fractures, is problematic. In addition, the small but finite risk of a radiation-induced malignancy is particularly troublesome in this young patient population, considering the tumor being treated is benign.

Recently, MR-HIFU has been assessed as a non-invasive therapy of desmoid tumors, showing good clinical success and even complete tumor eradication in some cases with low number and relative mild adverse events, which typically promptly resolve. The Sonalleve® MR-HIFU device offers a novel, non-invasive, MRI-guided method to treat desmoid tumors.

This technology is ideally suited for the treatment of desmoid tumors in a patient population that is generally young, otherwise healthy, and would like to avoid the morbidity of traditional surgical, radiation, and medical therapies for a benign disease. Magnetic resonance imaging provides visualization of critical neurovascular structures and allows sparing of these structures during therapy. While complete ablation of a desmoid tumor may not be possible in all cases because of involvement of these structures, significant reduction in tumor volume is often obtained with a corresponding improvement in pain and functional impairment. As the natural history of the disease often

involves recurrence, the ability to re-treat with MR-HIFU without an upper dose limit is also an advantage. The clinical evidence to date demonstrates that MR-HIFU provides a safe and effective treatment of desmoid tumors.

**Business Update and Sales Strategy**

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 recurring revenue model that includes durable hardware usage, one-time-use devices and Profound's Genius services, which includes necessary 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 nine months ended September 30, 2024, approximately 81%, 11% and 8% of revenues were generated in the United States, EU and Asia, respectively, compared to approximately 69%, 27% and 4% of revenues which were generated in the United States, EU and Asia, respectively for the nine months ended September 30, 2023. Revenue on a quarter over quarter basis is expected to fluctuate given the Company is maintaining a limited European commercial effort and remains primarily focused on the US market.

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 seeking to take 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.

On January 21, 2019, the Company entered into an agreement with Siemens (the "**Siemens Agreement**"). Under 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 has been supplied with additional information to utilize the ExSI interface, which has allowed Profound to interface with GE MRI scanners and GE is helping support the development efforts of Profound to achieve compatibility with its GE MRI scanners which was achieved on March 1, 2022 when the Company signed the first site agreement for a Tulsa-PRO® system interfaced with a GE scanner.

On February 8, 2024, Profound entered into a non-exclusive collaboration with Siemens Healthineers, aimed at laying the groundwork for Profound to begin marketing a complete therapeutics solution, combining its TULSA-PRO® system with the MAGNETOM Free.Max magnetic resonance scanner from Siemens Healthineers, via Profound's own sales force. Profound will continue to market TULSA-PRO® as a stand-alone offering, providing its customers with the flexibility to use the technology with the MR hardware of their choice.

**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 Profound's 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 prostatectomy; (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 radical prostatectomy 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, provides a more favorable side-effect profile, and allows for safe and effective salvage treatment options if required in the future.

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 and total ablation volume. Profound believes that a transurethral (inside out) ablation approach with millimeter accuracy has advantages over HIFU in ablating the whole gland safely, as well as ablating larger prescribed treatment plans for patients with multi-focal disease, BPH, and those who have prostate cancer concurrent with BPH.

*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 public or private 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 and related procedures. The availability of coverage and adequate reimbursement to hospitals and physicians using Profound's products therefore is important to its 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 payors.

On November 4, 2024, it was announced that U.S. Centers for Medicare and Medicaid Services ("**CMS**") has issued its Final Rule establishing, for the first time, a Category 1 CPT code for the TULSA procedure, effective January 1, 2025.

According to the Final Rule, TULSA will have three codes to cover how therapy is delivered depending on if there are one or two physicians involved in the procedure: CPT 51721 TULSA Device Management and CPT 55881 TULSA Treatment, when two physicians are involved in the procedure, and CPT 55882 TULSA Complete Procedure, when performed by a single physician. All three TULSA codes will have a 0-day global period, indicating that the payment associated with the codes will only cover the work performed on the day TULSA is performed. Physicians will thereby bill for any pre- or post-procedure patient visits separately using existing evaluation and management (E/M) codes. This will provide physicians with the most flexibility to assess the appropriate number of visits needed by each patient and enable their safe and fast recovery.

Uniquely for prostate treatment modalities, TULSA codes have been assigned to all three sites of service: Hospital Outpatient ("**HOPD**"), Ambulatory Surgical Center ("**ASC**"), and Private Office/Non-Facility ("**OBL**"). The spectrum of the location of service will ensure TULSA patients can be treated in a number of settings.

For Hospital Payment, the Final Rule has established TULSA CPT 55882 as a Level 7 Urology Ambulatory Payment Classification ("APC") for 2025 of $12,992 (Medicare National Average). For ASCs, the facility payment for CPT 55882 will be $10,728 (Medicare National Average). This represents increases of approximately 41% and 49% for hospitals and ASCs, respectively, over TULSA payments previously set in the Proposed Rule announced in July 2024 and is also 25% higher than the Final Rule for robotic radical proctectomy, a mainstream treatment modality for prostate cancer, and 41% higher than the 2025 payment classification for benign prostatic hyperplasia ("**BPH**") treatments.

The Final Rule for the Physician Fee Schedule has set the total Facility (HOPD or ASC) Relative Value Units ("**RVU**") at 6.47 for CPT 51721 TULSA Device Management and 14.56 RVU for CPT 55881 TULSA Treatment, when 2 physicians are involved in the TULSA procedure. If one physician performs the complete TULSA procedure, the RVU is 17.91 for CPT 55882.

