



Profound Medical Inks Exclusive Distribution Agreement for TULSA-PRO® and Sonalleve® with Al Faisaliah Medical Systems in Saudi Arabia

Agreement creates runway for Profound's incision-free and radiation-free therapies for the ablation of diseased tissue, to penetrate the largest healthcare market in the Middle East

All required regulatory approvals to import and sell Profound's two advanced ablative technologies in Saudi Arabia are already in place

TORONTO and RIYADH, Saudi Arabia, Nov. 11, 2025 -- [Profound Medical Corp.](#) (NASDAQ:PROF; TSX:PRN) ("Profound" or the "Company"), a commercial-stage medical device company that develops and markets artificial intelligence ("AI")-powered, MRI-guided, incision-free therapies for the ablation of diseased tissue, is pleased to announce that it has entered into an exclusive distribution and supply agreement for its TULSA-PRO® and Sonalleve® technologies in Saudi Arabia with Al Faisaliah Medical Systems Co. ("FMS"), a subsidiary of one of the Kingdom's most prominent business conglomerates, Al Faisaliah Group ("AFG").

Profound is the only company that combines the real-time imaging and thermography capabilities of magnetic resonance ("MR") with AI-driven treatment designs to allow physicians to precisely and gently address diseased tissue without any incision, associated tissue boiling or charring, blood loss, severe/prolonged pain, or need for overnight hospital stay.

U.S. commercialization of TULSA-PRO, designed specifically for the treatment of prostate disease (prostate cancer and/or benign prostatic hyperplasia, "BPH"), remains the top priority for the Company's direct sales team. The [TULSA Procedure™](#), performed using Profound's TULSA-PRO system, is a significant advancement in prostate care. Instead of surgery or radiation, the TULSA procedure is performed inside an MRI suite to precisely and gently heat prostate tissue to 'kill temperature' (55-57° C) with directional ultrasound, while protecting surrounding nerves and anatomy. By intention-to-treat, while TULSA-PRO has the flexibility to be used for all ablations, including focal and hemi-gland, the majority of TULSA Procedures are either whole-gland or near-whole-gland ablations. In late 2024, the U.S. Centers for Medicare & Medicaid Services (CMS) issued its outpatient prospective payment system (OPPS) final rule ("Final Rule") for the three new CPT® Category 1 codes and their descriptors covering the TULSA procedure, which became effective on January 1, 2025. With the Final Rule, TULSA reimbursement was established at Urology Level 7 Ambulatory Payment Classification (APC). To-date, more than 4,000 men have undergone the TULSA Procedure, and as of [last report](#) (October 2025), Profound's TULSA-PRO installed base stood at 67 systems.

Profound's second product, Sonalleve, which is offered primarily as a one-time capital sale, is also gaining increasing commercial interest, particularly outside of the United States. Sonalleve uses the same MR imaging and thermographic technology as TULSA-PRO, and combines that with focused ultrasound from outside the body to treat disease. There are currently ten Sonalleve devices operational in parts of Europe, China and Southeast Asia – where over 4,000 women have already been treated with the technology for adenomyosis and uterine fibroids, diseases of the uterus that can cause chronic pain and heavy and/or prolonged menstruations. Treatment with Sonalleve has demonstrated pain and symptom relief without affecting the ovarian reserve, and with reports of women preserving their fertility. Sonalleve is also now being used in research and clinical trials in Europe for the ablation of pancreatic cancer tissue and other oncological disease. Over the last five years, approximately \$10 million has been granted by research organizations in Europe and Canada to further conduct clinical research using Sonalleve for multiple, often life-threatening, diseases.

As user interest in Profound's technologies continues to build, the Company is deploying its own direct sales team in North America, while partnering with select strategic distribution partners to support the business potential and the customer base in other parts of the world.

"We're honored to partner for the distribution of both TULSA-PRO and Sonalleve with FMS, one of the leading medical device distributors in the Kingdom of Saudi Arabia," commented Profound's CEO and Chairman, Arun Menawat. "Successfully marketing and distributing our incision-free therapies for the ablation of diseased tissue requires a deep understanding of regional market dynamics and the specific needs of local clinicians and patients. With its proven track record in introducing advanced oncological procedures and other medical technologies in the Kingdom, we're confident that FMS is the ideal partner for us."

FMS' GM, Mr. Abdullah Al Melik, said, "As Saudi Arabia moves toward economic diversification under [Vision 2030](#), both FMS and our parent company, AFG, are committed to playing a crucial role in shaping the country's future. The group is a major provider of equipment and services to existing hospitals, and also actively owns and operates its own specialized medical facilities. With our partnership with Profound, we're extremely excited to bring its unique, incision- and radiation-free ablative technologies to Saudi hospitals and treatment centers that aim to be worldwide leaders in patient outcomes. We look forward to working closely with the Profound team."

