

Profound Medical Announces Fourth Quarter and Full Year 2020 Financial Results

TORONTO, March 02, 2021 (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 fourth quarter and full year ended December 31, 2020.

Change in Presentation Currency

Effective December 31, 2020, Profound changed its presentation currency from the Canadian dollar to the United States dollar. The Company believes that changing its presentation currency to U.S. dollars will result in more relevant and reliable information for its financial statement users, and will more accurately reflect the results of its operations.

For the period ended September 30, 2020 and for all prior periods, Profound presented its financial statements in Canadian dollars. The comparative figures disclosed in this press release have been retrospectively changed to reflect the change in presentation currency to the U.S. dollar, as if the U.S. dollar had been used as the presentation currency for all prior periods. 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.

Full Year 2020 and Recent Corporate Highlights

- On January 10, 2020, Profound signed its first U.S. multi-site imaging center agreement for TULSA-PRO[®] with [RadNet, Inc.](#), a national leader in providing diagnostic imaging services through a network of 334 owned and/or operated outpatient imaging centers.
- On January 10, 2020, Profound announced that it had submitted its application for a Healthcare Common Procedure Coding System C-Code from the Centers for Medicare & Medicaid Services ("CMS") for the TULSA-PRO[®] procedure. Subsequent to this announcement, based upon feedback that Profound received from CMS and potential hospital customers, the Company requested that CMS set aside its application and recommends that hospitals consider using a previously established C-Code. In addition, as part of its overall reimbursement strategy, Profound continues to plan and conduct additional trials designed to support TULSA-PRO[®] to potentially qualify for a specific CPT code.
- On January 27, 2020, the Company closed an underwritten offering of common shares, including the full exercise of the over-allotment option, for gross proceeds of approximately \$39.5 million.
- On February 4, 2020, Profound announced that it had retired its C\$12.5 million in principal amount loan with Canadian Imperial Bank of Commerce approximately 30 months ahead of schedule, thereby extinguishing all of its long-term debt.
- On April 3, 2020, Profound launched a TULSA procedure website, www.tulsaprocedure.com, as a resource for patients with prostate disease.
- On July 21, 2020, Profound closed an underwritten offering of common shares, including the full exercise of the over-allotment option, for gross proceeds of approximately \$46.0 million.
- On November 30, 2020, the Company announced the resignation of Dr. Linda Maxwell from its Board of Directors and the appointment of Murielle Lortie, CPA, CA.
- On November 30, 2020, Profound announced that Sonalleve[®] received U.S. Food and Drug Administration approval under a Humanitarian Device Exemption for the treatment of osteoid osteoma.
- On December 21, 2020, Profound announced an agreement with GE Healthcare to expand provider access to TULSA-PRO[®].

"We are energized for 2021 after having successfully executed against our strategic priorities last year," said Arun Menawat, Profound's CEO. "Our continuing focus is on our U.S. commercial activities. While our near-term outlook for TULSA-PRO[®] adoption remains cautious in the face of COVID-19 headwinds, we are encouraged by the growing interest in the technology we are seeing from both surgeons and prostate disease patients across the United States."

Summary Fourth Quarter 2020 Results

For the quarter ended December 31, 2020, the Company recorded revenue of approximately \$2.9 million, with \$2.6 million from the sale of products, \$145,000 from pay per procedure and \$179,000 from installation, training and support of the multi-use system components. This was slightly higher than the Company's preliminary unaudited revenue estimate of \$2.8 million (C\$3.7 million) announced on January 5, 2021, and represented revenue growth of 36% year-over-year and 29% sequentially over the previous quarter.

Total operating expenses, which consist of research and development (“R&D”), general and administrative (“G&A”), and selling and distribution expenses, were approximately \$6.1 million in the fourth quarter of 2020, an increase of 14% compared with approximately \$5.3 million in the fourth quarter of 2019.

Expenditures for R&D for the three months ended December 31, 2020 were approximately \$2.5 million, an increase of 4% compared with approximately \$2.4 million in the three months ended December 31, 2019, primarily driven by increased spending for the setup and administrative costs of new clinical trials, options awarded to employees, additional headcount and overall increase to general expenses, partially offset by decreases in materials costs, consulting fees and travel expenses. G&A expenses for the 2020 fourth quarter decreased by 6% to approximately \$1.8 million, compared with approximately \$1.9 million in the same period in 2019, due to lower consulting fees, travel, software, bad debt and depreciation expenses, which were partially offset by increases in salaries and benefits and share based compensation. Fourth quarter 2020 selling and distribution expenses increased by 79% to approximately \$1.7 million, compared with \$977,000 in the fourth quarter of 2019. Historically, selling and distribution expenses have been lower than R&D expenses; however, in the future, Profound expects selling and distribution expenses to exceed R&D expenses as the Company continues to commercialize the TULSA-PRO[®] system in the United States.

Fourth quarter 2020 net loss was approximately \$7.5 million, or \$0.38 per common share, compared to approximately \$3.9 million, or \$0.33 per common share, in the three months ended December 31, 2019.

Summary Full Year 2020 Results

For the year ended December 31, 2020, the Company recorded revenue of approximately \$7.3 million, with \$6.2 million from the sale of products, \$347,000 from pay per procedure and \$724,000 from installation, training and support of the multi-use system components. This represents an increase of 75% from approximately \$4.2 million in the twelve months ended December 31, 2019.

Profound's full year 2020 total operating expenses were approximately \$22.3 million, a 29% increase compared to approximately \$17.3 million in the same period of 2019.