The Proposed Rule for Physician fee schedule for Non-Facility (OBL or Private Office) has set RVU at 16.25 for CPT 51721 TULSA Device Management and 263.05 RVU for CPT 55881 TULSA Treatment, when 2 physicians are involved in the TULSA procedure. If one physician performs the complete TULSA procedure, the RVU is 272.21 for CPT 55882.

As noted above, the TULSA procedure will have a 0-day Global Period, meaning that all post-operative visits are billed separately. This is distinct from all other comparable prostate treatments which are 90-day Global Period and therefore include bundled payments for all post-operative visits performed in the first 90 days. The typical range of post-operative office visits would be approximately 9-11 total RVUs in the first 90-days.

The below tables summarize the proposed rule Codes, RVUs and Facility Dollar Amounts.

Facility Fee Schedule:

| CPT Code | Description | APC 5377: Level 7 Urology-HOPD | APC: ASC |
|---|---|---|---|
| 55882 | TULSA Complete Procedure | $12,992.42[1] | $10,728.00[1] |

[1] Amounts are exact, not in thousands.

Physician Fee Schedule:

| CPT Code | Description | Physician Total RVU | | Typical 90-Day Follow-up | Physician Total RVU with typical 90-day Follow-Up | |
|---|---|---|---|---|---|---|
| | | Facility (HOPD, ASC) | Non-Facility (OBL) | | Facility (HOPD, ASC) | Non-Facility (OBL) |
| 51721 | TULSA Device Management | 6.47 | 16.25 | 9.37 - 11.61 | 15.84 - 18.08 | 25.62 – 27.86 |
| 55881 | TULSA Treatment | 14.56 | 263.05 | n/a | 14.56 | 263.05 |
| 51721 & 55881 Total | Procedure Total (Two Physician) | 21.03 | 279.30 | 9.37 - 11.61 | 30.40 - 32.66 | 288.67 – 290.91 |
| 55882 | TULSA Complete Procedure (One Physician) | 17.91 | 272.21 | 9.37 - 11.61 | 27.28 - 29.52 | 281.58 - 283.82 |

In USD$ (000s)

## HIGHLIGHTS

- On July 11, 2024, Profound announced Category 1 CPT codes proposed CY2025 rule for TULSA to treat prostate diseases.
- On September 16, 2024, Profound announced PRO-Talk Live! Event featuring the present and future of TULSA.
- On October 16, 2024, Profound appointed Tom Tamberrino as Chief Commercial Officer.
- On November 4, 2024, Profound announced TULSA reimbursement raised to Urology APC Level 7 under CMS Outpatient Prospective Payment System final rule for CY2025.
- On November 7, 2024, Profound announced the promotion of Mathieu Burtnyk, PhD, from Chief Operating Officer to President.

## SELECTED FINANCIAL INFORMATION

The following selected financial information as at and for the nine months ended September 30, 2024 and 2023, have been derived from the unaudited interim condensed consolidated financial statements and should be read in conjunction with those unaudited interim condensed consolidated financial statements and related notes.

| | For nine months ended September 30, 2024 | 2023 |
|---|---|---|
| | $ | $ |
| Revenue | 6,504 | 5,190 |
| Operating expenses | 28,792 | 23,131 |
| Other (income) expense | (2,084) | (545) |
| Net loss for the period | 22,869 | 19,416 |
| Basic and diluted loss per share | 0.94 | 0.92 |

| | September 30, 2024 $ | December 31, 2023 $ |
|---|---|---|
| | | |
| Total assets | 41,893 | 43,956 |
| Total non-current financial liabilities | 3,689 | 5,504 |

Revenue has increased for the nine months ended September 30, 2024 due to higher capital and disposable sales compared to the nine months ended September 30, 2023.

Operating expenses increased for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 due to the continued focus of commercialization of the TULSA-PRO® within the US market based on increased selling and distribution expenses attributed to personnel and marketing.

The increase in other (income) expense for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 was primarily the impact of the change in the foreign exchange rates for Profound's foreign currency denominated cash and interest income from cash held in the bank.

The Company reported total assets of $41,893 as at September 30, 2024 compared to $43,956 as at December 31, 2023. The decrease in 2024 was primarily the result of the decrease in inventory and prepaid expenses and deposits which were offset by an increase in cash due the Public Offering and Private Placement for net proceeds of $21,079.

The Company reported total non-current financial liabilities of $3,689 as at September 30, 2024 compared to $5,504 as at December 31, 2023. The increase in the nine month period of 2024 was a result of the higher accruals.

