# Management Discussion and Analysis of Profound Medical Corp. for the Three Months Ended March 31, 2016

The following Management Discussion and Analysis ("MD&A") prepared as of May 4, 2016 should be read in conjunction with the March 31, 2016 unaudited interim condensed consolidated financial statements and related notes of Profound Medical Corp. ("Profound") and its subsidiaries (together, the "Company"). The unaudited interim condensed consolidated financial statements of Profound's and related notes were prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") applicable to the preparation of interim financial statements and are presented in Canadian dollars unless otherwise noted. Unless stated otherwise, all references to "\$" are to Canadian dollars.

#### FORWARD-LOOKING STATEMENTS

This MD&A contains "forward-looking statements" which include all statements other than statements of historical fact contained in this MD&A, such as statements that relate to the Company's current expectations and views of future events. Often, but not always, forward-looking statements can be identified by the use of words such as "may", "will", "expect", "anticipate", "predict", "aim", "estimate", "intend", "plan", "seek", "believe", "potential", "continue", "is/are likely to", "is/are projected to" or the negative of these terms, or other similar expressions intended to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to expectations regarding future clinical trials, expectations regarding regulatory approvals, expectations regarding the safety and efficacy of its product, expectations regarding the use of its product and its revenue, expenses and operations, plans for and timing of expansion of its product and service offerings, future growth plans, ability to attract and develop and maintain relationships with suppliers, physicians/clinicians, etc., ability to attract and retain personnel, expectations regarding growth in its product markets, competitive position and its expectations regarding competition, ability to raise debt and equity capital to fund future product development, and anticipated trends and challenges in Profound's business and the markets in which it operates.

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The results, performance and achievements of the Company will be affected by, among other things, the "Risk Factors' set out in Profound's Management Discussion and Analysis prepared as of March 1, 2016 for the year ended December 31, 2015 available on SEDAR at www.sedar.com.

Forward-looking statements contained herein are made as of the date of this MD&A and Profound disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or results or otherwise, unless required by applicable law. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements due to the inherent uncertainty in them.

#### **OVERVIEW**

## **Qualifying Transaction**

On April 29, 2015, Profound entered into an amalgamation agreement (the "Amalgamation Agreement") and completed its qualifying transaction (the "Transaction"). The Transaction proceeded by way of a "three-cornered" amalgamation among Mira IV Acquisition Corp. ("Mira IV"), a capital pool company listed on the Toronto Stock Exchange Venture Exchange (the "Exchange"), Mira IV Subco Inc., a wholly-owned subsidiary of Mira IV, and Profound Medical Inc. ("PMI"), a private Ontario corporation incorporated on June 13, 2008. On June 5, 2015, and prior to the completion of the Transaction, Mira IV changed its name to "Profound Medical Corp." and completed a consolidation of its share capital on the basis of one post-consolidation common share for every 13.6363 preconsolidation common shares. As a result of the Transaction, PMI became a wholly-owned subsidiary of Profound.

The Transaction resulted in a reverse takeover of Mira IV by the shareholders of PMI (the "Reverse Takeover") and,

for accounting purposes, PMI was deemed the acquirer. The Transaction constituted a reverse takeover but did not meet the definition of a business under IFRS 3 - Business Combinations; accordingly the Company has accounted for the Transaction in accordance with IFRS 2, Share Based Payments. The identifiable assets and liabilities of Mira IV are recognized at fair value as at the acquisition date, with the excess of the fair value of the equity interest issued over the fair value of net assets charged to the consolidated statement of loss and comprehensive loss as a listing expense.

Following the completion of the Transaction, a total of 39,442,337 common shares of Profound were issued and outstanding.

On June 8, 2015, the shares of Profound commenced trading on the TSX Venture Exchange under the ticker symbol PRN.

As at May 4, 2016, a total of 39,473,327 common shares were issued and outstanding.

#### **BUSINESS UPDATE AND STRATEGY**

Profound is a Canadian medical device company that has developed a unique MR guided ablation procedure for prostate care. Profound's novel technology combines real-time MR imaging with transurethral, robotically-driven therapeutic ultrasound and closed-loop thermal feedback control. It provides a highly precise treatment tailored to patient-specific anatomy and pathology. This method of prostate ablation offers short treatment times and low morbidity, allowing for fast patient recovery.

