



**PROFOUND MEDICAL CORP.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**MARCH 31, 2019**

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

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The following Management's Discussion and Analysis ("**MD&A**") prepared as of May 6, 2019 should be read in conjunction with the March 31, 2019 unaudited interim condensed consolidated financial statements and related notes of Profound Medical Corp. ("**Profound**", the "**Company**", "**us**" or "**our**"). The unaudited interim condensed consolidated financial statements of Profound 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, including International Accounting Standard ("**IAS**") 34, Interim Financial Reporting. Unless stated otherwise, all references to "\$" are to Canadian dollars. In this MD&A, unless the context requires otherwise, references to "we" or "our" are references to Profound.

## FORWARD-LOOKING STATEMENTS

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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:

- the completion of the TACT Pivotal Clinical Trial (as defined herein) and the timing thereof;
- the submission of an application to the FDA (as defined herein) for approval to market the TULSA-PRO® in the United States;
- the use of proceeds of the 2018 Offering (as defined herein);
- expectations regarding current and future clinical trials and the costs thereof;
- expectations regarding reoccurring revenue generated from sales;
- expectations regarding regulatory approvals;
- expectations regarding reimbursements;
- expectations regarding the safety, efficacy and advantages of our products;
- expectations regarding our products fulfilling unmet clinical needs;
- expectations regarding the Company's relationship with Philips and Siemens (as each defined herein);
- expectations regarding the use of our products including treating conditions that our products do not currently treat;
- plans for and timing of expansion of our product and service offerings;
- the Company's mission and future growth plans;
- our ability to attract, develop and maintain relationships with suppliers, manufacturers, distributors, strategic partners, physicians/clinicians, etc.;
- our ability to attract and retain personnel;
- expectations regarding growth in our product markets, sales and competitive position;
- our ability to raise debt and equity capital to fund future product development;
- anticipated trends and challenges in Profound's business and the markets in which we operate;
- ability to integrate acquired businesses, including Sonalleve®, new products and services offerings; and
- expectations regarding the additional consideration to be paid to Philips pursuant to the Sonalleve® Transaction (as defined herein).

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of Profound to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including those factors discussed in the section entitled "Risk Factors" in the Company's Annual Information Form prepared as of March 7, 2019 for the year ended December 31, 2018 (the "**AIF**") available on SEDAR at [www.sedar.com](http://www.sedar.com), such as:

- successful completion of clinical trial phases with respect to Profound's devices;
- risks related to the integration of business and products acquired by the Company, including Sonalleve®, with the current businesses and product offerings of the Company;
- obtaining regulatory approvals in relevant jurisdictions to market Profound's devices;
- risks related to the regulation of Profound products, including the broader healthcare markets;
- lack of funding may limit the ability to commercialize and market Profound's devices;
- fluctuating input prices, international trade and political uncertainty;
- healthcare regulatory regimes may affect financial viability;
- reimbursement models in relevant jurisdictions may not be advantageous;
- risks related to managing growth;
- competition may limit the growth of Profound;
- reliance on third parties and risks related to the transition of manufacturing and installation services;

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- if Profound breaches any of the agreements under which it licenses rights from third parties, Profound could lose license rights that are key to its business;
- loss of key personnel may significantly harm Profound's business;
- past performance is not indicative of future performance; and
- a history of negative operating cash flows.

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 laws. 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.

## **BUSINESS OVERVIEW**

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Profound (TSX: PRN; OTCQX: PRFMF) develops and markets customizable, incision-free therapies for the ablation of diseased tissue. Profound is 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.

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 for ablation of targeted benign and malignant prostate tissue and is commercially launched in key European and other CE mark jurisdictions. The TULSA-PRO® system received CE Certificate of Conformity from its notified body in the European Union in April 2016 and the Company initiated a limited commercial launch within the jurisdiction in Q4 2016. 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).

In the Phase I clinical trial results published in 2016, TULSA-PRO® demonstrated accurate and precise ablation of targeted prostate tissue, while providing a well-tolerated favourable safety profile with minor impact on urinary, erectile and bowel function at 12 months.

TULSA-PRO® ablation clinical trial protocol (the "**TACT Pivotal Clinical Trial**"), is a prospective, open-label, single-arm pivotal clinical study, of 115 prostate cancer patients across 13 research sites in the United States, Canada and Europe. The TACT Pivotal Clinical Trial completed patient enrolment in February 2018, and 12-month follow-up outcomes were shared as a late-breaking abstract presentation during the American Urological Association's (AUA) 2019 Annual Meeting Plenary Program on May 5<sup>th</sup>, 2019 in Chicago, IL. The TACT study met its primary PSA reduction endpoint in 110 of 115 (96%) patients, with median (IQR) PSA reduction of 95% (91-98%) and nadir of 0.34 (0.12-0.56) ng/ml, and with low rates of severe toxicity and residual clinically significant prostate cancer. The TACT 12-month follow-up data supports Profound's application with the U.S. FDA for approval 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.

The Company will continue to invest in additional research and development, clinical studies, and acquisitions in order to expand the applications of its platform technologies and sales.

