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## Profound Medical Announces Third Quarter 2024 Financial Results

TORONTO, Nov. 07, 2024 (GLOBE NEWSWIRE) -- [Profound Medical Corp.](#) (NASDAQ:PROF; TSX:PRN) ("Profound" or the "Company"), a commercial-stage medical device company that develops and markets customizable, incision-free therapies for the ablation of diseased tissue, today reported financial results for the third quarter ended September 30, 2024. Unless specified otherwise, all amounts in this press release are expressed in U.S. dollars and are presented in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### Business Highlights

- Q3-2024 revenue growth of 64% over Q3-2023.
- Profound continued to see a wide variety of prostate disease patients treated by its TULSA-PRO<sup>®</sup> customers in the third quarter of 2024:
  - 64% were treated for prostate cancer only, 28% were hybrid patients suffering from both prostate cancer and benign prostatic hyperplasia ("BPH"), 6% were salvage, and 2% were men with BPH only;
  - For cancer grade, 7% were GG1, 66% were GG2, 16% were GG3, and 11% were GG4 & GG5;
  - In terms of ablation, 53% were whole gland; 25% were sub-total but more than half the gland; and 22% were hemi-ablations or focal therapy; and
  - For prostate size, 6% were < 20cc; 40% were 20 – 40cc; 33% were 40-60cc; 15% were 60-100cc; and 6% were over 100cc.
- In September 2024, Profound hosted its second 'PRO-TALK Live!' event in Las Vegas with 70 physicians participating, 31 of whom being existing TULSA-PRO<sup>®</sup> users and the other 39 being potential users. The program featured presentations on TULSA-PRO<sup>®</sup> and its flexibility to treat the widest variety of prostate disease patients from key opinion leaders who have gained first-hand experience with the technology. In addition, members of Profound's management team provided clinical, technology and commercial updates, with a focus on the future of TULSA-PRO<sup>®</sup>. Finally, participants heard from representatives of two leading global medical technology companies, Siemens Healthineers and Cook Medical, who discussed their shared common vision with Profound of creating a total magnetic resonance (MR) solution to support the Modern Treatment Pathway that allows for more accurate and precise prostate disease diagnosis, the TULSA Procedure, and follow-up.
- In October 2024, the Company announced the appointment of Tom Tamberrino as its new Chief Commercial Officer. Mr. Tamberrino has an accomplished history of sales and marketing leadership, business development, executive management and entrepreneurial success, most of which was gained in the U.S. healthcare industry.
- The ongoing Level 1 CAPTAIN trial comparing the TULSA procedure to radical prostatectomy in men with localized prostate cancer remains on track to complete patient enrollment by the end of this year, and Profound anticipates beginning to report interim data from this post-market study in the first half of 2025.
- A few days ago, 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<sup>®</sup> Category 1 codes and their descriptors covering the TULSA procedure, which will become effective on January 1, 2025. With the Final Rule, TULSA reimbursement was raised to Urology Level 7 Ambulatory Payment Classification ("APC") from the Urology APC Level 6 proposed in July 2024.
- The TULSA-PRO<sup>®</sup> systems installed base now totals 59. In light of the positive reimbursement news, Profound is transitioning from a pure recurring revenue model in the U.S. to a more

traditional medtech business model that includes both capital and consumable sales, as well as the sale of service/maintenance contracts.

- Today, Profound announces the promotion of Mathieu Burtnyk, PhD, from Chief Operating Officer to President to further support growth as the Company transitions to a reimbursement business model. Dr. Burtnyk, along with Rashed Dewan, Profound's CFO, and Tom Tamberrino, its Chief Commercial Officer, will continue to report to Dr. Menawat.

"As excited as we were in July that TULSA was poised to start competing with other major prostate treatment modalities on a level playing field, now with the Final Rule, not only will TULSA be uniquely reimbursed at a higher Urology APC Level 7, but also feasible at an unrivaled number of locations compared to other prostate disease treatment modalities. We believe this will enable needed physician and patient access to innovative therapy that men deserve, and be an inflection point for our business," said Arun Menawat, Profound's CEO and Chairman.

### **Third Quarter 2024 Results**

For the quarter ended September 30, 2024, the Company recorded revenue of \$2.83 million, with \$2.65 million from recurring revenue, which consists of the sale of TULSA-PRO<sup>®</sup> consumables, lease of medical devices, procedures and services associated with extended warranties, and \$179,000 for one-time sale of capital equipment. Third quarter 2024 revenue increased 64% from \$1.73 million in the same three-month period a year ago.

Total operating expenses, which consist of research and development ("R&D"), general and administrative ("G&A"), and selling and distribution ("S&D") expenses, were \$10.8 million in the third quarter of 2024, an increase of 42% compared with \$7.6 million in the third quarter of 2023.