PMI was founded, initially, on certain research conducted at Sunnybrook Health Sciences Centre ("Sunnybrook"), pursuant to licensing arrangements between Sunnybrook and PMI. In 2010, in collaboration with Sunnybrook, PMI developed working prototypes and completed institutionally sponsored clinical research trials. In 2011, PMI finalized the system design under formal design controls. In 2012, preclinical studies were completed leading to the finalization of development of our clinical stage device and successful outsourcing of the manufacturing. In April 2013, PMI announced initiation of the Health Canada approved 30 patient multi-center TULSA (Transurethral Ultrasound Ablation) safety and feasibility study of its device. Clinical sites were subsequently expanded to include Germany and the United States, with approvals from the Federal Institute for Drugs and Medical Devices in Germany in July 2013 and the United States Food and Drug Administration ("FDA") in September 2013. In March 2014, PMI completed enrollment and treatment of 30 patients in the TULSA multi-jurisdictional safety and feasibility study. On October 15, 2015, the Company presented 12-month follow-up data Phase I clinical outcomes at the European Symposium on Focused Ultrasound Therapy held in London, England. The study demonstrated that Profound's TULSA procedure is well tolerated by patients and to date resulted in low side effects. On April 11, 2016, Profound announced that it was granted CE approval for the commercial sale of TULSA-PRO™ in Europe and in other CE Mark jurisdictions Profound also expects to pursue regulatory market clearance in Canada in 2016.

Profound expects to apply for an Investigational Device Exemption ("IDE") in Q2 2016, a prerequisite to launching the Pivotal Trial (as more fully described in the Filing Statement of Profound, dated May 22, 2015 (the "Filing Statement"). Also see the Filing Statement for a full description of the regulatory approval process under the heading "Government Regulation", which process is intended to provide evidence and reasonable assurance of safety and efficacy in order to obtain FDA clearance for marketing the Company's device. Based on a new predicate device cleared by the FDA in October of 2015, Profound intends to pursue a 510K submission of the TULSA-PRO™ system with the FDA as a Class II device and has engaged in pre-submission consultations with FDA officials in this regard. The Company plans to demonstrate appropriate clinical data through the Pivotal Trial (which is currently designed to involve approximately 110 patients from approximately 10-15 clinical sites in total. These clinical sites will be located in the United States, Canada and Europe). Assuming that Profound is able to obtain the above-noted IDE, the Pivotal Trial is expected to commence in mid-2016.

# **CORPORATE HIGHLIGHTS**

- On January 29, 2016, Profound established a fully owned subsidiary of Profound Medical Inc. named Profound Medical GmbH.
- On February 29, 2016, Profound announced that it had entered into a strategic collaboration agreement with Siemens Healthcare GmbH, pursuant to which the companies will each invest approximately USD \$2,000,000 on marketing and sales resources in support of the marketing and sale of TULSA-PRO™.
- On April 11, 2016, Profound announced that it was granted CE Mark approval for the commercial sale of TULSA-PRO™ in Europe and in other CE Mark jurisdictions.
- On April 28, 2016, Profound announced that it has received first PO for commercial sale of TULSA-PRO<sup>TM</sup> from ResoFus Alomar in Spain.

## RESULTS OF OPERATIONS

The following is selected unaudited financial information for the three months ended March 31, 2016 and March 31, 2015.

	Three mon	ths ended	
	March 31, 2016	March 31, 2015	Change
	\$	<u> </u>	\$
Expenses			
Research and development	2,475,997	835,201	1,640,796
Selling, General and administrative	1,126,825	582,510	544,315
Total operating expenses	3,602,822	1,417,711	2,185,111
Finance costs - net			
Interest and accretion expense	283,961	317,469	(33,508)
Interest income	(50,564)	(7,771)	(42,793)
Preferred share dividend expense	-	287,098	(287,098)
Loss on recognition of convertible notes	-	2,094,565	(2,094,565)
Fair value gain on convertible notes	-	(370,073)	370,073
Change in fair value of derivatives	<u> </u>	(1,861,970)	1,861,970
Total finance costs	233,397	459,318	(225,921)
Loss before income taxes	3,836,219	1,877,029	1,959,190
Part VI.1 tax expense		72,920	(72,920)
Net loss for the period	3,836,219	1,949,949	1,886,270
Basic and diluted net loss per common share	0.10	0.90	(0.80)