### **Business Update**

Over time, surgery has evolved from an 'open' technique, to laparoscopic, to robotic surgery. The surgeon's motivation behind this evolution has been to perform procedures that reduce invasiveness, improve clinical outcomes, and reduce recovery times. Profound is now taking this concept to the next level by enabling customizable, incision-free therapies for the MRI-guided ablation of diseased tissue with the TULSA-PRO® and Sonalleve® systems. These incision-free and radiation-free procedures offer surgeons the option of providing predictable and customizable procedures that eliminate invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

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TULSA-PRO<sup>®</sup> revenues may include the sale of the capital equipment, procedure related sales of disposable single use components of the system, and service revenue for ongoing maintenance of the system. Profound is currently pursuing a limited commercial launch of TULSA-PRO<sup>®</sup> in CE marked jurisdictions. The key customer segments targeted by Profound include academic/university/clinical leadership hospitals as well as private clinics with access to MRI scanners. Profound collaborates with its strategic partners Philips and Siemens Healthcare GmbH ("**Siemens**") for lead generation and distribution of the capital equipment. Profound is establishing its own direct sales and marketing teams for sales of the capital and disposable components of the TULSA-PRO<sup>®</sup> and Sonalleve<sup>®</sup> systems. The primary focus of the direct sales team is to cultivate adoption of the TULSA-PRO<sup>®</sup> technology, support clinical customers TULSA-PRO<sup>®</sup> procedures and increase the utilization of the systems and disposable components. Recurring revenues are expected to be generated from the sale of disposables and service.

Sales of Sonalleve<sup>®</sup> currently are primarily a one-time capital sale with limited recurring service revenue. Given that it is currently only compatible on the Philips MRI scanners, Profound relies primarily on its strategic partnership with Philips for lead generation and sale of the capital units. With regulatory approval for sale in a number of jurisdictions, the 2019 focus will be primarily in Asia. In May 2018, the Chinese Food and Drug Administration approved Sonalleve<sup>®</sup> for the non-invasive treatment of uterine fibroids.

Profound continues to focus on further demonstrating the clinical and economic value of its products.

On May 5, 2019, Dr. Scott Eggener presented 12-month results of the TACT study, including the primary efficacy and safety endpoints, as well as key secondary endpoints. The median age of enrolled patients was 65 years and the median Prostate-Specific Antigen ("PSA") level was 6.3 ng/ml. The study focused on a clinically significant prostate cancer population, where 67.0% (77 out of 115) had NCCN intermediate-risk disease, and 62.6% (72 out of 115) had Grade Group 2 (GG2) or Gleason Score 7 (GS7) disease. Of the 43 patients with GG1 or GS6 disease, 60.5% (26 out of 43) had high-volume disease ( $\geq 3$  cores positive, or  $\geq 50\%$  cancer core length). Treatment intent was whole-gland ablation with sparing of the urethra and urinary sphincter. Median targeted prostate volume was 40 cc with treatment delivery time of 51 minutes. A median of 97.6% of the prescribed target volume was heated to ablative temperatures with spatial ablation precision of  $\pm 1.4$  mm measured on MRI thermometry during treatment.

The primary efficacy endpoint of TACT is the proportion of patients achieving a post-treatment PSA reduction  $\geq 75\%$  of their pre-treatment baseline value. The FDA-approved protocol's pre-established performance goal for the success proportion was 50% of patients. In the TACT trial, the median PSA reduction was 94.9% (nadir 0.34 ng/ml), and 95.7% of patients (110 out of 115) achieved the PSA reduction endpoint.

Secondary efficacy endpoints include prostate volume reduction on 12-month MRI and histological response on 12-month 10-core prostate biopsy. The median perfused prostate volume of patients in TACT decreased from 41 cc to 4 cc, based on assessment from the local research sites, pending review by a central radiology core lab. Of the 115 patients enrolled in the study, only 4 (3.5%) did not undergo follow-up biopsy, in all cases due to patient refusal. Among 68 men with pre-treatment intermediate-risk GG2 disease, 54 (79.4%) were free of GG2 disease on one-year biopsy. Among 94 men with pre-treatment GG2 or high-volume GG1 disease, 72 (76.6%) were free of GG2 or high-volume GG1 disease on follow-up biopsy. Of the 111 men with one-year biopsy data, 72 (64.9%) had a complete histological response with no evidence of any cancer, and 16 (14.4%) had low-volume GG1 disease which has virtually no potential for metastases or cancer-related mortality. The 20.6% rate of residual clinically significant prostate cancer in an intermediate-risk patient population is similar or better than that reported in prospective studies of modern external beam radiation therapy and other ablation technologies. In addition, the TACT patients remain amenable to re-treatment with TULSA-PRO<sup>®</sup> or standard of care therapies.

The primary safety endpoint of TACT is the frequency and severity of adverse events graded according to the Common Terminology Criteria for Adverse Events, or CTCAE. The rate and nature of attributable adverse events were similar to the favorable safety profile reported in the Phase I Safety & Feasibility Study of TULSA-PRO<sup>®</sup>. In the TACT study, attributable serious adverse events occurred in 7.0% of patients, including 4.3% genitourinary infection, 0.9% urinary retention, 0.9% urinoma, 0.9% ileus (related to urinary catheter), 0.9% deep vein thrombosis, and 0.9% urethral stricture, all resolved. Similarly, 7.8% of patients experienced an attributable severe (Grade 3) adverse event, all resolved. There was no rectal injury or fistula, and no attributable Grade  $\geq 4$  adverse events.

