

Profound Medical Announces First Quarter 2019 Financial Results

- Receives Notification of FDA Acceptance of 510(k) Application Filing for TULSA-PRO® -

TORONTO, May 06, 2019 -- [Profound Medical Corp.](#) (TSX:PRN; OTCQX:PRFMF) ("Profound" or the "Company"), the only company to provide customizable, incision-free therapies which combine real-time Magnetic Resonance Imaging ("MRI"), thermal ultrasound and closed-loop temperature feedback control for the radiation-free ablation of diseased tissue, today reported financial results for the three months ended March 31, 2019, and provided an update on its operations.

Recent Corporate Highlights

- On January 21, 2019, the Company and Siemens Healthcare GmbH ("Siemens") executed a new co-marketing and co-selling agreement, pursuant to which all prior financial commitments and obligations owed to Siemens under the previous agreement were released and replaced with a one-time, fixed license fee of US\$100,000 and a relatively small annual license fee for each TULSA-PRO® system interfaced to a Siemens MRI Scanner.
- On April 4, 2019, Profound announced positive [topline results](#) from the TACT (TULSA-PRO® Ablation Clinical Trial) pivotal study designed to support its application to the U.S. Food and Drug Administration ("FDA" or the "Agency") for 510(k) clearance to market TULSA-PRO® in the United States. In the TACT trial, all primary efficacy and safety endpoints, as well as all key secondary endpoints, were achieved.
- On April 11, 2019, the Company hosted its first [Analyst & Investor Day](#) in New York, NY. The program featured presentations on TULSA-PRO® from key opinion leaders in the United States who have gained first-hand experience with the technology as investigators for the TACT trial and from current commercial users in Europe. In addition, leading global researchers and clinicians presented on both current and potential future applications for Sonalleve®.
- On April 17, 2019, Profound announced that the first prostate cancer treatment using a first-of-its-kind installation combining its TULSA-PRO® system with Philips' newest digital MR solution, the Ingenia Elition, was performed in Trier, Germany.
- On May 5, 2019, Dr. Scott Eggener, Chief Investigator of the TACT study, and Director of the Prostate Cancer Program at the University of Chicago, shared detailed results from TACT during a [late-breaking abstract](#) presentation as part of the plenary session programming at the American Urological Association's ("AUA") 2019 Annual Meeting being held in Chicago, IL.

"Building on this quarter's financial results, momentum from the compelling pivotal clinical trial data from TACT, positive user feedback on TULSA-PRO® and Sonalleve® presented by leading researchers and clinicians during our first Analyst & Investor Day event, and the strong reception that TULSA-PRO® received at AUA, we are very well positioned for growing commercial traction throughout the remainder of 2019," said Arun Menawat, Profound's CEO.

510(k) Application Acceptance for TULSA-PRO®

Profound announced today that its 510(k) application for premarket clearance filed recently with the FDA for TULSA-PRO® has cleared the Agency's acceptance review. The application now moves to a substantive review. The Company's TACT clinical trial, designed to support the 510(k) application, demonstrated that treatment with TULSA-PRO® provides safe and effective prostate tissue ablation, with little impact on men's functional ability compared to well-established treatment modalities such as radical prostatectomy and radiation therapy. The study also demonstrated a superior risk-benefit profile compared to other ablative approaches, including whole-gland HIFU and cryotherapy.

Dr. Menawat commented, "With the FDA having found that our submission contained all the necessary elements and information, we look forward to the Agency's substantive review and clearance of TULSA-PRO®."

Summary First Quarter 2019 Results

All amounts, unless specified otherwise, are expressed in Canadian dollars and are presented in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, applicable to the preparation of interim financial statements, including IAS 34, Interim Financial Reporting.

For the quarter ended March 31, 2019, the Company recorded revenue of \$1,475,788, with \$1,347,781 from the sale of products and \$128,007 from installation and training services. First quarter 2019 revenue increased approximately 292% from \$376,335 in the same three-month period a year ago.

The Company recorded a net loss for the three months ended March 31, 2019 of \$2,926,686, or \$0.03 per common share, compared to a net loss of \$4,938,186, or \$0.06 per common share, for the three months ended March 31, 2018. The decrease

in net loss was primarily attributed to a decrease in selling and distribution expenses of \$1,476,247, net finance costs of \$107,355 and an increase in gross profit of \$797,172. These were partially offset by an increase in research and development ("R&D") expenses of \$160,965 and an increase in general and administration (G&A") expenses of \$210,909.

Expenditures for R&D for the three months ended March 31, 2019 increased \$160,965 compared to the three months ended March 31, 2018. Materials increased by \$489,386 due to increased spending and testing on R&D projects and investment tax credits decreased by \$60,000 because of lower eligibility for refundable tax credits. Offsetting these amounts were decreases in clinical trial costs, consulting fees and rent of \$332,549, \$52,210 and \$38,030, respectively, due to the completion of the TACT trial enrollment initiatives and the adoption of IFRS 16 resulting in the recognition of lower rental costs. Depreciation expense increased by \$28,412 partly due to the adoption of IFRS 16 with the depreciation of the right-of-use assets.

G&A expenses for the first quarter of 2019 were higher by \$210,909 compared to the three months ended March 31, 2018. Salaries and benefits increased by \$195,151 due to increased employee head count, board members and overall salary increases. These costs were offset by a decrease in rent and office and other of \$15,470 and \$18,508, respectively, due to the adoption of IFRS 16 resulting in lower rental costs and decreased spending on office supplies. Depreciation expenses increased by \$73,580 partly due to the adoption of IFRS 16 with the depreciation of the right-of-use assets.

Liquidity and Outstanding Share Capital

As at March 31, 2019, the Company had cash of \$27,048,837.