## Research and Development

Our research and development ("R&D") expenses are comprised of costs incurred in performing R&D activities, including clinical trial and related clinical manufacturing costs, materials and supplies, salaries and benefits, contract research costs, patent procurement costs, and occupancy costs. Our R&D activities occur in clinical R&D. Clinical R&D refers to internal and external activities associated with clinical studies of TULSA-PRO in humans and advancing the clinical product towards a goal of obtaining regulatory approval to manufacture and market this product in various jurisdictions.

Expenditures for R&D for the three months ended March 31, 2016 were higher by \$1,640,796 compared to the three months ended March 31, 2015. The increase was primarily due to the activities in preparing regulatory filings for marketing approval of TULSA-PRO in Europe and Canada, preparation for the initiation of the multi-jurisdictional Pivotal Trial and preparation of the 12-month clinical outcomes from the 30 patient multi-jurisdictional TULSA Phase 1 safety and feasibility trial. Profound is certified to the ISO13485:2003 standard including the Canadian Medical Devices Conformity Assessment System and CE Full Quality Assurance certification. These certifications are required as part of the Canadian Medical Device License applications. Preparations for the Pivotal Trial include organizing the IDE submission and a Pivotal Trial in at least 10 clinical sites, designed to support a 510(k) submission in the United States to provide a pathway for Class II classification for the TULSA-PRO system. As a result material costs increased by \$542,524. The number of employees involved in R&D also increased during this period to support these activities resulting in salaries and benefits increasing by \$313,257. The increases were offset by reduced investment tax credits recorded in the three months ended March 31, 2016. Since becoming a public entity as of June 4, 2015, the Company does not qualify for refundable investment tax credits other than Ontario Innovation tax credits.

We expect that our R&D expenditures throughout 2016 will be higher as compared to the same periods in 2015, due to the ongoing submission preparation for a Canadian Medical Device License, the development of a commercial system, preparation for an IDE submission, and initiation of the Pivotal Trial.

## Selling, general and Administrative

Our selling, general and administrative ("SG&A") expenses are comprised of management and business development costs related to the development and commercialization of our TULSA-PRO system, including salaries, benefits, our various management and administrative support functions and other operating and occupancy costs.

SG&A expenses for the three months ended March 31, 2016 were higher by \$544,315 compared to the three months ended March 31, 2015, primarily due to an increase in the number of employees in SG&A, resulting in higher salaries and benefits of \$122,291 and share-based compensation of \$157,800. Professional and consulting fees increase of \$218,340 related to recruiting fees, Board of Directors fees, and legal fees related to contracts and corporate matters.

## Preferred share dividend expense

The holders of Series A1 preferred shares and A2 preferred shares (collectively, the "Preferred Shares") were, when such Preferred shares were issued and outstanding, entitled to receive, if, as and when declared by the board of directors, cumulative dividends at an annual rate of 8%, compounded annually commencing on their respective date of issuance. The Preferred Shares were converted into common shares of Profound pursuant to the Transaction. Accordingly, there was no preferred share dividend expense for the three months ended March 31, 2016. The preferred share dividend expense for the three months ended March 31, 2015 was \$287,098.

## Interest and accretion expense

Interest and accretion expense relates to (i) the preferred shares accreting to their respective redemption prices over their expected life using the effective interest rate method, including accelerated accretion due to the conversion of the preferred shares prior to their maturity date, (ii) the Federal Economic Development Agency loan accreting to the principal amount repayable using the effective interest rate method, (iii) the Health Technology Exchange loan accreting to the principal amount repayable using the effective interest rate method and its related interest expense, (iv) the Knight loan accreting to the principal amount repayable using the effective interest rate method and its related interest expense, (v) the convertible notes (the Notes) interest expense, (vi) the bank loan interest expense, and (vii) the 0.5% royalty to Knight accreting using the effective interest rate method.