Additional secondary endpoints of TACT focus on functional side effects commonly associated with current prostate cancer therapies, such as erectile dysfunction and urinary incontinence. At 12 months, 23.5% of patients had moderate erectile dysfunction (surgeon assessed Grade 2 adverse event, intervention such as medication indicated) and no patient experienced severe erectile dysfunction (Grade 3, intervention such as medication not helpful). Erectile function was also evaluated using the International Index of Erectile Function ("IIEF") Patient-Reported Questionnaire. The median change in IIEF-5 was a decrease in 3 points, less than the minimal clinically important difference in erectile function. At 12 months, 75.0% (69 out of 92) of previously potent patients were able to maintain erections sufficient for penetration (IIEF question 2  $\geq 2$ ). With respect to urinary function, 2.6% of patients had moderate urinary incontinence (surgeon assessed Grade 2 adverse event, pads indicated) at 12 months. Urinary function was also evaluated using the Expanded Prostate Cancer Index Composite ("EPIC") Patient-Reported Questionnaire. At 12 months, there was 99.1% (111 out of 112) preservation of urinary continence ( $\leq 1$  pad/day), and a 96.2% rate of leak-free continence (leak  $< 1$  time/day).

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Multivariate predictors of GG2 disease at one-year biopsy included presence of intraprostatic calcifications at screening, MRI thermal coverage of target volume, and PIRADS  $\geq 3$  lesion at one-year post-treatment MRI ( $p < 0.05$ ).

The 12-month outcomes of the TACT Pivotal Clinical Trial supports Profound's application to the FDA for approval to market the TULSA-PRO<sup>®</sup> in the United States. Based on a new predicate device cleared by the FDA in October 2015, Profound intends to pursue a 510(k) submission of the TULSA-PRO<sup>®</sup> system with the FDA as a Class II device.

In 2017, Profound made reimbursement progress in Germany for TULSA-PRO<sup>®</sup>. TULSA-PRO<sup>®</sup> received a dedicated procedure code in Germany, securing an initial Diagnosis-Related Group payment of €3,963 starting in January 1, 2018. The Company believes that this reimbursement will help to offset approximately 40-60% of the cost of the procedure and is working closely with clinicians and reimbursement consultants to further enhance reimbursement.

Sonallevé<sup>®</sup> currently does not have significant reimbursement in the European markets.

The Company is engaged in further reimbursement activities for the United States and certain key European markets.

### Sonallevé<sup>®</sup> Transaction

On July 31, 2017, Profound closed an asset and share purchase agreement (the "**Agreement**") with Philips in order to expand the existing collaboration and acquired Philip's Sonallevé<sup>®</sup> MR-HIFU business (the "**Sonallevé<sup>®</sup> Transaction**"), establishing Profound as a market leader in MR-ultrasound ablation therapy.

Under the terms of the Agreement, Philips transferred its Sonallevé<sup>®</sup> assets to Profound for upfront consideration of 7,400,000 common shares ("**Common Shares**") in the capital of Profound. Under the Agreement, the earn-out provisions include a requirement that Profound pay additional consideration of: (i) 5% of Net Sales occurring after July 31, 2017 for the calendar year 2017; (ii) 6% of Net Sales occurring in the calendar year 2018; and (iii) 7% of Net Sales occurring in calendar years 2019 and 2020. To the extent that the cumulative Net Sales for the full calendar years 2017 through 2020 exceeds €45,300,000, Profound will be required to pay an additional earn-out equal to 7% of Net Sales for the period beginning after July 31, 2017 through December 31, 2019. For the period ended March 31, 2019, Profound paid €99,059 as part of the earn-out provision.

"**Net Sales**" include the revenue received by Profound or its affiliates or others on their behalf in respect of the sale or transfer of Sonallevé<sup>®</sup>, any subsequent, successor or next-generation product of which the treatment technology is primarily based on Sonallevé<sup>®</sup> and which utilizes intellectual property rights acquired under the Agreement or any future product that combines the technologies of Sonallevé<sup>®</sup> and TULSA-PRO<sup>®</sup> and any amounts received by Profound with respect to service agreements, but does not include any revenue with respect to disposables.

As part of the Sonallevé<sup>®</sup> Transaction, Philips and Profound expanded their non-exclusive strategic sales relationship for Profound's TULSA-PRO<sup>®</sup> system to include distribution of Sonallevé<sup>®</sup>.

The Sonallevé<sup>®</sup> Transaction has expanded Profound's core competency in MR-ultrasound ablation therapy. Management believes that Profound is now the only company to provide a therapeutics platform that provides the precision of real-time MR imaging combined with the safety and ablative power of directional (inside-out) and focused (outside-in) ultrasound technology for the incision-free ablation of diseased tissue.

### Sales Strategy

Profound sells capital equipment and disposables, which are sold on a per patient basis. The Company has partnered with Philips and Siemens for sales of its capital equipment, while it intends to sell the disposables to the end users, directly. As of January 1, 2018, the capital parts of the TULSA-PRO<sup>®</sup> and Sonallevé<sup>®</sup> systems are available through the Philips sales catalog. Similarly, as of April 1, 2018, TULSA-PRO<sup>®</sup> systems are available for sale through the Siemens sales catalog. The catalogs provide access and enable the sales teams of each company to provide quotations for potential sales, in those jurisdictions where the product is approved for sale by the relevant regulatory bodies.