In USD$ (000s)

## RESULTS OF OPERATIONS

| | Three months ended September 30 | | | | Nine months ended September 30 | | | |
|---|---|---|---|---|---|---|---|---|
| | 2024 $ | 2023 $ | Change $ | % | 2024 $ | 2023 $ | Change $ | % |
| Revenue | 2,832 | 1,728 | 1,104 | 64% | 6,504 | 5,190 | 1,314 | 25% |
| Cost of sales | 1,044 | 686 | 358 | 52% | 2,429 | 1,919 | 510 | 27% |
| **Gross profit** | 1,788 | 1,042 | 746 | 72% | 4,075 | 3,271 | 804 | 25% |
| **Operating expenses** | | | | | | | | |
| Research and development | 4,166 | 3,427 | 739 | 22% | 12,316 | 10,446 | 1,870 | 18% |
| Selling, general and administrative | 6,620 | 4,184 | 2,436 | 58% | 16,476 | 12,685 | 3,791 | 30% |
| **Total operating expenses** | 10,786 | 7,611 | 3,175 | 42% | 28,792 | 23,131 | 5,661 | 24% |
| Other (income) expense | 190 | (1,026) | 1,216 | -119% | (2,084) | (545) | (1,539) | 282% |
| **Net loss before income taxes** | 9,188 | 5,543 | 3,645 | 66% | 22,633 | 19,315 | 3,318 | 17% |
| Income tax expense | 177 | 18 | 159 | 883% | 236 | 101 | 135 | 134% |
| **Net loss attributed to shareholders for the period** | 9,365 | 5,561 | 3,804 | 68% | 22,869 | 19,416 | 3,453 | 18% |
| **Other comprehensive loss/(income)** | | | | | | | | |
| Item that may be reclassified to (income) loss | | | | | | | | |
| Foreign currency translation adjustment | (584) | 937 | (1,521) | -162% | 855 | (24) | 879 | -3663% |
| **Net loss and comprehensive loss for the period** | 8,781 | 6,498 | 2,283 | 35% | 23,724 | 19,392 | 4,332 | 22% |
| **Loss per share** | | | | | | | | |
| Basic and diluted net loss per Common Share | 0.38 | 0.26 | 0.12 | 46% | 0.94 | 0.92 | 0.02 | 2% |

**Revenue**

Profound deploys a recurring revenue business model in the US to market TULSA-PRO®, charging a one-time payment that includes a 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 one-time capital sales model with limited recurring service revenue. 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. Revenue is comprised of recurring – non-capital revenue, which consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties and one-time sale of capital equipment.

For the three months ended September 30, 2024, the Company recorded revenue totaling $2,832 with $179 from the one-time sale of capital equipment and $2,653 coming from recurring – non-capital revenue. For the three months ended September 30, 2023, the Company recorded revenue totaling $1,728 with all $1,728 coming from recurring – non-capital revenue. The increase in revenue for the three months ended September 30, 2024, was a result of higher capital and disposable sales. 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 US market which continues to see growth quarter over quarter.

For the nine months ended September 30, 2024, the Company recorded revenue totaling $6,504 with $952 from the one-time sale of capital equipment and $5,552 from recurring – non-capital revenue, which consists of the sale of one-time-use devices, lease of medical devices, procedures and services associated with extended warranties. For the nine months ended September 30, 2023, the Company recorded revenue totaling $5,190 with $393 from the one-time sale of capital equipment and $4,797 from recurring – non-capital revenue. The increase in revenue for the nine months ended September 30, 2024, was the result of higher capital and disposable sales.

**Cost of sales**

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

For the three months ended September 30, 2024, the Company recorded cost of sales of $1,044, related to the sale of medical devices, capital and non-capital, which reflects a 63% gross profit margin. For the three months ended September 30, 2023, the Company recorded cost of sales of $686, related to the sale of medical devices, non-capital, which reflects a 60% gross profit margin. The gross profit margin was higher in 2024 due to higher capital sales.

For the nine months ended September 30, 2024, the Company recorded cost of sales of $2,429, related to the sale of medical devices, capital and non-capital, which reflects a 63% gross profit margin. For the nine months ended September 30, 2023, the Company recorded a cost of sales of $1,919, related to the sale of medical devices, capital and non-capital, which reflects a 63% gross profit margin. The gross profit margin was slightly higher due to the higher number of capital sales.

**Operating Expenses**

Operating expenses consist of two components: research and development ("**R&D**"), selling, general and administrative ("S**G&A**") and selling and distribution expenses.

*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 September 30, 2024, R&D expenses were higher by $739 compared to the three months ended September 30, 2023. Clinical trial costs, material and salaries and benefits increased by $173, $168 and $504, respectively. The increases were due to increased CAPTAIN trial treatments and clinical trial recruitment efforts, various R&D projects undertaken during the period which included fixture developments, yield improvements and additional materials for clinical trials, higher headcount and lower reimbursement of workforce costs. Offsetting these amounts was a decrease of $36 in share based compensation due to fewer awards granted to employees, a decrease of $26 in travel due to lower service calls and repairs and an overall decrease to the general office expense of $53.

For the nine months ended September 30, 2024, R&D expenses were higher by $1,870 compared to the nine months ended September 30, 2023. Clinical trial costs, materials, consulting fees and salaries and benefits increased by $387, $649, $76 and $1,160, respectively. The increase in clinical trial costs was due to CAPTAIN trial treatments and clinical trial recruitment efforts, materials expenses were higher due to spending on R&D initiatives for fixture development and yield improvements, consulting fees increased due to microbiology

and Medical Device Regulatory audits and salaries increased due to higher headcount and lower reimbursement of workforce costs. Offsetting these amounts was a decrease in rent of $94 due to lower MRI time usage, a decrease of $146 to share based compensation due to fewer awards granted to employees and an overall decrease to the general office expense of $144.

*SG&A expenses*

Selling, general and administrative expenses are comprised of business development costs related to the market development activities and commercialization of our systems, including salaries and benefits, marketing support functions, occupancy costs, insurance, various management and administrative support functions and other miscellaneous marketing and management costs.