Interest and accretion expense for the three months ended March 31, 2016 was lower by \$33,508 compared to the three months ended March 31, 2015. The decrease is primarily due to accretion expense on the preferred shares and

Notes which terminated with their conversion to common shares on June 4, 2015 pursuant to the terms of the Transaction, partially offset by the Knight Loan which was entered into on April 30, 2015.

# Loss on recognition of convertible notes

On January 27, 2015, the Company closed a financing of Notes in the principal amount of \$1,500,000, with an original maturity date of January 27, 2016. The Notes accrued interest at a rate of 12% per annum. All or any part of the Notes were convertible at any time after February 20, 2015 at a conversion price per preferred share equal to the preferred share conversion price at the option of the holder. In the event that a financing occurred, all of the Notes would automatically convert into the class or series of preferred shares, common shares or units acquired by the new investors at a price per share or unit equal to 75% of the price paid. On April 20, 2015, the Notes were amended to eliminate the discount such that the Notes automatically convert at a price per common share or unit equal to 100% of the price paid by the new investors.

The Notes represented a financial liability that included embedded derivatives related to the conversion feature that required separation. The Company had elected an accounting policy choice to measure the Notes at fair value without separating the embedded derivatives. On initial recognition the fair value of the Notes was \$3,594,565 and the difference between the fair value and the initial value of \$1,500,000, or \$2,094,565 was recognized in the interim consolidated statements of loss and comprehensive loss for the three months ended March 31, 2015.

# Fair value gain on convertible notes

The Notes are re-measured at fair value at each period with any changes recognized in the interim consolidated statements of loss and comprehensive loss. For the three months ended March 31, 2015 a fair value gain on the Notes of \$370,073 was recognized due to an increase in the credit spread.

## Change in fair value of derivatives

The Preferred shares when outstanding, represented a financial liability that includes multiple embedded derivatives that require separation. The embedded derivatives are then measured at fair value at each reporting period with any changes recognized in the interim consolidated statements of loss and comprehensive loss.

There were no derivatives related to the Preferred shares as at March 31, 2016. The change in fair value of derivatives for the three months ended March 31, 2016 was \$nil compared to a gain of \$1,861,970 for the three months ended March 31, 2015.

## Part VI.1 tax expense

If holders of preferred shares were paid, or were deemed to have been paid, any dividends on such shares, the Company would have become liable for the payment of taxes under Part VI.1 of the Income Tax Act (Canada). On conversion of the Preferred shares, no dividends were paid or deemed paid, resulting in the reversal of all the accrued Part VI.1 taxes payable. Part VI.1 tax expense for the three months ended March 31, 2016 was \$nil, compared to \$72,920 for the three months ended March 31, 2015.

## Net loss

The Company recorded a net loss for the three months ended March 31, 2016 of \$3,836,219 or \$0.10 per common share, compared with a net loss of \$1,949,949 or \$0.90 per common share for the three months ended March 31, 2015. For the three months ended March 31, 2016, the net loss was primarily attributed to the R&D expenses of \$2,475,997, the SG&A expenses of \$1,126,825 and the interest and accretion expense of \$283,961 partially offset by the interest income of \$50,564. For the three months ended March 31, 2015, the net loss was attributed to the ongoing R&D expenses of \$835,201, and the SG&A expenses of \$582,510, the ongoing dividend expense related to the preferred shares of \$287,098, the loss on recognition of the Notes of \$2,094,565, the interest and accretion expense of \$317,469 largely related to the accretion of the preferred shares, partially offset by the gain on fair value of derivatives of \$1,861,970, and the fair value gain on the Notes of \$370,073.