The Company continues to pursue growth opportunities both organically, increasing its existing business by gaining new customers, increasing product and service penetration with existing clients, as well as through transactions in which the Company acquires new operating entities. Over the past year, the Company has enhanced its corporate development capabilities to execute transactions, through significant investments in people, technology and other organizational resources, and has developed techniques, processes and other intellectual capital, all with the objective of creating a powerful combination of real-time MR-guidance imaging platforms and ultrasound for delivering non-invasive ablative tools to clinicians.

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The Company replaced the original co-marketing and co-selling agreement with Siemens with a new agreement ("**New Siemens Agreement**"). Under the New Siemens Agreement, all prior financial commitments and obligations owed to Siemens are released and replaced with a one-time fixed licence fee and a per annum payment per device interfaced to a Siemens MRI scanner. In exchange for the one-time fixed licence fee and per annum payments, the Company obtained a non-exclusive licence and support for the term of the New Siemens agreement.

## **Competition**

### TULSA-PRO®

The most widely used treatment options for prostate cancer currently are: (1) watchful waiting/active surveillance; (2) radical prostatectomy (includes open, laparoscopic and robotic procedures); (3) radiation therapies including, external beam radiation therapy, brachytherapy and high dose radiation; (4) cryoablation and (5) trans-rectal HIFU. In addition to these widely used treatment options, certain adjunct or less common treatments are used or are under development, such as androgen deprivation therapy and proton beam therapy.

Active surveillance is generally recommended for patients who have been diagnosed with earlier stage, lower risk, disease where the possibility of side effects from intervention may outweigh the expected benefit of the chosen procedure. For clinicians and patients, the gap between active surveillance and the most commonly utilized treatment options of surgery or radiation therapy imposing the possibility of substantial side effects, create an unmet clinical need for treatment options that could address the cancer with a more favourable side-effect profile.

Profound believes that its TULSA-PRO® system will become a compelling option for clinicians in treating prostate cancer with a favorable side-effect profile, fulfilling an unmet clinical need. Profound believes that the flexibility of the TULSA-PRO® system will allow Profound to demonstrate its use as a tool to treat either the whole prostate gland or a customized partial gland option with greater speed, accuracy, less side effects and greater precision than the current treatment options. Profound believes that it will possibly be able to generate clinical data to demonstrate a clear safety advantage without compromising efficacy.

Profound believes that the TULSA-PRO® system may provide a treatment option that could fulfill an unmet clinical need by providing an ablation tool for prostate cancer while minimizing potential side effects. Profound believes that the TULSA-PRO® system may overcome certain limitations of HIFU, such as complications associated with trans-rectal delivery and limitations relating to prostate size. As noted above, Profound believes that a transurethral (inside-out) ablation approach with millimetre accuracy has advantages over HIFU in treating the whole or partial gland safely.

### Sonalleve®

The treatment choices of uterine fibroids usually depends on the symptoms of the patient, size of the fibroid, desire for future pregnancy, and preference of the treating gynecologist. Most common treatment options for uterine fibroids include: (1) hormonal medications including gonadotrophin-releasing hormone agonists; (2) progesterone releasing intra-uterine devices; (3) surgical procedures such as hysterectomy and myomectomy; and (4) uterine artery embolization.

Profound believes that the Sonalleve® system may provide a treatment option that is more convenient and comfortable with less side effects than surgical procedures, such as hysterectomy or myomectomy.

For a detailed description of competition associated with the Company, refer to the "Competition" section of the AIF, which is available on SEDAR at [www.sedar.com](http://www.sedar.com).

## **HIGHLIGHTS**

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- On April 16, 2019, Profound announced the first prostate cancer treatment using a first-of-its-kind TULSA-PRO installation had been performed in Trier, Germany.
- On April 4, 2019, Profound announced positive topline results from TACT Pivotal Clinical Trial of TULSA-PRO in patients with prostate cancer.
- On March 5, 2019, Profound announced that the Company would present at the Cowen and Company 39<sup>th</sup> Annual Health Care Conference.
- On February 28, 2019, Profound announced that it would host an inaugural Analyst & Investor Day on April 11, 2019.

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- On February 20, 2019, Profound announced the participation in 2019 BTIG MedTech, Life Science & Diagnostic Tools Conference.

**SELECTED FINANCIAL INFORMATION**

The following selected financial information as at and for the three month periods ended March 31, 2019, 2018, and 2017, have been derived from the interim financial statements and should be read in conjunction with those interim financial statements and related notes. The results of the acquisition is added from the date of completion.

	For the three month periods ended March 31,		
	2019	2018	2017
	\$	\$	\$
Revenue	<b>1,475,788</b>	376,335	591,517
Operating expenses	<b>3,662,514</b>	4,766,887	4,151,642
Finance costs	<b>314,685</b>	319,963	289,700
Net loss for the period	<b>2,926,886</b>	4,938,186	4,114,782
Basic and diluted loss per share	<b>0.03</b>	0.06	0.07
Total assets	<b>44,874,851</b>	41,966,220	20,764,743
Total non-current liabilities	<b>13,665,070</b>	2,973,954	3,203,913

Over the past year, the Company has enhanced its corporate development capabilities to execute transactions, through significant investments in people, technology and other organizational resources. With regard to TULSA-PRO®, the Company is maintaining a limited European commercial effort and remains focused on US regulatory approval, revenues on a quarter over quarter basis are expected to fluctuate in the near term. The period ended March 31, 2017 was the first year of commercial sales.