SG&A expenses for the three months ended September 30, 2024 increased by $2,436 compared to the three months ended September 30, 2023. Salaries and benefits, consulting fees, travel, software, office expenses, expected credit loss and bad debt expense increased by $327, $651, $181, $130, $156, $608 and $390, respectively, due to increased salesforce and commission payments, increased legal and accounting fees associated with the expected loss of Emerging Growth Company status in the United States, increased hosting, license and user costs, coupled with the increase in number of users, increased in-person conferences, meetings and largest event hosted, Pro-Talk Live, overall increase in general expenses and bad debt expense associated with one customer.

SG&A expenses for the nine months ended September 30, 2024 increased by $3,791 compared to the nine months ended September 30, 2023. Salaries and benefits, consulting fees, travel, software, expected credit loss and bad debt expense increased by $1,231, $1,206, $387, $162, $607 and $390, respectively, due to higher cost of living salary increases increased legal and accounting fees associated with the expected loss of Emerging Growth Company status in the United States, increased hosting, license and user costs, coupled with the increase in number of users, increased in-person conferences, meetings and largest event hosted, Pro-Talk Live, and bad debt expense associated with one customer. Offsetting these amounts was a decrease in share based compensation of $206 due to fewer awards granted to employees.

### Other (income) expense

Other (income) expense is primarily comprised of the following: (i) the CIBC Loan Agreement (as defined herein) accreting to the principal amount repayable and its related interest expense; (ii) interest income from cash and cash equivalents; (iii) the lease liability interest expense; (iv) the interest income on trade and other receivables; and (v) foreign exchange gain or losses.

Other (income) expense increased $1,216 to $190 during the three months ended September 30, 2024, compared to ($1,026) during the three months ended September 30, 2023. The increase in other (income) expense was due to the change in the amortized cost of trade and other receivables being fully recognized, increase in interest income from cash and cash equivalents, decrease in the CIBC Loan interest and accretion expenses and a decrease in the foreign exchange gain.

Other (income) expense decreased $1,539 to ($2,084) during the nine months ended September 30, 2024, compared to ($545) during the nine months ended September 30, 2023. The increase in other (income) expense was due to the change in the amortized cost of trade and other receivables being fully recognized, increase in interest income from cash and cash equivalents, decrease in the CIBC Loan interest and accretion expenses and an increase in the foreign exchange gain.

### Net loss

Net loss for the three months ended September 30, 2024, was $9,365 or $0.38 per Common Share, compared to a net loss of $5,561 or $0.26 per Common Share for the three months ended September 30, 2023.

Net loss for the nine months ended September 30, 2024, was $22,869 or $0.94 per Common Share, compared to a net loss of $19,416 or $0.92 per Common Share for the nine months ended September 30, 2023.

## 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 US GAAP Standards in US dollars.

In USD$ (000s)

| | 2024 | | | 2023 | | | | 2022 |
|---|---|---|---|---|---|---|---|---|
| | Q3 | Q2 | Q1 | Q4 | Q3 | Q2 | Q1 | Q4 |
| | $ | $ | $ | $ | $ | $ | $ | $ |
| **Revenue** | 2,832 | 2,233 | 1,439 | 2,009 | 1,728 | 1,602 | 1,860 | 1,257 |
| **Cost of sales** | 1,044 | 812 | 573 | 968 | 686 | 568 | 665 | 840 |
| **Gross profit** | 1,788 | 1,421 | 866 | 1,041 | 1,042 | 1,034 | 1,195 | 417 |
| | | | | | | | | |
| **Operating expenses** | 10,786 | 9,263 | 8,743 | 9,832 | 7,611 | 7,478 | 8,402 | 9,248 |
| **Other (income) expenses** | 190 | (942) | (1,332) | 345 | (1,026) | 517 | (36) | 62 |
| **Loss before income taxes** | 9,188 | 6,900 | 6,545 | 9,136 | 5,543 | 6,961 | 6,811 | 8,893 |
| | | | | | | | | |
| **Income taxes** | 177 | 19 | 40 | (229) | 18 | 35 | 48 | 206 |
| | | | | | | | | |
| **Net loss for the period** | 9,365 | 6,919 | 6,585 | 8,907 | 5,561 | 6,996 | 6,859 | 9,099 |
| | | | | | | | | |
| **Loss per common share** | | | | | | | | |
| **Basic and diluted** | 0.38 | 0.28 | 0.27 | 0.42 | 0.26 | 0.33 | 0.33 | 0.44 |

The third quarter of 2024 revenue continued to increase compared to prior quarters as patient procedures and capital equipment sales increased. In addition, there was an increase in net finance costs due to the US dollar and Euro foreign currency rates, triggering a foreign exchange loss.

The second quarter of 2024 revenue increased compared to the prior quarter as a result of capital sales. Operating expenses were higher due to the increase in headcount and lower workforce reimbursement from the European ministry of research. In addition, there was an increase in finance income due to the US dollar and Euro foreign currency rate, triggering a foreign exchange gain.

The first quarter of 2024 revenue decreased compared to the majority of prior quarters as a result of timing for capital equipment sales. Operating expenses increased against several of the prior quarters due to additional headcount within sales and distribution and expenses associated with the continued TULSA-PRO® commercialization with the US market.

In the fourth quarter of 2023 revenue continued to increase compared to prior quarters as new sites became operational and increased patient procedures. Operating expenses were higher than prior quarters due to ATM offering fees as well as overall increase to the salesforce.