## SUMMARY OF QUARTERLY RESULTS

		Basic and diluted net	
Quarter Ended	Net loss	loss per common share	
	\$	\$	
March 31, 2016	3,836,219	0.10	
December 31, 2015	2,769,896	0.07	
September 30, 2015	2,957,179	0.08	
June 30, 2015	8,698,717	0.67	
March 31, 2015	1,949,949	0.90	
December 31, 2014	2,408,512	1.11	
September 30, 2014	1,528,125	0.71	
June 30, 2014	3,931,446	1.81	

It is important to note that historical patterns of revenue and expenditures cannot be taken as an indication of future revenue and expenditures. Net loss has been variable and has been impacted primarily by the availability of funding, the level of our R&D spending, listing costs related to the Transaction, and conversion of the Notes and preferred shares into common shares.

The net loss in the first quarter of 2016 of \$3,836,219 was primarily attributed to the ongoing R&D expense of \$2,475,997 and the SG&A expense of \$1,126,825. The net loss in the fourth quarter of 2015 of \$2,769,896 was primarily attributed to the ongoing R&D expenses of \$1,538,566 and the SG&A expenses of \$1,010,613. The net loss in the third quarter of 2015 of \$2,957,179 was primarily attributed to the ongoing R&D expenses of \$1,657,700 and the SG&A expenses of \$1,099,798. The net loss in the second quarter of 2015 of \$8,698,717 was attributed to the finance costs related to the listing expense of the Transaction of \$2,058,234, the interest and accretion expense of \$4,764,823 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 on conversion of the Notes of \$1,759,885, the ongoing R&D expenses of \$1,105,381, and the SG&A expenses of \$3,393,128. SG&A expense includes marketing expense of \$2,303,034 related to the Knight loan. The net loss in the first quarter of 2015 of \$1,949,949 was attributed to the ongoing R&D expenses of \$835,201, and the finance costs related to the loss on initial recognition of the Notes \$2,094,565, partially offset by the change in fair value of derivatives of \$1,861,970. Upon closing of the Transaction on June 4, 2015, the number of common shares outstanding increased significantly, resulting in a lower loss per share in the subsequent periods.

The net loss in the fourth quarter of 2014 of \$2,408,512 was attributed to the SG&A expenses of \$1,018,906, the ongoing R&D expenses of \$879,062, and the finance costs related to the preferred shares and long-term debt of \$521,329. The Company incurred additional SG&A expenses in the fourth quarter of 2014 related to the adoption of IFRS in the preparation of audited financial statements, increased legal costs related to the Transaction discussed above and an increase in the number of employees. The net loss in the third quarter of 2014 of \$1,528,125 was attributed to the finance costs related to the preferred shares and long-term debt of \$668,730, the ongoing R&D expenses of \$453,669 and the SG&A expenses of \$353,067. The net loss in the second quarter of 2014 of \$3,931,446 was attributed to the interest and accretion expense of \$238,859, preferred share dividend expense of \$277,396, the ongoing R&D expenses of \$480,842, the SG&A expenses of \$338,380 and the change in fair value of derivatives of \$2,607,042.

## LIQUIDITY AND CAPITAL RESOURCES

	Three mon	ths ended	
	March 31, 2016	March 31, 2015	Change
	\$	\$	\$
Cash flows used in operating activities	(3,223,250)	(647,558)	(2,575,692)
Cash flows used in investing activities	(93,931)	(65,596)	(28,335)
Cash flows provided by financing activities	(221,675)	793,959	(1,015,634)
Increase (decrease) in cash	(3,538,856)	80,805	(3,619,661)
Cash and cash equivalents- beginning of period	10,522,520	406,495	10,116,025
Cash and cash equivalents- end of period	6,983,664	487,300	6,496,364

The Company had cash and short-term investments of \$16,983,664 as at March 31, 2016 compared to \$20,522,520 as at December 31, 2015. The decrease in cash and short-term investments during the three months ended March 31, 2016 is mainly a result of the cash used in operating activities and changes in working capital balances.

For the three months ended March 31, 2016, net cash flows used in operating activities increased to \$3,223,250 as compared to net cash flows used in operating activities for the three months ended March 31, 2015 of \$647,558. The March 31, 2016 increase was primarily due to the preparations for an IDE submission and a Pivotal Trial in at least 10 clinical sites, designed to support a 510(k) submission in the United States to provide a pathway for Class II classification for the TULSA-PRO<sup>TM</sup> system. The number of employees also increased. For the three months ended March 31, 2016 and March 31, 2015, R&D expense was \$2,475,997 and \$835,201, respectively.

