

Profound Medical Announces Third Quarter 2022 Financial Results

TORONTO, Nov. 03, 2022 -- [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, 2022. 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.

Third Quarter 2022 and Recent Corporate Highlights

- The Current Procedural Terminology ("CPT®") Category 1 application for Transurethral Ultrasound Ablation ("TULSA"), performed with its TULSA-PRO® system, was withdrawn for consideration at the September 2022 CPT® Editorial Panel Meeting. The Company anticipates submitting an updated application, which will include 2022 utilization data, at the appropriate time in 2023.
- Profound made changes to its commercial organization to support continued growth, which included the appointments of Abbey Goodman and Hartmut Warnken as Chief Commercial Officer – U.S. and Chief Commercial Officer – OUS, respectively, with each having overall responsibility for leading Profound's commercial strategy, sales, sales operations, and marketing activities in their corresponding geographies.
- At the FOCAL 2022 conference, Laurence Klotz, M.D., FRCSC, CM, Professor of Surgery, University of Toronto and Sunnybrook Chair of Prostate Cancer Research, presented four-year follow-up data from the TACT (TULSA-PRO® Ablation Clinical Trial) pivotal study which continued to demonstrate durable and stable safety and efficacy outcomes following TULSA treatment of men with localized prostate cancer.
- On November 3, 2022, the Company entered into a term loan agreement with CIBC Innovation Banking to provide a secured loan for total initial gross proceeds of C\$10.0 million, maturing 5 years from the closing date, with an interest rate based on prime plus 2.0% (the "2022 CIBC Term Loan"). The Company is required to make interest-only payments for 12 months after the closing date, followed by 48 equal monthly principal payments, plus accrued interest. All obligations of the Company under the term 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.

"As clinical data continue to demonstrate that TULSA is the best modality when it comes to prostate cancer treatment outcomes and side effects, and more physicians learn of our technology's flexibility to treat an unrivaled variety of prostate disease patients, our confidence is growing in its potential to change the current standard of care," said Dr. Menawat. "Among the keys to reaching that level of long-term success will be continuing to expand our installed base of TULSA-PRO® systems and helping to drive increased per-site utilization."

Summary Third Quarter 2022 Results

For the quarter ended September 30, 2022, the Company recorded revenue of approximately \$2.0 million, compared to approximately \$2.5 million for the same three-month period a year ago. Recurring revenue, which consists of the sale of TULSA-PRO® consumables, lease of medical devices, procedures and services associated with extended warranties, increased approximately 14% to \$1.2 million, while one-time sale of capital equipment declined 45% to \$800,000.

Total operating expenses, which consist of research and development ("R&D"), general and administrative ("G&A"), and selling and distribution expenses, were approximately \$9.3 million in the third quarter of 2022, an increase of 8% compared with approximately \$8.6 million in the third quarter of 2021.

Expenditures for R&D for the three months ended September 30, 2022 were approximately \$4.7 million, an increase of 17% compared with approximately \$4.1 million in the three months ended September 30, 2021, primarily driven by CAPTAIN trial enrolment and treatment of patients, various quality and cost improvement projects, traveling for off-site MRI testing and site installation, and additional headcount. These were offset partially by decreases in share-based compensation and software licence costs.

G&A expenses for the 2022 third quarter decreased by 5% to approximately \$2.4 million, compared with approximately \$2.5 million in the same period in 2021, due to a decrease in share-based compensation, partially offset by additional headcount and new license costs for enterprise resource planning (ERP) and customer relationship management (CRM) software.

Third quarter 2022 selling and distribution expenses increased by 8% to approximately \$2.2 million, compared with \$2.0 million in the third quarter of 2021. While selling and distribution expenses have historically been lower than R&D expenses, Profound continues to expect that, in the future, selling and distribution expenses will exceed R&D expenses as the Company continues to commercialize the TULSA-PRO® system in the United States.

Primarily due to a higher foreign exchange gain, net finance income for the three months ended September 30, 2022 was approximately \$3.3 million, compared with approximately \$1.7 million in the three months ended September 30, 2021.

Third quarter 2022 net loss was approximately \$5.0 million, or \$0.24 per common share, compared to approximately \$6.0 million, or \$0.29 per common share, in the three months ended September 30, 2021.

Liquidity and Outstanding Share Capital

As at September 30, 2022, Profound had cash of approximately \$46.2 million. The Company noted that this did not include any of the proceeds from the C\$10.0 million 2022 CIBC Term Loan, which closed subsequent to quarter end.

As at November 3, 2022, Profound had 20,876,027 common shares issued and outstanding.