On July 31, 2017, Profound closed an asset and share purchase agreement with Philips in order to expand the prior collaboration and acquired its Sonalleve® MR-HIFU business, establishing Profound as a market leader in MR-ultrasound ablation therapy. The Sonalleve® Transaction has led to a higher net loss for the period ended March 31, 2018 of \$4,938,186 compared to the net loss of \$4,114,782 for the comparable period in 2017. The lower net loss in 2019 of \$2,926,886 compared to 2018 was attributed to higher revenue and the replacement of the original co-marketing and co-selling agreement with Siemens with the New Siemens Agreement. Under the New Siemens Agreement, all prior financial commitments and obligations owed to Siemens were released resulting in a one-time recovery.

The Company reported total assets of \$44,874,851 as at March 31, 2019 as compared to \$41,966,220 as at March 31, 2018 and \$20,764,743 for March 31, 2017. The increase in 2019 was a result of the change in accounting policy for *IFRS 16 Leases* ("**IFRS 16**"), which required the recognition of a \$2,513,092 right-of-use asset. The increased total assets in 2018 compared to 2017 related to the proceeds from the CIBC Loan (as defined herein), the build-up of inventory and net proceeds from the 2018 Offering. Inventory increased throughout the period ended March 31, 2019 compared to 2018 and 2017 because of purchases relating to the Sonalleve® business, which were not present in 2017. Total non-current liabilities were higher than in the comparable periods of 2018 and 2017 due to the CIBC Loan, which was obtained in the third quarter of 2018. The period ended 2018 non-current liabilities was lower than 2017 primarily resulting from the prior debt and other liabilities becoming current, in line with contractual repayment terms.

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**RESULTS OF OPERATIONS**

	Three months ended		Change	
	March 31		\$	%
	2019	2018		
	\$	\$		
<b>Revenue</b>	<b>1,475,788</b>	376,335	1,099,453	292%
<b>Cost of sales</b>	<b>533,356</b>	231,075	302,281	131%
<b>Gross profit</b>	<b>942,432</b>	145,260	797,172	549%
<b>Expenses</b>				
Research and development – net of investment tax credits	<b>2,677,746</b>	2,516,781	160,965	6%
General and administrative	<b>1,514,113</b>	1,303,204	210,909	16%
Selling and distribution – net of revenue share obligation reversal	<b>(529,345)</b>	946,902	(1,476,247)	-156%
<b>Total operating expenses</b>	<b>3,662,514</b>	4,766,887	(1,104,373)	-23%
Finance costs	<b>314,685</b>	319,963	(5,278)	-2%
Finance income	<b>(141,881)</b>	(39,804)	(102,077)	256%
<b>Net finance costs</b>	<b>172,804</b>	280,159	(107,355)	-38%
<b>Loss before income taxes</b>	<b>2,892,886</b>	4,901,786	(2,008,900)	-41%
<b>Income tax expense</b>	<b>33,800</b>	36,400	(2,600)	-7%
<b>Net loss attributable to shareholders for the period</b>	<b>2,926,686</b>	4,938,186	(2,011,500)	-41%
<b>Other comprehensive loss</b>				
<b>Item that may be reclassified to profit or loss</b>				
Foreign currency translation adjustment - net of tax	<b>(46,389)</b>	43,248	(89,637)	-207%
<b>Net loss and comprehensive loss for the period</b>	<b>2,880,297</b>	4,981,434	(2,101,137)	-42%
<b>Basic and diluted net loss per common share</b>	<b>0.03</b>	0.06	(0.03)	-50%



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#### **Revenue**

For the three months ended March 31, 2019, the Company recorded revenue totaling \$1,475,788 with \$1,347,781 from the sale of products and \$128,007 from installation and training services, related to the commercial sales of the systems and disposables. For the three months ended March 31, 2018, the Company recorded revenue \$376,335, with \$372,494 from sale of products and \$3,841 from installation and training services. The Company primarily sold the systems and disposables through its partnership agreements with Siemens and Philips. The increase in revenue was the result of increased system and disposable sales in Q1 2019 as well as increased service contracts. As the Company is maintaining a limited European commercial effort and remains focused on US regulatory approval, revenues on a quarter over quarter basis are expected to fluctuate in the near term.

#### **Gross Margin**

For the three months ended March 31, 2019, the Company recorded a cost of sales of \$533,356, related to the commercial sale of systems and disposables, which reflects a 64% gross margin. For the three months ended March 31, 2018, the Company recorded a cost of sales of \$231,075, related to the commercial sale of systems and disposables, which reflects a 39% gross margin. Cost of sales include cost of finished goods, inventory provisions, royalties, warranty, freight and direct overhead expenses. The gross margin was higher in Q1 2019 due to increased disposable and service revenue, which contain higher margins.

#### **Operating Expenses**

##### ***Research and development***

Our research and development ("**R&D**") expenses are comprised of costs incurred in performing R&D activities, including new product development, continuous product improvement, investment in clinical trials and related clinical manufacturing costs, materials and supplies, salaries and benefits, contract research costs, patent procurement costs, and occupancy costs.