In the third quarter of 2023 operating expenses were higher compared to the prior quarter due to increased consulting costs associated with regulatory and foreign consultants for additional approval in other countries. In addition, there was also an increase in finance income due to the US dollar and Euro foreign currency rate, triggering a foreign exchange gain.

The second quarter of 2023 revenue was lower compared to the prior quarter due to decreased one-time capital sales. Operating expenses were lower compared to the prior quarters due to decreased share based compensation expenses and lower amortization expenses as a result of intangible assets being fully amortized.

The first quarter of 2023 cost of sales decreased from the quarterly periods in 2022 as a result of manufacturing operating at a higher efficiency rate based on improvements to quality and training that were implemented in the manufacturing process.

The fourth quarter of 2022 revenue was lower compared to prior quarters due to decreased one-time capital sales, primarily resulting from lower capital sales than previous quarters. Operating expenses were higher due to goodwill impairment.

## LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2024, the Company had cash of $27,123 compared to $26,213 at December 31, 2023. Historically, the Company's primary source of cash has been financing activities, e.g., equity offerings as well as the CIBC Loan (as defined below).

**Going Concern**

In USD$ (000s)

The Company is subject to a number of risks, including the successful development and marketing of its products and the ability to raise additional financing to support these activities. The Company depends on various financing from investors or other sources of capital to fund its operations, achieve its business plan and the realization of its assets and liabilities in the normal course of operations.

Management believes that current cash balances as of September 30, 2024 will not be sufficient to finance all of its planned business operations over the next year. The Company intends to seek additional financing from investors or other sources of capital in order to fund its operations and activities over the next year. There can be no assurance that the steps management are taking will be successful. Considering the need for additional financing, there exists a material uncertainty that may raise significant doubt (or raise substantial doubt as contemplated by PCAOB standards) about the Company's ability to continue as a going concern.

These interim condensed consolidated financial statements have been prepared on a going concern basis, which asserts the Company has the ability in the near term to continue to realize its assets and discharge its liabilities and commitments in a planned manner giving consideration to the above and expected possible outcomes. Conversely, if the going concern assumption is not appropriate, adjustments to the carrying amounts of the Company's assets, liabilities, revenues, expenses and balance sheet classifications may be necessary, and these adjustments could be material.

**Use of Proceeds**

2024 Offering and non-brokered private placement

The Company received net proceeds of $21,079 from the Public Offering and Private Placement. The Company intends to use net proceeds from the Public Offering and Private Placement to fund the continued commercialization of the TULSA-PRO® system in the United States, the continued development and commercialization of the TULSA-PRO® system and the SONALLEVE® system globally and for working capital and general corporate purposes. The Company confirms that there have been no material variances in the estimated use of proceeds from the net proceeds of the Public Offering since the date of the Company's prospectus supplement dated December 27, 2023. In addition, there have been no material adjustments to the cost or timing of the business objective previously disclosed in such prospectus supplement.

| | Total spending as at September 30, 2024 |
|---|---|
| | $ |
| TULSA-PRO® commercialization | 11,660 |
| Sonalleve® development and commercialization | 1,951 |
| Working capital and general corporate purposes | 7,468 |
| Total | 21,079 |

CIBC Loan

Profound Medical Inc. ("**PMI**") entered into a loan agreement with Canadian Imperial Bank of Commerce ("**CIBC**") on November 3, 2022 (the "**CIBC Loan Agreement**"), for gross proceeds of C$10,000, maturing on November 3, 2027, with an interest rate based on CIBC prime plus 2% (the "**CIBC Loan**"). The Company was required to make interest-only payments until October 31, 2023, and monthly repayments on the principal of C$208 plus accrued interest commenced on October 31, 2023. All obligations of the Company under the CIBC Loan Agreement are guaranteed by current and future subsidiaries of the Company and include security of first priority interests in the assets of the Company and its subsidiaries. Initially, the Company had financial covenants in relation to the CIBC loan where unrestricted cash is at all times greater than EBITDA for the most recent six-month period, reported on a monthly basis and that revenue for any fiscal quarter must be 15% greater than revenue for the same fiscal quarter in the prior fiscal year, reported on a quarterly basis.

On September 26, 2023 an amendment to the CIBC Loan resulted in a change to the financial covenants. The amended covenants are that unrestricted cash must at all times be greater of: (i) to the extent EBITDA is negative for such period, EBITDA for the most recent nine-month period or (ii) $7,500, reported on a monthly basis; and that recurring revenue for any fiscal quarter must be 15% greater than recurring revenue for the same fiscal quarter in the prior fiscal year, reported on a quarterly basis.

On May 3, 2024, a second amendment to the CIBC Loan resulted in another amendment to the financial covenants. The amended covenants are that the recurring revenue covenant shall not be tested for any fiscal quarter in the 2024 fiscal year so long as unrestricted cash is no less than 2.5 multiplied by the principal amount of outstanding CIBC Loan at all times. The Company is in compliance with these financial covenants as at September 30, 2024. Based on the Company's future cash flow forecasts, if additional financing or other sources of capital is not raised by the end of the second half of 2025, the Company may have difficulty complying with the unrestricted cash covenant.

