Profound Medical Corp. Announces Fourth Quarter and Full Year 2016 Financial Results

TORONTO, March 06, 2017 (GLOBE NEWSWIRE) -- Profound Medical Corp. (TSX-V:PRN) ("Profound" or the "Company"), an emerging medical device company focused on prostate care, today reported financial results for the fourth quarter and full year ended December 31, 2016. 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.

2016 Corporate Highlights

- On February 29, 2016, Profound announced a strategic collaboration agreement with Siemens Healthcare to help advance the commercial launch of Profound's TULSA-PRO® system.
- On April 13 2016, the Company received CE Mark approval for the commercial sale of TULSA-PRO® system.
- On May 11, 2016, Profound announced that it had signed a sales and marketing agreement with Royal Philips to further advance the commercialization of TULSA-PRO® system in Europe followed by Canada, the United States, and other markets, subject to regulatory clearance in those jurisdictions.
- On September 22, 2016, the Company announced that the first patient had been treated in the TACT Pivotal Clinical Trial, designed to further evaluate the safety and efficacy of TULSA-PRO® system to ablate prostate tissue in patients with localized, organ-confined prostate cancer, at Vanderbilt University Medical Center in Nashville, TN.
- On November 14, 2016, Profound announced that it had completed a bought deal offering of 15,820,000 common shares of the Company at a price of $1.10 per common share for gross proceeds of approximately $17.4 million.

"2016 was an historic year for Profound in its journey to establish TULSA-PRO® system as a new therapeutic standard in prostate cancer," commented Dr. Arun Menawat, the Company's CEO. "With the invaluable support of our commercial partners, the financial resources required to complete the TACT Pivotal Clinical Trial, and the early success of our pilot commercial launch in Europe, Profound is very well-positioned to continue its strong growth trajectory in 2017. We look forward to updating our stakeholders on Profound's progress in the months ahead."

Summary of Full Year 2016 Results

The Company recorded a net loss for the year ended December 31, 2016 of $16,326,769 or $0.39 per common share, compared with a net loss of $16,375,741 or $0.69 per common share for the year ended December 31, 2015. For the year ended December 31, 2016, the increase in net loss was primarily attributed to higher R&D expenses of $4,851,845, offset by lower finance costs of $5,206,614 and G&A expenses of $434,328. Finance costs were significantly lower in 2016 due to costs incurred in 2015 with respect to the Company's qualifying transaction and the acceleration of the accretion on the preferred

shares at the time of their conversation to common shares. For the year ended December 31, 2015, the net loss was attributed to the finance costs related to the listing expense of the qualifying transaction of $2,058,234, the loss on recognition of the convertible notes of $2,094,565, the interest and accretion expense of $5,625,257 largely related to acceleration of the accretion of the preferred shares at the time of their conversion to common shares, partially offset by the gain in fair value of derivatives of $2,084,652, partially offset by the gain on conversion of the Notes of $1,759,885, the ongoing R&D expenses of $5,136,848, and the G&A expenses of $6,086,049.

Expenditures for R&D for the year ended December 31, 2016 were higher by $4,851,845 compared to the year ended December 31, 2015. The increase was primarily related to the preparation of clinical data from the 30 patient TULSA safety and feasibility trial. The increase was also due to preparations for an Investigational Device Exemption from the U.S. Food and Drug Administration and Institutional Review Board submissions to support a 510(k) submission in the United States to provide a pathway for Class II device classification for the TULSA-PRO® system. In addition, the increase included costs related to development initiatives associated with the TACT Pivotal Clinical Trial, including an increase in salaries and benefits of $1,398,341, an increase in consulting expenses of $923,990, an increase in clinical trial expenses of $708,869 and an increase in materials costs of $641,941. Other expenses included an increase of $295,943 primarily related to insurance costs for the TACT Pivotal Clinical Trial and increased freight costs attributed to shipping products to hospitals, and an increase in rent expense by $175,564, while investment tax credits were lowered by $430,825.

G&A expenses for the year ended December 31, 2016 were lower by $434,328 compared to the year ended December 31, 2015. This decrease was primarily due to a non-recurring marketing expense of $2,303,034 related to the excess of proceeds received on the $4,000,000 secured loan from Knight Therapeutics, which represented additional value provided to the Company, as a result of the Knight relationship. This was offset by higher salaries and benefits of $617,932, related to the recruitment of new members on the senior management team. In addition, professional and consulting fees increased by $382,251 and office and other expenses increased by $344,631, which included higher insurance premiums due to increased liability limits.

Summary Fourth Quarter 2016 Results

The Company recorded a net loss for the three months ended December 31, 2016 of $4,788,617 or $0.10 per common share, compared with a net loss of $2,769,896 or $0.07 per common share for the three months ended December 31, 2015. For the three months ended December 31, 2016, the net loss was primarily attributed to an increase in R&D expenses of $1,220,321 and an increase in G&A expenses of $1,058,585 over the prior quarter.