For the three months ended March 31, 2019, R&D expenses were higher by \$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 Pivotal Clinical Trial enrollment initiatives and the adoption of IFRS 16 resulting in the recognition of lower rental costs. Depreciation expenses increased by \$28,412 due to the adoption of IFRS 16 with the depreciation of the right-of-use assets.

##### ***General and administrative expenses***

Our general and administrative ("**G&A**") expenses are comprised of management costs, including salaries and benefits, various management and administrative support functions, insurance and other operating and occupancy costs.

G&A expenses for the three months ended March 31, 2019 increased by \$210,909 compared to the three months ended March 31, 2018. Salaries and benefits increased by \$195,151 due to increased G&A personnel, 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 expense increased by \$73,580 due to the adoption of IFRS 16 with the depreciation of the right-of-use assets.

##### ***Selling and distribution expenses***

Our selling, marketing and distribution expenses are comprised of business development costs related to the market development activities and commercialization of our systems, including salaries and benefits, management and support functions and other operating and occupancy costs.

Selling and distribution expenses for the three months ended March 31, 2019 were lower by \$1,476,247 compared to the three months ended March 31, 2018. Revenue share obligation decreased by \$1,224,507 related to the replacement of the original Siemens agreement with the New Siemens Agreement whereby all prior financial commitments and obligations owed to Siemens were released, resulting in a recovery. Marketing expenses decreased by \$76,118 due to lower tradeshow attendance in Q1 2019 and share based compensation expense was lower by \$177,591 due to employee forfeiture of options.

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

#### Finance costs

Finance costs are primarily comprised of interest and accretion expenses relating to the following: (i) the Federal Economic Development Agency Loan (as defined herein) accreting to the principal amount repayable; (ii) the Health Technology Exchange Loan (as defined herein) accreting to the principal amount repayable and its related interest expense; (iii) the Knight Loan (as defined herein) accreting to the principal amount repayable and its related interest expense; (iv) the 0.5% royalty liability to Knight Therapeutics Inc. ("Knight") accreting to the estimated amount payable; (v) the change in fair value of the contingent consideration payable to Philips; (vi) the CIBC Loan accreting to the principal amount repayable and its related interest expense; (vii) the change in the fair value of the derivative liability warrants; and (viii) the lease liability interest expense related to the adoption of IFRS 16.

Finance costs for the three months ended March 31, 2019 were lower by \$5,278 compared to the three months ended March 31, 2018. During the three months ended March 31, 2019, the Company recognized \$11,923 of foreign exchange gain and a \$72,876 gain on the change in fair value to the contingent consideration and a \$57,471 loss on the change in fair value of the derivative liability warrants, respectively. The Company recognized CIBC Loan interest of \$305,509 and lease liability interest expense of \$33,593.

#### Net loss

Net loss for the three months ended March 31, 2019 was \$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 R&D expenses of \$160,965 and an increase in G&A expenses of \$210,909.

#### SUMMARY OF QUARTERLY FINANCIAL RESULTS

The summary financial information provided below is derived from the Company's interim financial statements for each of the last eight quarters that are prepared under IFRS in Canadian dollars.

	2019		2018				2017		
	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2	
	\$	\$	\$	\$	\$	\$	\$	\$	
Revenue	1,475,788	1,708,936	303,664	213,343	376,335	1,890,482	1,465,412	957,139	
Cost of Sales	533,356	1,180,481	240,686	126,259	231,075	1,063,950	1,185,674	471,359	
Gross profit	942,432	528,455	62,978	87,084	145,260	826,532	279,738	485,780	
Operating expenses	3,662,514	5,309,931	5,238,977	5,697,663	4,766,887	5,155,423	5,148,434	5,043,710	
Net finance costs	172,804	(60,151)	(73,733)	196,249	280,159	130,632	651,378	98,207	
Loss before income taxes	2,892,886	4,721,325	5,102,266	5,806,828	4,901,786	4,459,523	5,520,074	4,656,137	
Income tax expense	33,800	136,884	32,700	24,200	36,400	69,470	-	2,356	
Net loss for the period	2,926,686	4,858,809	5,134,966	5,831,028	4,938,186	4,528,993	5,520,074	4,658,493	
Loss per common share									
Basic and diluted	0.03	0.04	0.05	0.05	0.06	0.06	0.09	0.08	

The initial pilot launch of The TULSA-PRO<sup>®</sup> system after receiving CE Certificate of Conformity from its notified body in the European Union commenced in 2017.

The third quarter of 2017 was impacted by the Sonalleve<sup>®</sup> acquisition that took place on July 31, 2017.

The second quarter of 2018 was affected by increased management compensation due to the hiring of key management personnel.

The third quarter of 2018 net finance costs were lower due to a gain on the change in fair value of contingent consideration and share warrants being recognized.

The fourth quarter of 2018 was impacted by increased commercial sales of systems, resulting in increased revenues. Net finance costs were lower due to a gain on the change in fair value of contingent consideration and share warrants.

## **Profound Medical Corp.**

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

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The first quarter of 2019 operating expenses were significantly lower due to the revenue share obligation recovery whereby all prior financial commitments and obligations owed to Siemens were released as part of the New Siemens Agreement.

## **LIQUIDITY AND CAPITAL RESOURCES**

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At March 31, 2019, the Company had cash of \$27,048,837 compared to \$30,687,183 at December 31, 2018.