In USD$ (000s)

**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'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.

The Company may require additional capital to fund R&D activities and any significant expansion of operations by the second half of the year ending December 31, 2025. 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 its 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2024<br>$ | 2023<br>$ | 2024<br>$ | 2023<br>$ |
| | | | | |
| Cash provided by (used in) operating activities | (6,826) | (4,465) | (17,574) | (15,089) |
| Cash provided by (used in) financing activities | (592) | (114) | 19,261 | 2,176 |
| Foreign exchange on cash | 462 | (1,071) | (777) | 21 |
| **Net increase (decrease) in cash** | (6,956) | (5,650) | 910 | (12,892) |

*Operating Activities*

Net cash provided by (used in) operating activities for the three months ended September 30, 2024 was $(6,826) versus $(4,465) for the three months ended September 30, 2023. The principal use of the operating cash flows during this period related to increased headcount, consulting expenses and marketing efforts in the US.

Net cash provided by (used in) operating activities for the nine months ended September 30, 2024 was $(17,574) versus $(15,089) for the nine months ended September 30, 2023. The primary change of the operating cash flows during this period related to increased headcount, consulting expenses and marketing efforts in the US.

*Financing Activities*

Net cash provided by (used in) financing activities for the three months ended September 30, 2024 was $(592) versus $(114) for the three months ended September 30, 2023. These cash flows relate to monthly payments of the long-term debt and lease liability.

Net cash provided by (used in) financing activities for the nine months ended September 30, 2024 was $19,261 versus $2,176 for the nine months ended September 30, 2023. These cash flows relate primarily to the 2024 Offering and non-brokered private placement pursuant to which the Company received net proceeds of $21,079.

*Foreign Exchange on Cash*

Cash was impacted by the change in the foreign exchange rates for the Company's foreign currency denominated cash (non-USD). The value of the Company's currencies decreased, resulting in a decrease in the Company's cash holdings.

**Contractual obligations**

In USD$ (000s)

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

| | September 30, 2024 | | | |
|---|---|---|---|---|
| | Carrying amount $ | Future cash flows $ | Less than 1 Year $ | Between 1 year and 5 years $ |
| Accounts payables and accrued expenses and other current liabilities | 3,401 | 3,401 | 3,401 | - |
| Lease liability | 556[1] | 667 | 292 | 375 |
| Long-term debt | 5,598 | 6,622 | 2,444 | 4,178 |
| **Total** | 9,555 | 10,690 | 6,137 | 4,553 |

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

**Non-GAAP Financial Measures**

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

The Company's working capital (defined as current assets less current liabilities) is a non-GAAP 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 September 30, 2024 and December 31, 2023 is set forth in the table below.

| | September 30, 2024 $ | December 31, 2023 $ |
|---|---|---|
| Current assets | 40,499 | 41,896 |
| Less: Current liabilities | 6,681 | 6,368 |
| **Working capital** | 33,818 | 35,528 |

Working capital decreased by $1,710 with a surplus of $33,818 as at September 30, 2024 compared to the surplus of $35,528 at December 31, 2023. The change in working capital is due to a decrease in current assets of $1,397, which was primarily the result of the increase in the cash balance of $910 which was offset by decreases in prepaids expenses and deposits of $1,024 and a decrease in inventory of $554. Current liabilities increased by $313 due to a decrease in accounts payable, accrued expenses and other liabilities and current portion of the long-term debt.

## 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.

In USD$ (000s)

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, accrued expenses and other liabilities and long-term debt. The fair values of these financial instruments, approximate carrying value as a result of their short-term nature. Financial assets measured at amortized cost include cash and trade and other receivables. The fair value of the long-term debt approximates its carrying amount as it has a floating interest rate.

Financial liabilities measured at amortized cost include accounts payable, accrued expenses and other liabilities and long-term debt.

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, 2023, nor has there been a significant change in the composition of its financial instruments since December 31, 2023.

## RELATED PARTY TRANSACTIONS

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

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | **2024 $** | **2023 $** | **2024 $** | **2023 $** |
| | | | | |
| Salaries and employee benefits | 565 | 434 | 1,588 | 1,165 |
| Directors' fees | 70 | 69 | 208 | 225 |
| Share-based compensation | 410 | 847 | 1,437 | 2,201 |
| **Total** | 1,045 | 1,350 | 3,233 | 3,591 |

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 November 7, 2024, the date of this MD&A, the Company had the following securities outstanding:

| | Number |
|---|---|
| Common Shares | 24,661,771 |
| Share purchase options | 1,464,797 |
| Deferred Share Units | 66,670 |
| Restricted Share Units | 284,289 |

## 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 US GAAP 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 year. 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 year in which they are determined.

### Critical accounting policies

*Revenue*
Revenue is derived primarily from the sale of the TULSA-PRO and Sonalleve systems and one time use devices. All products generally contain a one-year warranty.

The Company recognizes revenue when the customer obtains control of promised goods or services and in an amount that reflects the consideration to which the Company expects to be entitled to receive in exchange for those goods or services. To achieve this core principle, the Company applies the five-step revenue model to contracts within its scope: (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 amount of revenue to be recognized is based on the transaction price the Company expects to receive in exchange for its goods and services. For contracts that contain multiple performance obligations, the Company allocates the transaction price to each performance obligation and recognizes the related revenue when or as control of each individual performance obligation is transferred to customers.

*Recurring – non-capital*
Recurring - non-capital revenue consists of the sale of one-time-use devices and services associated with extended warranties. Revenue from sale of one-time-use devices is recognized when control is transferred to the customers, which generally occurs at the time of shipment. Service revenue related to extended warranties is deferred and recognized on a straight-line basis over the extended warranty period covered by the customer contract.