As an R&D company, Profound may claim investment tax credits ("ITCs") from various levels of government related to the Canadian Federal Scientific Research & Experimental Development ("SR&ED") program. Eligible SR&ED expenses include salaries for employees involved in SR&ED, cost of materials, third party contract services and overhead expenditures. As of April 29, 2015, the date of the amalgamation agreement which formed a component of the Transaction, the Company is no longer eligible for the enhanced refundable ITCs, but will be eligible for the refundable Ontario innovation tax credit. Based on management's best estimate, realization of SR&ED amounts is subject to review and approval by the tax authorities. The Company expects to receive \$55,000 from the tax authorities related to the three months ended March 31, 2016.

For the three months ended March 31, 2016, net cash flows used in investing activities of \$93,931 related mainly to the purchase of research equipment in support of further optimization of the TULSA-PRO system, and ERP implementation. For the three months ended March 31, 2015, net cash flows used in investing activities of \$65,596 related mainly to the purchase of research equipment in support of further optimization of the TULSA-PRO<sup>TM</sup> system.

Net cash flows used by financing activities for the three months ended March 31, 2016 of \$221,675 relate principally to the repayment of Health Technology Exchange and Federal Economic Development Agency loans. Net cash flows provided by financing activities for the three months ended March 31, 2015 of \$793,959 relate principally to the \$1,500,000 proceeds from the Notes, partially offset by the \$700,000 repayment of the bank loan.

Working capital (defined as current assets minus current liabilities) of \$15,724,630 as at March 31, 2016 was a decrease of \$3,935,696 from the December 31, 2015 working capital of \$19,660,326.

We expect to satisfy our operating cash requirements beyond the next twelve months from cash on hand, through managing operating expense levels, from proceeds of equity and/or debt financings and/or new strategic partnership agreements to fund some or all costs of development.

We will need additional capital beyond the next 12 months to fund any R&D activities and to fund any significant expansion of our operations. Potential sources of capital could include equity and/or debt financings, development agreements or marketing license agreements, the collection of revenues resulting from future commercialization

activities and/or new strategic partnership agreements to fund some or all costs of development, although there can be no assurance that we will be able to obtain any such capital on terms or in amounts sufficient to meet our needs or at all. The availability of equity or debt financing will be affected by, among other things, the results of our R&D, our ability to obtain regulatory approvals, the market acceptance of our product, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if we raise additional funds by issuing equity securities, our existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that would restrict our operations. Any failure on our part to raise additional funds on terms favorable to us or at all may require us to significantly change or curtail our current or planned operations in order to conserve cash until such time, if ever, that sufficient proceeds from operations are generated, and could result in our not taking advantage of business opportunities, in the termination or delay of clinical trials for our product, in curtailment of our product development programs designed to identify new products, in the sale or assignment of rights to our technologies, product and/or our inability to file market approval applications at all or in time to competitively market our product.

#### **OUTSTANDING SHARE INFORMATION**

The number of common shares outstanding as of March 31, 2016 was 39,473,327, no change from December 31, 2015. The number of share options outstanding as of March 31, 2016 was 3,268,060, a decrease of 139,223 from December 31, 2015 (no new options granted, 139,223 forfeited). The number of compensation options outstanding as of March 31, 2016 was 649,568, no change from December 31, 2015.

## OFF BALANCE SHEET ARRANGEMENTS

The Company has no off-balance sheet arrangements.

#### RELATED PARTY TRANSACTIONS

During the three months ended March 31, 2016 the Company did not enter any material transactions with related parties.

Details of the transactions between the Company, key management and other related parties are disclosed below. Key management includes the Company's directors and senior management. The remuneration of directors and the senior management team for the period ended March 31, 2016 and March 31, 2015 were as follows:

	Three months ended	
	March 31, 2016	March 31, 2015
	\$	\$
Salaries and employee benefits	244,497	226,002
Directors' fees	41,375	11,351
Share-based compensation	192,587	38,130
	478,459	275,483

Executive employment agreements allow for additional payments in the event of a liquidity event, or if the executive is terminated without cause.