About with Al Faisaliah Medical Systems Co.

Founded in 1973, FMS was initially the healthcare division of AFG, until its establishment as an independent company in 1993. Its broad portfolio of partners and products enables it to deliver complex, integrated, single-source healthcare equipment

solutions to the largest healthcare providers in the region. With operations across the Kingdom of Saudi Arabia, FMS is a major provider of diversified healthcare solutions, supplying state-of-the-art equipment and solutions for various uses such as oncology, operations, monitoring and critical care, cardiovascular and others. For further information, visit www.tibbiyah.com/fms.

About Al Faisaliah Group

AFG is a privately held holding company headquartered in Riyadh, Saudi Arabia, operating across the wider Middle East. Its name is derived from the name of its founder, Abdullah Al Faisal, eldest son of the late King Faisal. Founded in 1971, the Group holds leading positions in multiple industries including Dairy, Electronics, Healthcare and Food Service. AFG also operates a corporate venture capital arm (Al Faisaliah Ventures) that invests in global and regional disruptive players. The Group is recognized across the region for its strongly-held values, professional management and decades-long strategic partnerships with leading local and global firms including notably Sony, Danone and Philips. For further information, visit www.alfaisaliah.com.

About Profound Medical Corp.

Profound is a commercial-stage medical device company that develops and markets AI-powered, MRI-guided, incision-free therapies for the ablation of diseased tissue.

Profound is commercializing TULSA-PRO[®], a technology that combines real-time MRI, AI-enhanced planning, robotically-driven transurethral ultrasound and closed-loop temperature feedback control. The [TULSA Procedure[™]](#), performed using the TULSA-PRO system, has the potential of becoming a mainstream treatment modality across the entire prostate disease spectrum; ranging from low-, intermediate-, or high-risk prostate cancer; to hybrid patients suffering from both prostate cancer and benign prostatic hyperplasia ("BPH"); to men with BPH only; and also, to patients requiring salvage therapy for radio-recurrent localized prostate cancer. The TULSA Procedure employs real-time MR guidance for precision to preserve patients' urinary continence and sexual function, while killing the targeted prostate tissue via precise sound absorption technology that gently heats it to 55-57°C. The TULSA Procedure is an incision- and radiation-free "one-and-done" procedure performed in a single session that takes a few hours. Virtually all prostate shapes and sizes can be safely, effectively, and efficiently treated with the TULSA Procedure. There is no bleeding associated with the procedure; no hospital stay is required; and most TULSA patients report quick recovery to their normal routine. TULSA-PRO is CE marked, Health Canada approved, and 510(k) cleared by the U.S. Food and Drug Administration ("FDA").

Profound is also commercializing Sonalleve[®], an innovative therapeutic platform that is CE marked for the treatment of uterine fibroids, adenomyosis, pain palliation of bone metastases, desmoid tumors and osteoid osteoma. Sonalleve has also been approved by the China National Medical Products Administration for the non-invasive treatment of uterine fibroids and has FDA approval under a Humanitarian Device Exemption for the treatment of osteoid osteoma. Profound is in the early stages of exploring additional potential treatment markets for Sonalleve where the technology has been shown to have clinical application, such as non-invasive ablation of abdominal cancers and hyperthermia for cancer therapy.

Forward-Looking Statements

This release includes forward-looking statements regarding Profound and its business which may include, but is not limited to, the expectations regarding the efficacy of Profound's technology in the treatment of prostate cancer, BPH, uterine fibroids, palliative pain treatment and osteoid osteoma; the extent and timing of Profound's completion of TULSA-PRO[®] system sales from its qualified sales pipeline; Profound's expectations for future revenues; and the success of Profound's commercialization strategy and activities for TULSA-PRO. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "is expected", "expects", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes" or variations (including negative variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Such statements are based on the current expectations of the management of Profound. The forward-looking events and circumstances discussed in this release, may not occur by certain specified dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting the Company, including risks regarding the medical device industry, regulatory approvals, reimbursement, economic factors, the equity markets generally and risks associated with growth and competition. Although Profound has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward-looking statement can be guaranteed. Other factors and risks that may cause actual results to differ materially from those set out in the forward-looking statements are described in Profound's Annual Report on Form 10-K and other filings made with U.S. and Canadian securities regulators, available at www.sedarplus.ca and www.sec.gov. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Profound undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, other than as required by law.

For further information, please contact:

Stephen Kilmer
Investor Relations
skilmer@profoundmedical.com
T: 647.872.4849