*Capital equipment*
Capital equipment revenue consists of the sale of capital equipment including installation and training amounts. Revenue is recognized when the Company transfers control to the customer, which is generally at the time of shipment. The Company's customer arrangements generally do not provide a right of return.

*Contract Assets*
Contract assets arise from billed amounts in customer arrangements and the Company's right to payment is not just subject to the passage of time, typically related to installation of the product. The Company recognizes a receivable at the point in time at which it has an unconditional right to payment.

*Sales to distributors*
The Company markets and sells its products primarily through its direct sales force, which sells its products to end customers. A portion of the Company's revenue is generated by sales to distributors primarily in Europe and Asia. When the Company transacts with a distributor, its contractual arrangement is with the distributor and not with the end customer. Whether the Company transacts business with and receives the order from a distributor or directly from an end customer, its revenue recognition policy and resulting pattern of revenue recognition for the order are generally the same.

### Critical accounting estimates

*Trade and other receivables*

The key judgements and estimates are used in determining the allowance for expected credit losses. Trade and other receivables are stated net of an allowance for expected credit losses. The Company grants credit to customers in the normal course of business and maintains an allowance for expected credit losses which reflect the current estimate of expected credit losses expected to be incurred over the life of the receivables. The Company considers various factors in establishing, monitoring, and adjusting its allowance for expected credit losses, including the aging of the accounts and aging trends, the historical level of charge-offs, and specific credit exposures related to particular customers. The Company also monitors other risk factors and forward-looking information, such as country risk, when determining credit limits for customers and establishing adequate allowances. Uncollectible accounts are written-off against

the allowance 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 180 days past due.

## 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*.

The Certifying Officers have concluded that as at September 30, 2024, the Company's DC&P has been designed effectively to provide reasonable assurance that (a) material information relating to the Company is made known to them by others, particularly during the period in which the annual filings are being prepared; and (b) information required to be disclosed by the Company in its annual filings, interim filings or other reports are filed or submitted, recorded, processed, summarized and reported within the time periods specified in the securities legislation.

There have been no significant changes to the Company's ICFR for the period ended September 30, 2024, which have materially affected, or are reasonably likely to materially affect the Company's ICFR. Based on their evaluation of these controls for the period ended September 30, 2024, the Certifying Officers have also concluded that the Company's ICFR have been designed effectively to provide reasonable assurance regarding the reliability of the preparation and presentation of the financial statements for external purposes and that ICFR were effective as at September 30, 2024. The Company used the Committee of Sponsoring Organizations of the Treadway Commission control framework to evaluate DC&P and ICFR.

It should be noted that while the Company's Certifying Officers believe that the Company's DC&P provides a reasonable level of assurance that they are effective, they do not expect that the disclosure controls will prevent all errors and fraud. A control system, no matter how well conceived or operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met.

ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the annual financial statements for external reporting purposes in line with US GAAP. Management is responsible for establishing and maintaining adequate internal controls over financial reporting appropriate to the nature and size of the Company. However, any system of internal control over financial reporting has inherent limitations and can only provide reasonable assurance with respect to annual financial statement preparation and presentation.

## ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Environmental, social and governance ("**ESG**") issues are an integral part of human life. They've also become a more conscious and explicit part of business life, especially for public entities like Profound. The Company believes ESG sensitivities are an integral part of growing a successful, sustainable business. The importance Profound places on ESG principles stems from its foundation as a company, whose mission is focused on providing customizable incision-free therapies that are flexible to treat different types of patients and can treat each patient differently. ESG is embedded in the Company's corporate strategy, which seeks to maximize long-term value by taking a disciplined and sustainable approach to changing the paradigm of prostate cancer treatment.
Through Profound's ESG plan, the Company intends to create enduring value for shareholders by:

- attracting, retaining and empowering a diverse, engaged workforce to bring unique perspectives and experiences to strategic decisions;
- ensuring safe and secure workplaces for its employees and contributing to their welfare;
- caring for the environment in which the Company operates;
- strengthening relationships with shareholders by working collaboratively to achieve positive social, economic and environmental outcomes; and
- operating transparently.

*Environmental*

Profound believes in the 3Rs: reduce, reuse, recycle. Profound strives to control the waste and, in its facilities, electronic equipment, paper, glass, plastic and metal items, as well as hazardous waste, are recovered and recycled. Given the finite resources in the world, Profound believes moving towards a circular economy in which Profound reduces waste production is critical for both business and

society. Recognizing the opportunity for the medical technology industry to support the transition towards lower waste and circular business models, including by minimizing Profound's waste footprint and exploring opportunities to reduce the volume of materials used. At Profound, focusing efforts on waste minimization through a repair first strategy, and by using materials that can be recycled to increase the supply of material for future reuse. The equipment that Profound provides to customers is collected, tested, repaired, or refurbished then redeployed thus contributing to a circular economy. Equipment which can no longer be redeployed is brought to organizations or third party vendors that partner with Profound to resell and recycle obsolete equipment.