Expenditures for R&D for the year ended December 31, 2020 were approximately \$9.9 million, an increase of 5% compared with approximately \$9.4 million in the year ended December 31, 2019, primarily driven by increased spending on materials and R&D projects for technology improvements and upgrades, options awarded to employees and additional headcount, partially offset by lower clinical trial costs, consulting fees and travel expenses. Full year 2020 G&A expenses increased by 31% to approximately \$7.6 million, compared with approximately \$5.8 million in 2019, due to salary increases and bonuses awarded to management, options issued to employees, increased insurance costs associated with being Nasdaq listed and overall increase in general costs, offset partially by lower depreciation expenses, travel costs and consulting fees. Selling and distribution expenses for the year ended December 31, 2020 increased by 131% to approximately \$4.9 million, compared with \$2.1 million in the year ended December 31, 2019.

The Company recorded a net loss for the year ended December 31, 2020 of approximately \$21.6 million, or \$1.25 per common share, compared to approximately \$15.1 million, or \$1.37 per common share, for the year ended December 31, 2019.

Liquidity and Outstanding Share Capital

As at December 31, 2020, Profound had cash of approximately \$83.9 million.

As at March 2, 2021, Profound had 20,289,899 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, March 2, 2021, at 4:30 pm ET during which time the results will be discussed.

Live Call: 1-833-710-1825 (Canada and the United States)
1-929-517-0404 (International)

Replay: 1-404-537-3406

Passcode: 7999443

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, 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.

For further information, please contact:

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Profound Medical Corp. Consolidated Balance Sheets In USD (000s)

	2020	2019
	\$	\$
Assets		
Current assets		
Cash	83,913	14,800
Trade and other receivables	7,431	3,125
Investment tax credits receivable	-	185
Inventory	5,331	3,668
Prepaid expenses and deposits	1,067	1,028
Total current assets	97,742	22,806
Property and equipment	859	527
Intangible assets	1,898	2,409
Right-of-use assets	1,424	1,693
Goodwill	2,678	2,625
Total assets	104,601	30,060

Liabilities

Current liabilities

Accounts payable and accrued liabilities	3,382	3,028
Deferred revenue	358	504
Long-term debt	-	3,961
Provisions	195	104
Other liabilities	99	221
Derivative financial instrument	450	196
Lease liabilities	312	199
Income taxes payable	13	11
Total current liabilities	4,809	8,224

Long-term debt	-	5,174
Deferred revenue	1,078	639
Provisions	-	15
Lease liabilities	1,364	1,637

Total liabilities	7,251	15,689
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Shareholders' Equity

Share capital	211,527	100,298
Contributed surplus	11,250	15,076
Accumulated other comprehensive loss	4,567	7,369
Deficit	(129,994)	(108,372)

Total Shareholders' Equity	97,350	14,371
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Total Liabilities and Shareholders' Equity	104,601	30,060
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Profound Medical Corp.

Consolidated Statements of Loss and Comprehensive Loss
In USD (000s)

	2020	2019
	\$	\$
Revenue		
Products	6,233	3,697
Services	724	477
Pay per procedure	347	-
	7,304	4,174
Cost of sales	3,830	1,784
Gross profit	3,474	2,390
Operating expenses		
Research and development	9,912	9,397
General and administrative	7,565	5,793
Selling and distribution	4,860	2,104
Total operating expenses	22,337	17,294
Operating Loss	18,863	14,904
Net finance costs	2,714	171
Loss before taxes	21,577	15,075

Income taxes	45	147
Net loss attributed to shareholders for the year	21,622	15,222
Other comprehensive loss		
Item that may be reclassified to loss		
Foreign currency translation adjustment - net of tax	2,802	4,490
Net loss and comprehensive loss for the year	24,424	19,712
Loss per share		
Basic and diluted loss per common share	1.25	1.37

Profound Medical Corp.

Consolidated Statements of Cash Flows

In USD (000s)

	2020	2019
	\$	\$
Operating activities		
Net loss for the year	(21,622)	(15,222)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation of property and equipment	352	394
Amortization of intangible assets	881	856
Depreciation of right-of-use assets	305	261
Share-based compensation	3,018	1,266
Interest and accretion expense	543	1,040
Deferred revenue	257	598
Change in fair value of derivative financial instrument	237	118
Change in fair value of contingent consideration	90	(623)
Changes in non-cash working capital balances		
Investment tax credits receivable	179	181
Trade and other receivables	(4,028)	(1,034)
Prepaid expenses and deposits	(17)	(833)
Inventory	(2,141)	(854)
Accounts payable and accrued liabilities	102	(83)
Provisions	71	(903)
Income taxes payable	1	(212)
Foreign exchange on cash	1,198	-
Net cash flow used in operating activities	(20,574)	(15,050)
Investing activities		
Purchase of intangible assets	(350)	(189)
Total cash used in investing activities	(350)	(189)
Financing activities		
Issuance of common shares	85,523	8,709
Transaction costs paid	(6,429)	(776)
Payment of other liabilities	(212)	(89)
Payment of long-term debt and interest	(9,317)	(1,009)
Proceeds from share options exercised	1,826	4
Proceeds from warrants exercised	16,331	-
Payment of lease liabilities	(289)	(241)
Total cash from financing activities	87,433	6,598
Net change in cash during the year	66,509	(8,641)
Foreign exchange on cash	2,604	946
Cash – Beginning of year	14,800	22,495

Cash – End of year

83,913

14,800