Expenditures for R&D for the three months ended December 31, 2016 were higher by $1,220,321 compared to the three months ended December 31, 2015. This increase was primarily related to development initiatives associated with the TACT Pivotal Clinical Trial, such as the ongoing activities related to initiation of clinical site visits, enrolment initiatives and patient treatments. As a result, salaries and benefits increased by $315,415, primarily due to higher headcount and an annual discretionary bonus, which was paid for the first time in 2016. In addition, material expenses increased by $308,017 and clinical trial costs increased by $248,584 compared to the prior period in 2015, respectively.

G&A expenses for the three months ended December 31, 2016 were higher by $1,058,585 compared to the three months ended December 31, 2015. The Company formed a German sales office in January 2016 and recruited a new Chief Executive Officer, Mr. Arun Menawat, resulting in an increase to salaries and

benefits expense of $312,755. In addition, share option expense increased by $396,918 and rent, office and other expenses increased by $205,759, respectively.

Liquidity and Outstanding Share Capital

As of December 31, 2016, the Company had cash and short-term investments of $20,833,061, compared to $20,522,520 as of December 31, 2015.
As at March 6, 2017, Profound had an unlimited number of authorized common shares with 55,319,327 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, March 6, 2017, at 5:00 p.m. ET during which time the results will be discussed. Also on the call to provide first-hand insights on the use of the TULSA-PRO® system in clinical practice will be Dr. Joseph L. Chin, Chief of Surgical Oncology for the London Health Sciences Centre at Western University.

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

Replay: 1-877-481-4010 (Canada and the United States)
1-919-882-2331 (International)
Replay ID: 10248

The call will also be broadcast live and archived on the Company's website at profoundmedical.com under "Investor Presentations" in the Investor Relations section.

Change to Board of Directors

Profound also announced today the resignation of Jonathan Ross Goodman and the appointment of Samira Sakhia to its Board of Directors.

Mrs. Sakhia currently serves as President of Knight Therapeutics Inc. Prior to joining Knight, Ms. Sakhia served as the CFO at Paladin Labs Inc. from 2001 to 2015. During her employment with Paladin, Ms. Sakhia was instrumental in executing in-licensing and acquisition transactions of Canadian and international pharmaceutical products and businesses. In addition, Ms. Sakhia led several M&A and strategic lending transactions as well as equity rounds on the TSX and completed the sale of Paladin to Endo International for over $3 billion. Ms. Sakhia holds an MBA and a Bachelors of Commerce degree from McGill University and is also a Chartered Professional Accountant.

Dr. Menawat said, "We are fortunate to have Samira join our team. She brings a tremendous wealth of experience in the healthcare industry and has a proven track record of accomplishment in finance, operations and human resources management. Her expertise in business development will be particularly invaluable to the success of the global commercialization of TULSA-PRO® system."

"On behalf of the Board and staff of Profound, I would like to take this opportunity to thank Jonathan for his many contributions to the Company. He was very instrumental in our going public and we are grateful for his continued guidance and support," added Dr. Menawat.

Profound is currently conducting a pilot commercial launch of the TULSA-PRO® system in key European and other CE mark jurisdictions. The Company is also sponsoring a multicenter, prospective FDA-registered clinical trial, TACT Pivotal Clinical Trial, which is designed to further demonstrate the safety and effectiveness of this innovative technology. If successful, the TACT Pivotal Clinical Trial is expected to support Profound's application to the U.S. Food and Drug Administration for approval to market the TULSA-PRO® system in the United States.

About Profound Medical Corp.

The Profound Medical team is committed to the effort to achieve a new therapeutic standard in prostate cancer. For the millions of men currently living with prostate cancer, and the thousands more who are diagnosed with it every year, current treatment options often mean having to make difficult choices based on potential side effects that can significantly impact quality of life. Our mission is to profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate cancerous prostate tissue with precision, while actively protecting critical anatomy from potential side effects; a tomorrow where patients have access to a safe, fast and effective treatment option, so they can quickly return to their daily lives.

Established in 2008, Profound Medical is commercializing a novel technology, TULSA-PRO® system, which combines real-time Magnetic Resonance Imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control that is designed to provide precise ablation of the prostate while simultaneously protecting critical surrounding anatomy from potential side effects. TULSA-PRO® system is CE Marked and Profound is sponsoring a multicenter, prospective FDA-registered clinical trial, TACT Pivotal Clinical Trial, which is designed to further demonstrate the safety and effectiveness of this innovative technology.

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. 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.