### CIBC Loan

Profound Medical Inc. ("PMI") entered into a loan agreement with Canadian Imperial Bank of Commerce ("CIBC") on July 30, 2018 (the "**CIBC Loan Agreement**"), for initial gross proceeds of \$12,500,000 with an interest rate based on prime plus 2.5% (the "**CIBC Loan**"). PMI is required to make interest only payments for the first 15 months and monthly repayments on the principal plus accrued interest afterwards for 33 months. All obligations of PMI under the CIBC Loan Agreement are guaranteed by the Company and certain of its current and future subsidiaries and include first priority security interests in the assets of the Company and such subsidiaries. PMI has the ability to draw an additional \$6,250,000 subject to the achievement of certain financing and product development milestones. In connection with the CIBC Loan Agreement, the Company also issued Common Share purchase warrants to CIBC, with each warrant entitling the holder to acquire one Common Share at a price of \$0.97 per Common Share until the date that is 60 months from the closing of the CIBC Loan Agreement, with a cashless exercise feature. The cashless exercise feature causes the conversion ratio to be variable and the warrants are therefore classified as a financial liability. Gains and losses on the warrants are recorded within finance costs on the consolidated statements of loss and comprehensive loss. A pricing model with observable market-based inputs was used to estimate the fair value of the warrants issued. The estimated fair value of the warrants at March 31, 2019 and December 31, 2018 was \$155,674 and \$98,203, respectively. As at March 31, 2019, the principal balance outstanding on the CIBC Loan Agreement was \$12,500,000.

### Federal Economic Development Agency Loan

Pursuant to a loan agreement dated December 16, 2011, the Federal Economic Development Agency provided the Company with an unsecured and non-interest bearing loan of \$867,000 (the "**Federal Economic Development Agency Loan**") with the final repayment of \$563,550 made on July 25, 2018.

### Health Technology Exchange Loan

Pursuant to a loan agreement dated May 25, 2011, as amended April 1, 2012, and a loan agreement dated May 31, 2014, the Health Technology Exchange provided the Company with an unsecured loan of \$1,500,000 bearing interest at 4.5% per annum (the "**Health Technology Exchange Loan**"). The final payment of \$1,094,698 including accrued interest was made on March 31, 2018.

### Knight Loan

Pursuant to a loan agreement dated April 30, 2015, Knight provided the Company with a secured loan of \$4,000,000 bearing interest at 15% per annum (the "**Knight Loan**"). On July 25, 2018, the full amount of the Knight Loan, including prepayment fees, was repaid for a total payment of \$3,188,023.

In addition to the Knight Loan, the Company granted Knight a 0.5% royalty on total net sales of all products until the original maturity date of the Knight Loan. The royalty was initially recorded at fair value and subsequently carried at amortized cost using the effective interest rate method. The initial fair value of the royalty was determined using future revenue forecasts for the term of the Knight Loan and a discount rate of 18%. During the three months ended March 31, 2019, the Company revised the fair value of the royalty, using future revenue forecasts for the term of the Knight Loan.

## **Cash Flow**

The Company manages liquidity risk by monitoring actual and projected cash flows. A cash flow forecast is performed regularly to ensure that the Company has sufficient cash to meet operational needs while maintaining sufficient liquidity.

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

The Company may require additional capital to fund R&D activities and any significant expansion of operations. Potential sources of capital could include equity and/or debt financings, development agreements or marketing agreements, the collection of revenue resulting from future commercialization activities and/or new strategic partnership agreements to fund some or all costs of development. There can be no assurance that the Company will be able to obtain the capital sufficient to meet any or all of the Company needs. 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 products, the state of the capital markets generally, strategic alliance agreements and other relevant commercial considerations. In addition, if the Company raises additional funds by issuing equity securities, existing security holders will likely experience dilution, and any incurring of indebtedness would result in increased debt service obligations and could require the Company to agree to operating and financial covenants that would restrict operations. Any failure on the Company's part to raise additional funds on terms favourable to the Company or at all may require the Company to significantly change or curtail 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 the Company not being in a position to take advantage of business opportunities, in the termination or delay of clinical trials for our products, in curtailment of product development programs designed to identify new products, in the sale or assignment of rights to technologies, product and/or an inability to file market approval applications at all or in time to competitively market products.

	Three months ended	
	March 31, 2019	March 31, 2018
	\$	\$
Cash provided by (used in) operating activities	(3,218,042)	(3,721,343)
Cash provided by (used in) financing activities	(420,304)	30,633,083
<b>Net increase (decrease) in cash</b>	<b>(3,638,246)</b>	<b>26,911,740</b>

Net cash provided by (used in) operating activities for the three months ended March 31, 2019 was \$(3,218,042) versus \$(3,721,343) for the three months ended March 31, 2018. The principal decreased use of the operating cash flows during this period related to decreased net loss for the period attributed to the entering into of the New Siemens Agreement.

Net cash provided by (used in) financing activities for the three months ended March 31, 2019 were \$(420,304) versus \$30,633,083 for the three months ended March 31, 2018. These cash flows related to the CIBC Loan interest payments in 2019 versus the Health Technology Exchange Loan, Federal Economic Development Agency Loan and the Knight Loan interest payments in 2018 and the 2018 Offering of \$34,500,000 less transactions costs.

