

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 12, 2026

PROFOUND MEDICAL CORP.

(Exact name of registrant as specified in its charter)

Ontario, Canada
(State or Other Jurisdiction of Incorporation)

001-39032
(Commission File Number)

Not Applicable
(I.R.S. Employer Identification No.)

2400 Skymark Avenue, Unit 6
Mississauga, Ontario, Canada L4W 5K5
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area Code: 647-476-1350

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On January 12, 2026, Profound Medical Corp. (the “Company”) issued a press release announcing that the Company’s TULSA-PRO® installed base stood at 78 systems as of December 31, 2025. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, or the Exchange Act, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, or the Securities Act. The information in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing with the U.S. Securities Exchange Commission, or the SEC, made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 12, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROFOUND MEDICAL CORP.

Date: January 12, 2026

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

Profound Surpasses 2025 TULSA-PRO® Installed Base Goal

Company's year-end TULSA-PRO installed base stood at 78 systems; qualified sales pipeline grew to 97 new systems

TORONTO, Jan. 12, 2026 (GLOBE NEWSWIRE) -- Profound Medical Corp. (NASDAQ:PROF; TSX:PRN) ("Profound" or the "Company"), a commercial-stage medical device company that develops and markets AI-powered, MRI-guided, incision-free therapies for the ablation of diseased tissue, is pleased to announce that its TULSA-PRO® system installed base stood at 78 as of December 31, 2025 — higher than its previously announced goal of 75 installs by the end of 2025.

Profound's TULSA-PRO qualified sales pipeline also grew to 97 new systems being classified within one of the "Verify, Negotiate and Contracting" stages at year-end.

"As the installed base grows, we expect that it will lead to higher patient treatment rates and, correspondingly, continued growth of our high margin recurring revenue," said Profound's CEO and Chairman, Arun Menawat. "That is being driven primarily by the TULSA Procedure's ability to treat an unrivaled range of prostate diseases, severities, and aggressions, while preserving crucial functions like continence and sexual health of the patient. We look forward to releasing our fourth quarter and full year 2025 financial results near the end of February 2026."

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 press 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; 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.

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