Profound is focused on waste reduction, waste avoidance, and waste management strategies for all materials, including plastic, metal, water and cardboard. To manage the Company's waste it segregates, recycles, and properly disposes of hazardous and non-hazardous materials and where possible, reuses materials such as alcohol and water through its recycling plan. Profound will continue managing its waste and material use through clear and consistent communication of best practices throughout the Company. Profound is committed to environmental sustainability and prioritizes efforts to prevent pollution and to conserve, recover, and recycle materials wherever possible. The Company attempts to distribute documents electronically to minimize paper consumption, waste and limit the use of single-use plastics. Since 2021, Profound has invested in upgrading its lighting in its manufacturing facilities by retrofitting its lighting to high-efficiency LED to reduce energy consumption and enhance the manufacturing facilities work environment for its employees. The Company plans to continue to invest in lighting where it can have a positive environmental impact and improve working conditions.

The repair first approach promotes reuse of existing materials and reduction of new materials (including packaging associated with replacing parts), therefore avoiding waste to landfill. To further support these key areas, the Company is exploring opportunities to recycle glass, water and metals. In Profound's facilities, multiple waterless urinals have been installed which save over 100,000 litres of water per urinal each year.

*Social*

As the demand for talent increases, the need for innovative attraction and retention strategies also increases. The Company recognizes that in a rapidly changing environment, its employees are central to its business performance. Profound's workforce is a key driver of its success, which is why providing a superior employee experience is one of its top priorities. This includes Profound's commitment to providing a safe and healthy workplace for all employees, consultants, and business partners. Profound does not simply consider this to be its duty of care but an important business practice as it lowers costs, reduces absenteeism and turnover, increases productivity and quality and raises employee morale.

In addition to competitive salaries, Profound offers other benefits to its employees. These benefits include a range of incentives, flexible and home-based work options and other health-related benefits. The human resources department is responsible for promoting a wide range of opportunities for innovation at work – which is a significant aspect of Profound's corporate strategy – and for helping employees to nurture their personal strengths while developing as individuals. In order to be best prepared for challenges, Profound emphasizes the acquisition of technical expertise as part of the qualification system.

Diversity and inclusion are long-standing core values that Profound embraces by fostering a respectful workplace where integrity, trust and inclusion are the norm. Profound believes that an inclusive workplace is one where everyone feels a sense of belonging, has a safe environment in which to work and develop, and shares equal opportunities for career advancement regardless of gender, skin colour, ethnicity, religion, age, disability or sexual orientation. Profound values diversity and inclusion as together they enable a highly collaborative and engaging work environment and drive innovation and the development of new ideas, which in turn directly correlates with improved Company performance.

Profound wants every employee to feel healthy, safe and productive at work. Cultivating a safe workplace helps advance the Company's purpose of enabling everyone to live healthier, fuller lives. Given the increased incidence of mental illness in the workplace, Profound's healthcare coverage offers access to quality counseling services.
Artificial intelligence is getting increasingly sophisticated at doing what humans do, but more efficiently, more quickly and at a lower cost. The potential for both AI and robotics in healthcare is vast. Just like in our every-day lives, AI and robotics are increasingly a part of our healthcare eco-system and a major factor for the Company. By analyzing large amounts of data in real time, AI can help improve clinical and nonclinical decision making, ablation planning, treatment time reduction and workflow ease of use optimization. Advances in technology are driving constant changes in the delivery of healthcare. Care providers must seek new training and education opportunities to adjust to this quickly evolving landscape. Artificial intelligence supports these efforts by revolutionizing the capture, storage, and analysis of training video.

Artificial intelligence has the potential to help solve some of the biggest challenges facing healthcare today, such as managing costs, physician burnout, and health equity. Our AI solutions are designed to give healthcare professionals the time and tools they need to deliver better care to more people around the world. The thermal boost technology enables predictable, customized ablation at the prostate capsule to ensure a reliable heating of the planned ablation volume. It demonstrates successful application for boosting the MRI-visible lesions to ensure reliable heating to the capsule, boosting in regions with larger prostate radii and boosting if the lethal heat did not initially reach the target boundary.

*Governance*

Profound's Board of Directors are responsible for the stewardship of the Company and for overseeing the conduct of business and the activities of management. The Human Resource and Corporate Governance Committee of the board of directors of Profound is responsible for providing leadership in shaping the Company's governance policies and practices. The Audit Committee is responsible for overseeing financial reporting and related internal controls, risk, independent and internal auditors, and ethics and compliance. The committees of the board of directors of Profound consist of many affluent senior leadership members within the industry that provide meaningful insight and guidance. Strong and effective governance practices are part of Profound's organizational culture. This encompasses sound and effective internal processes and procedures, minimizing risks, continuous enhancement of human resource policies and practices, a cyber security strategy and promoting efficiency.

The Company holds itself to a high standard of governance and it is continually taking steps to strengthen its performance and accountability in critical areas. Profound's Code of Business Conduct and Ethics and Whistleblower policies provide the standards for ethical behavior throughout Profound's business activities and reflect its commitment to conducting a culture of honesty, integrity, and accountability.

As Profound continues to work towards its mission, the Company is committed to conducting its business in a responsible and sustainable manner by aspiring to develop healthy, resilient communities through its dedication to social, economic and environmental sustainability. By unlocking value through its core activities, Profound remains focused on execution on all fronts including in fulfilling its commitment to ESG best practices in the years to come.

## 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.sedarplus.ca 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. Profound's overall risk management program and business practices seek to minimize any potential adverse effects on the Company's consolidated financial performance. Financial risk management is carried out under practices approved by Profound's audit committee. This includes reviewing and making recommendations to the board of directors regarding the adequacy of the Company's 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.sedarplus.ca 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".
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