As at May 6, 2019, Profound had an unlimited number of authorized common shares with 108,054,939 common shares issued and outstanding.

For complete financial results, please see our filings at www.sedar.com and our website at www.profoundmedical.com.

Conference Call Details

Profound Medical is pleased to invite all interested parties to participate in a conference call today, May 6, 2019, at 4:30 pm.ET during which time the results will be discussed.

Live Call: 1-877-407-9210 (Canada and the United States)
1-201-689-8049 (International)

Replay: 1-919-882-2331
Replay ID: 46016

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 develops and markets customizable, incision-free therapies for the ablation of diseased tissue.

Profound is commercializing TULSA-PRO[®], a novel 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[®] is CE marked and commercially launched in key European and other CE mark jurisdictions. TULSA-PRO[®] is demonstrating 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).

Profound recently announced positive topline results from a multicenter, prospective clinical trial, TACT. In the TACT trial, all primary efficacy and safety endpoints, as well as all key secondary endpoints, were achieved. Data from the TACT trial are expected to support Profound's recent application to the FDA for 510(k) clearance to market TULSA-PRO[®] in the United States.

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 Food and Drug Administration for the non-invasive treatment of uterine fibroids. 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 and

palliative pain treatment. 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 pharmaceutical industry, 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. 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

Profound Medical Corp.

Interim Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2019 \$	December 31, 2018 \$
Assets		
Current assets		
Cash	27,048,837	30,687,183
Trade and other receivables	3,046,677	2,686,112
Investment tax credits receivable	480,000	480,000
Inventory	3,414,010	3,631,623
Prepaid expenses and deposits	183,220	434,871
Total current assets	34,172,744	37,919,789
Property and equipment	1,048,399	1,207,357
Intangible assets	3,731,451	4,013,561
Right-of-use assets	2,513,092	-
Goodwill	3,409,165	3,409,165
Total assets	44,874,851	46,549,872
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	3,581,671	3,912,350
Deferred revenue	417,669	312,558
Long-term debt	1,962,416	1,339,583
Provisions	99,890	1,352,017
Other liabilities	618,491	567,296
Derivative financial instrument	155,674	98,203
Lease liabilities	203,807	-
Income taxes payable	309,926	297,353
Total current liabilities	7,349,544	7,879,360

Long-term debt	9,966,848	10,615,662
Deferred revenue	712,239	379,044
Provisions	45,744	49,319
Other liabilities	578,393	1,000,153
Lease liabilities	2,335,767	-
Total liabilities	20,988,535	19,923,538
Shareholders' Equity		
Share capital	120,932,404	120,932,404
Contributed surplus	16,828,932	16,756,294
Accumulated other comprehensive loss	(75,092)	(28,703)
Deficit	(113,799,928)	(111,033,661)
Total Shareholders' Equity	23,886,316	26,626,334
Total Liabilities and Shareholders' Equity	44,874,851	46,549,872

Profound Medical Corp.

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

	Three months ended March 31, 2019 \$	Three months ended March 31, 2018 \$
Revenue		
Products	1,347,781	372,494
Services	128,007	3,841
Total revenue	1,475,788	376,335
Cost of sales	533,356	231,075
Gross profit	942,432	145,260
Expenses		
Research and development - net of investment tax credits of \$nil (2018 – \$60,000)	2,677,746	2,516,781
General and administrative	1,514,113	1,303,204
Selling and distribution - net of revenue share obligation reversal	(529,345)	946,902
Total expenses	3,662,514	4,766,887
Finance costs	314,685	319,963
Finance income	(141,881)	(39,804)

Net finance costs	172,804	280,159
Loss before income taxes	2,892,886	4,901,786
Income tax expense	33,800	36,400
Net loss attributable to shareholders for the period	2,926,686	4,938,186
Other comprehensive income		
Item that may be reclassified to profit or loss		
Foreign currency translation adjustment - net of tax	(46,389)	43,248
Net loss and comprehensive loss for the period	2,880,297	4,981,434
Basic and diluted weighted average shares outstanding	108,054,939	77,334,044
Basic and diluted loss per common share	0.03	0.06

Profound Medical Corp.

Interim Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended March 31, 2019 \$	Three months ended March 31, 2018 \$
Cash provided by (used in)		
Operating activities		
Net loss for the period	(2,926,686)	(4,938,186)
Depreciation of property and equipment	129,325	141,729
Amortization of intangible assets	282,110	282,109
Depreciation of right-of-use assets	102,224	-
Share-based compensation	72,638	241,058
Interest and accretion expense	342,012	187,597
Change in deferred rent	-	6,048
Deferred revenue	438,306	9,138
Change in fair value of derivative financial instrument	57,471	-
Change in fair value of contingent consideration	(72,876)	48,647
Net change in non-cash working capital balances		
Investment tax credits receivable	-	(60,000)
Trade and other receivables	(360,565)	3,205,680
Prepaid expenses and deposits	41,650	(206,100)
Inventory	217,613	(391,994)
Accounts payable and accrued liabilities	(347,454)	(2,321,907)
Provisions	(1,206,383)	34,498
Income taxes payable	12,573	40,340
Total cash used in operating activities	(3,218,042)	(3,721,343)
Financing activities		
Issuance of common shares	-	34,500,000
Transaction costs paid	-	(2,194,123)
Payment of other liabilities	(8,545)	(143,897)
Payment of long-term debt and interest	(331,490)	(1,528,897)
Payment of lease liabilities	(80,269)	-

Total cash (used in) provided by financing activities	(420,304)	30,633,083
Increase (decrease) in cash during the period	(3,638,346)	26,911,740
Cash – Beginning of period	30,687,183	11,103,223
Cash – End of period	27,048,837	38,014,963