For complete financial results, please see Profound's filings at www.sedar.com, www.sec.gov and on the Company's website at 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 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[®], a technology that combines real-time MRI, robotically-driven transurethral ultrasound and closed-loop temperature feedback control. TULSA-PRO[®] is designed to provide customizable and predictable radiation-free ablation of a surgeon-defined prostate volume while actively protecting the urethra and rectum to help preserve the patient's natural functional abilities. TULSA-PRO[®] has the potential to be a flexible technology in customizable prostate ablation, including intermediate stage cancer, localized radio-recurrent cancer, retention and hematuria palliation in locally advanced prostate cancer, and the transition zone in large volume benign prostatic hyperplasia ("BPH"). 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 and palliative pain treatment of bone metastases. 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. The Company 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. 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. In addition, there is uncertainty about the spread of the COVID-19 virus and the impact it will have on Profound's operations, the demand for its products, global supply chains and economic activity in general. 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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Profound Medical Corp.

Interim Condensed Consolidated Balance Sheets

In USD (000s)

(Unaudited)

	September 30, 2022 \$	December 31, 2021 \$
Assets		
Current assets		
Cash	46,208	67,152
Trade and other receivables	3,458	1,412
Inventory	7,440	7,413
Prepaid expenses and deposits	447	1,148
Total current assets	57,553	77,125
Trade and other receivables	2,569	3,622
Property and equipment	891	788
Intangible assets	721	1,435
Right-of-use assets	863	1,116
Goodwill	2,487	2,689
Total assets	64,084	86,775
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	2,537	3,180
Deferred revenue	479	477
Provisions	57	87
Derivative financial instruments	13	161
Lease liabilities	230	250
Total current liabilities	3,316	4,155
Deferred revenue	779	875
Lease liabilities	870	1,127
Total liabilities	4,965	6,157
Shareholders' Equity		
Share capital	203,398	219,579
Contributed surplus	16,818	16,986
Accumulated other comprehensive income	19,738	4,746
Deficit	(179,835)	(160,693)
Total Shareholders' Equity	60,119	80,618
Total Liabilities and Shareholders' Equity	65,084	86,775

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Interim Condensed Consolidated Statements of Loss and Comprehensive Loss/Income

In USD (000s)

(Unaudited)

	Three months ended September 30, 2022 \$	Three months ended September 30, 2021 \$	Nine months ended September 30, 2022 \$	Nine months ended September 30, 2021 \$
Revenue				
Capital equipment	800	1,457	2,004	3,150
Recurring - non-capital	1,235	1,080	3,420	2,725
	2,035	2,537	5,424	5,875
Cost of sales	945	1,550	2,962	3,420
Gross profit	1,090	987	2,462	2,455
Operating expenses				
Research and development	4,733	4,054	11,601	10,578
General and administrative	2,393	2,506	7,371	7,091
Selling and distribution	2,198	2,034	6,794	5,349
Total operating expenses	9,324	8,594	25,766	23,018
Operating Loss	8,234	7,607	23,304	20,563
Net finance income	(3,271)	(1,663)	(4,243)	(161)
Loss before taxes	4,963	5,944	19,061	20,402
Income taxes	34	52	81	136
Net loss attributed to shareholders for the period	4,997	5,996	19,142	20,538
Other comprehensive loss				
Item that may be reclassified to loss				
Foreign currency translation adjustment - net of tax	11,103	3,931	14,992	1,016
Net loss and comprehensive loss/(income) for the period	(6,106)	2,065	4,150	19,522
Loss per share				
Basic and diluted loss per common share	0.24	0.29	0.92	1.01

Profound Medical Corp.

Interim Condensed Consolidated Statements of Cash Flows

In USD (000s)

(Unaudited)

	Nine months ended September 30, 2022 \$	Nine months ended September 30, 2021 \$
Operating activities		
Net loss for the period	(19,142)	(20,538)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation of property and equipment	520	371
Amortization of intangible assets	654	763
Depreciation of right-of-use assets	174	249
Share-based compensation	3,673	4,792
Interest and accretion expense	46	67
Deferred revenue	13	31

Change in fair value of derivative financial instruments	(145)	(183)
Interest income on trade and other receivables	(251)	-
Changes in non-cash working capital balances		
Trade and other receivables	(1,235)	(531)
Prepaid expenses and deposits	654	974
Inventory	(1,294)	(2,025)
Accounts payable and accrued liabilities	(476)	(1,237)
Provisions	(25)	3
Income taxes payable	-	(13)
Foreign exchange on cash	(2,348)	(30)
Net cash flow used in operating activities	(19,182)	(17,307)
Investing activities		
Purchase of property and equipment	-	(32)
Purchase of intangible assets	-	(434)
Total cash used in investing activities	-	(466)
Financing activities		
Payment of other liabilities	-	(99)
Proceeds from share options exercised	263	582
Proceeds from warrants exercised	-	5,839
Payment of lease liabilities	(240)	(286)
Total cash from financing activities	23	6,036
Net change in cash during the period	(19,159)	(11,737)
Foreign exchange on cash	(1,785)	42
Cash – Beginning of period	67,152	83,913
Cash – End of period	46,208	72,218