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in policies of

the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

Profound Medical Corp.
Consolidated Balance Sheets
As at December 31, 2016 and 2015

	2016 $	2015 $
Assets		
Current assets		
Cash	20,833,061	10,522,520
Short-term investment	-	10,000,000
HST receivable and other assets	266,336	92,479
Investment tax credits receivable	264,000	173,000
Inventory	416,823	-
Prepaid expenses and deposits	696,909	139,305
	22,477,129	20,927,304
Property and equipment	953,029	229,112
Intangible assets	262,685	32,500
	23,692,843	21,188,916
Liabilities		
Current liabilities		
Accounts payable and accrued liabilities	1,771,427	980,278
Customer deposits	259,293	-
Long-term debt	2,877,050	286,700
Other liability	39,357	-
	4,947,127	1,266,978
Long-term debt	3,760,826	5,560,674
Provisions	39,619	-
Other liability	109,044	397,814
	8,856,616	7,225,466
Shareholders' Equity		
Share capital	83,272,678	67,082,821
Contributed surplus	3,000,563	2,002,190
Foreign currency translation reserve	11,316	-
Deficit	(71,448,330)	(55,121,561)
	14,836,227	13,963,450
	23,692,843	21,188,916

Consolidated Statement of Loss and Comprehensive Loss
For the years ended December 31, 2016 and 2015

	2016 $	2015 $
Expenses		
Research and development	9,988,693	5,136,848
Selling, general and administrative	5,651,721	6,086,049
Total operating expenses	15,640,414	11,222,897
Finance costs - net		
Interest and accretion expense	829,899	5,625,257
Interest income	(157,598)	(137,710)
Listing expense	-	2,058,234
Loss on recognition of convertible notes	-	2,094,565
Change in fair value of convertible notes	-	(334,680)
Gain on conversion of convertible notes	-	(1,759,885)
Gain on extinguishment of long-term debt	-	(63,568)
Change in fair value of derivatives	-	(2,084,652)
Preferred share dividend expense	-	481,354
Total finance costs	672,301	5,878,915
Loss before income taxes	16,312,715	17,101,812
Income tax expense (recovery)	14,054	(726,071)
Net loss for the year	16,326,769	16,375,741
Item that may be reclassified to profit or loss		
Foreign currency translation adjustment	11,316	-
Net loss and comprehensive loss for the year	16,338,085	16,375,741
Basic and diluted weighted average shares outstanding	41,510,145	23,683,822
Basic and diluted net loss per common share	0.39	0.69

Profound Medical Corp.
Consolidated Statement of Cash Flows
For the years ended December 31, 2016 and 2015

	2016 $	2015 $
Cash provided by (used in)		
Operating activities		
Net loss for the year	(16,326,769)	(16,375,741)
Depreciation of property and equipment	167,335	116,525
Amortization of intangible assets	19,673	2,500
Loss on disposal of property and equipment	10,248	-
Share-based compensation	1,001,558	644,733
Preferred share dividend expense	-	481,354
Loss on recognition of convertible notes	-	2,094,565
Gain on extinguishment of long-term debt	-	(63,568)
Change in fair value of convertible notes	-	(334,680)
Change in fair value of derivatives	-	(2,084,652)
Selling, general and administrative expenses	-	2,303,034

Listing expense	-	2,058,234
Gain on conversion of convertible notes	-	(1,759,885)
Interest and accretion expense	829,899	5,625,257
Net change in non-cash working capital balances		
Investment tax credits receivable	(91,000)	1,101,899
HST receivable and other assets	(173,857)	235,198
Prepaid expenses and deposits	(557,604)	(88,490)
Inventory	(416,823)	-
Accounts payable and accrued liabilities	775,781	(90,423)
Customer deposits	259,293	-
Income tax payable	-	(726,071)
	(14,502,266)	(6,860,211)
Investing activities		
Cash acquired from Profound	-	1,157,535
Sale (purchase) of short-term investment	10,000,000	(10,000,000)
Purchase of intangible assets	(223,174)	-
Purchase of property and equipment	(863,991)	(167,009)
	8,912,835	(9,009,474)
Financing activities		
Proceeds from convertible notes	-	1,500,000
Issuance of common shares	17,402,000	24,008,828
Proceeds from long-term debt	-	4,000,000
Payment of long-term debt	(286,700)	(72,250)
Transaction costs paid	(1,219,003)	(2,749,984)
Repayment of bank loan	-	(700,000)
Proceeds from share option exercised	3,675	7,438
Interest paid	-	(8,322)
	15,899,972	25,985,710
Increase in cash during the year	10,310,541	10,116,025
Cash - Beginning of year	10,522,520	406,495
Cash - End of year	20,833,061	10,522,520
Supplemental information		
Transaction costs included in accounts payable and accrued liabilities	-	545,876
Intangible asset additions included in accounts payable and accrued liabilities	26,684	-
Property and equipment additions included in provisions	37,509	-

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