Expenditures for R&D for the three months ended September 30, 2024 were \$4.2 million, an increase of 22% compared with \$3.4 million in the three months ended September 30, 2023, primarily due to increases in clinical trial costs, material, and salaries and benefits. The increases were the result of 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. Partially offsetting these was a decrease in share based compensation due to fewer awards granted to employees, a decrease in travel due to lower service calls and repairs, and an overall decrease to the general office expense.

G&A expenses for the 2024 third quarter were \$3.7 million, an increase of 84% compared with \$2.0 million in the three months ended September 30, 2023, primarily due to increase in salaries and benefits, consulting fees, software, office expenses, expected credit loss and bad debt as a result of 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, the overall increase in general expenses and bad debt expense associated with one customer. Partially offsetting these was a decrease to insurance expense due to lower premium rates and decrease to share based compensation due to fewer awards granted to employees.

Third quarter 2024 S&D expenses increased by 34% to \$2.9 million, compared with \$2.2 million in the third quarter of 2023. This was driven by increases in salaries and benefits, consulting fees, marketing expenses, travel and general office expenses, as a result of increased salesforce and commission payments, consultants engaged to assist with sales and marketing efforts, increased in-person conferences, meetings and largest event hosted, PRO-Talk *Live!*, coupled with an increase to the general office expenses. Partially offsetting these was a decrease in share based compensation due to fewer awards granted to employees.

Net finance expense for the three months ended September 30, 2024 was \$199,000, compared with net finance income of \$1.0 million in the three months ended September 30, 2023.

Third quarter 2024 net loss was \$9.4 million, or \$0.38 per common share, compared to \$5.6 million, or \$0.26 per common share, in the three months ended September 30, 2023.

### **Current 2024 Outlook**

As previously disclosed, based on the Company's current business planning and budgeting activities, Profound anticipates its total revenue for full-year 2024 to be in the range of \$11.0 million

to \$12.0 million, representing total year-over-year revenue growth of 53% to 67%.

## **Liquidity and Outstanding Share Capital**

As at September 30, 2024, Profound had cash of \$27.1 million.

As at November 7, 2024, Profound had 24,661,771 common shares issued and outstanding.

For complete financial results, please see Profound's filings at [www.sedarplus.ca](http://www.sedarplus.ca), [www.sec.gov](http://www.sec.gov) and on the Company's website at [www.profoundmedical.com](http://www.profoundmedical.com) under "Financial" in the Investors section.

## **Conference Call Details**

Profound Medical is pleased to invite all interested parties to participate in a conference call today at 4:30 pm ET during which time the results will be discussed.

To participate in the conference call by telephone, please pre-register via this [link](#) to receive the dial-in number and your unique PIN.

The call will also be broadcast live and archived on the Company's website at [www.profoundmedical.com](http://www.profoundmedical.com) under "Webcasts" in the Investors section.

## **About Profound Medical Corp.**

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

Profound is commercializing TULSA-PRO<sup>®</sup>, a technology that combines real-time MRI, robotically-driven transurethral ultrasound and closed-loop temperature feedback control. The TULSA procedure, performed using the TULSA-PRO<sup>®</sup> 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. TULSA employs real-time MR guidance for pixel-by-pixel precision to preserve prostate disease patients' urinary continence and sexual function, while killing the targeted prostate tissue via a precise sound absorption technology that gently heats it to kill temperature (55-57°C). TULSA 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 TULSA. 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<sup>®</sup> is CE marked, Health Canada approved, and 510(k) cleared by the U.S. Food and Drug Administration ("FDA").

Profound is also commercializing Sonalleve<sup>®</sup>, an innovative therapeutic platform that is CE marked for the treatment of uterine fibroids and palliative pain treatment of bone metastases. Sonalleve<sup>®</sup> 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. The Company is in the early stages of exploring additional potential treatment markets for Sonalleve<sup>®</sup> 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, any express or implied statements regarding current or future financial performance and position, including the Company's year 2024 financial outlook and related assumptions; 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 its future revenues/financial results. 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, statements and projections regarding financial guidance and goals and the attainment of such goals may differ from actual results based on market factors and Profound's ability to execute its operational and budget plans; and actual financial results may not be consistent with expectations, including that revenue, operating expenses and cash usage may not be within management's expected ranges. For additional risks, please see the Company's annual information form for the year ended December 31, 2023 and other disclosure documents available on [www.sedarplus.ca](http://www.sedarplus.ca) and [www.sec.gov](http://www.sec.gov). 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. 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.

### Financial Outlook

This press release contains a financial outlook within the meaning of applicable securities laws. The financial outlook has been prepared by management of the Company to provide an outlook for the Company's forecasted revenue for the 12 months to be ended December 31, 2024 and may not be appropriate for any other purpose. The financial outlook has been prepared based on a number of assumptions including the assumptions discussed under the heading "Forward-Looking Statements" herein. The actual results of the Company's operations for any period may vary from the amounts set forth in these projections and such variations may be material. The Company and its management believe that the financial outlook has been prepared on a reasonable basis. However, because this information is highly subjective and subject to numerous risks, including the risks discussed under the heading "Forward-Looking Statements" herein, it should not be relied on as necessarily indicative of future results.

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### Profound Medical Corp.

Interim Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2024 \$	December 31, 2023 \$
<b>Assets</b>		
<b>Current assets</b>		
Cash	27,123	26,213
Trade and other receivables	7,030	7,288
Inventory	6,435	6,989
Prepaid expenses and deposits	296	1,406
<b>Total current assets</b>	<b>40,884</b>	<b>41,896</b>
Property and equipment	581	909

Intangible assets	329	490
Right-of-use assets	441	616
<b>Total assets</b>	<b>42,235</b>	<b>43,911</b>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Accounts payable and accrued liabilities	3,396	3,282
Deferred revenue	801	721
Long-term debt	2,200	2,104
Lease liability	265	259
Income tax payable	15	-
<b>Total current liabilities</b>	<b>6,677</b>	<b>6,366</b>
Deferred tax liability	59	59
Long-term debt	3,398	5,000
Deferred revenue	672	728
Lease liability	365	578
<b>Total liabilities</b>	<b>11,171</b>	<b>12,731</b>
<b>Shareholders' Equity</b>		
Share capital	235,674	217,393
Contributed surplus	19,414	19,687
Accumulated other comprehensive income	16,389	12,031
Deficit	(240,413)	(217,931)
<b>Total Shareholders' Equity</b>	<b>31,064</b>	<b>31,180</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>42,235</b>	<b>43,911</b>

### Profound Medical Corp.

Interim Condensed Consolidated Statements of Loss and Comprehensive Loss  
(Unaudited)

	Three months ended September 30, 2024 \$	Three months ended September 30, 2023 \$	Nine months ended September 30, 2024 \$	Nine months ended September 30, 2023 \$
<b>Revenue</b>				
Recurring - non-capital	2,653	1,728	5,595	4,797
Capital equipment	179	-	1,380	393
	2,832	1,728	6,975	5,190
<b>Cost of sales</b>	1,026	668	2,462	1,867
<b>Gross profit</b>	<b>1,806</b>	<b>1,060</b>	<b>4,513</b>	<b>3,323</b>

<b>Operating expenses</b>				
Research and development	4,154	3,415	12,280	10,410
General and administrative	3,725	2,024	8,221	6,210
Selling and distribution	2,915	2,181	8,315	6,537
<b>Total operating expenses</b>	<b>10,794</b>	<b>7,620</b>	<b>28,816</b>	<b>23,157</b>
<b>Operating loss</b>	<b>8,988</b>	<b>6,560</b>	<b>24,303</b>	<b>19,834</b>
Net finance expense/(income)	199	(1,014)	(2,057)	(275)
<b>Loss before income taxes</b>	<b>9,187</b>	<b>5,546</b>	<b>22,246</b>	<b>19,559</b>
Income tax expense	177	18	236	101
<b>Net loss attributed to shareholders for the period</b>	<b>9,364</b>	<b>5,564</b>	<b>22,482</b>	<b>19,660</b>
<b>Other comprehensive loss/(income)</b>				
Item that may be reclassified to loss				
Foreign currency translation adjustment- net of tax	2,919	(3,915)	(4,358)	249
<b>Net loss and comprehensive loss for the period</b>	<b>12,283</b>	<b>1,649</b>	<b>18,124</b>	<b>19,909</b>
<b>Loss per share</b>				
Basic and diluted loss per common share	0.38	0.26	0.92	0.93

## Profound Medical Corp.

Interim Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	<b>Nine months ended September 30, 2024</b>	<b>Nine months ended September 30, 2023</b>
	<b>\$</b>	<b>\$</b>
<b>Operating activities</b>		
Net loss for the period	(22,482)	(19,660)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation of property and equipment	547	532
Amortization of intangible assets	151	152
Depreciation of right-of-use assets	162	163
Share-based compensation	2,139	2,510
Interest and accretion expense	489	582

Deferred revenue	64	163
Change in fair value of derivative financial instrument	-	232
Net change in amortized cost of trade and other receivables	(238)	(119)
Changes in non-cash working capital balances		
Trade and other receivables	310	(155)
Prepaid expenses and deposits	1,140	574
Inventory	181	(54)
Accounts payable and accrued liabilities	162	165
Income taxes payable	14	45
Foreign exchange on cash	(450)	(410)
<b>Net cash flow used in operating activities</b>	<b>(17,811)</b>	<b>(15,280)</b>
<b>Financing activities</b>		
Issuance of common shares	22,938	-
Transactions cost paid	(1,859)	-
Payment of long-term debt	(1,819)	(489)
Proceeds from share options exercised	1	241
Proceeds from warrants exercised	-	2,423
Payment of lease liability	(218)	(220)
<b>Total cash flow from financing activities</b>	<b>19,043</b>	<b>1,955</b>
Net change in cash during the period	1,232	(13,325)
Foreign exchange on cash	(322)	433
Cash – Beginning of period	26,213	46,517
<b>Cash – End of period</b>	<b>27,123</b>	<b>33,625</b>