### Contractual obligations

The following table summarizes the Company's significant contractual obligations:

	March 31, 2019				
	Carrying amount \$	Future cash flows \$	Less than 1 Year \$	Between 1 year and 5 years \$	Greater than 5 years \$
Accounts payables and accrued liabilities	3,581,671	3,581,671	3,581,671	-	-
Long-term debt	11,929,264	14,366,717	3,119,139	11,247,578	-
Other liabilities	1,196,884	1,261,718	560,776	700,942	-
Lease liability	2,539,754	3,089,997	454,453	1,747,706	887,838
<b>Total</b>	<b>19,247,393</b>	<b>22,300,103</b>	<b>7,716,039</b>	<b>13,696,226</b>	<b>887,838</b>

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

#### Use of Proceeds

##### 2018 Offering

The Company received net proceeds of \$32,027,502 from the public offering of units completed on March 20, 2018 (the "2018 Offering"). Each unit consisted of one Common Share and one-half of one warrant of the Company. The following table compares the intended use of net proceeds with the actual expenditures as at March 31, 2019, by which time the proceeds from the 2018 Offering were partially expended.

	<b>Estimated per 2018 Offering</b>	<b>Total spending as at March 31, 2019</b>
To support certain costs and expenses of other clinical trial support and the ongoing TACT Pivotal Clinical Trial follow up and finalization		
Patient follow up costs (based on an agreed amount for each patient with the participating hospitals)	\$2,100,000 to \$2,700,000	\$1,802,000
Increased personnel requirements and employee travel expenses related to support of the clinical procedures for patients	\$1,200,000 to \$1,500,000	\$1,627,000
Ongoing expansion of infrastructure to execute on global sales and marketing plans with respect to the TULSA-PRO® system and Sonalleve® MR-HIFU system		
TULSA-PRO® sales and marketing activities	\$3,300,000 to \$3,800,000	\$2,096,000
Sonalleve® MR-HIFU sales and marketing activities	\$2,000,000 to \$2,200,000	\$1,922,000
To support ongoing research and development and continue to invest in additional research and development and acquisitions in order to expand the applications for current and future platforms	\$6,400,000 to \$7,100,000	\$7,098,000
For general corporate purposes		
Scheduled repayment under the Knight Loan and other indebtedness	\$4,200,000	\$5,982,000
Material and inventory purchases	\$3,800,000 to \$4,100,000	\$5,189,000
General working capital purposes	\$2,000,000 to \$2,200,000	\$1,641,000
<b>Totals</b>		<b>\$27,357,000</b>

Although it is intended the remainder of the net proceeds from the 2018 Offering of \$4,670,502 will be used as set out above based on the current knowledge and planning of the Company's management, there may be circumstances where, for sound business reasons, a reallocation of funds may be deemed prudent or necessary and the use of proceeds may vary materially from that set forth above.

#### Non-IFRS Financial Measures

Non-IFRS measures are not recognized measures under IFRS and do not have a standardized meaning prescribed by IFRS. These measures are defined with reference to the nearest comparable IFRS measure such that a reconciliation to the nearest comparable IFRS measure can be completed. Accordingly, these measures may not be comparable to similar measures presented by other companies. We use non-IFRS measures in order to provide additional financial information to complement the closest IFRS measures in order to provide investors with a further understanding of our operations from management's perspective. Investors should not consider that these non-IFRS measures are a substitute for analyses of the financial information that we report under IFRS. We use these non-IFRS measures in order to provide investors with a supplemental measure of our operating performance and thus highlight trends in our business that may not otherwise be apparent when relying solely on IFRS measures.

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

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The Company's working capital (defined as current assets less current liabilities) is a non-IFRS financial measure. The working capital as at March 31, 2019 is set forth in the table below. The Company defines working capital as current assets less current liabilities, with the exclusion of deferred revenue. Deferred revenue represents the excess of amounts billed and revenue recognized on service contracts. The amount is amortized into revenue as services are rendered, in accordance with the revenue recognition policies described in the Company's interim financial statements.

Deferred revenue is a non-cash liability and therefore management believes that adding back the deferred revenue provides a more accurate reflection of the liquidity and working capital position of the Company.

	March 31, 2019	December 31, 2018
	\$	\$
Current assets	34,352,745	37,919,789
Less: Current liabilities	7,349,544	7,879,360
Working capital	27,003,201	30,040,429
Add back: Deferred revenue	417,669	312,558
<b>Net working capital</b>	<b>27,420,870</b>	<b>30,352,987</b>

Working capital has decreased by \$2,923,117 with a surplus of \$27,420,870 at March 31, 2019 compared to the surplus of \$30,352,987 at December 31, 2018. The change in working capital is due to a decrease in current liabilities of \$529,816, which was primarily the result of the New Siemens Agreement whereby all obligations owed to Siemens were released. Accounts payable and accrued liabilities decreased by \$330,679 due to the timing of payments made to certain vendors. The decrease in working capital correlates to the decreased cash balance of \$27,048,837 resulting from general working capital payments.

## COMMITMENTS & CONTINGENCIES

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All directors and officers of the Company are indemnified by the Company for various items including, but not limited to, all costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors' and officers' liability insurance to mitigate the cost of any potential future lawsuits or actions. The term of the indemnification is not explicitly defined but is limited to events for the period during which the indemnified party served as a director or officer of the Company. The maximum amount of any potential future payment cannot be reasonably estimated but could have a material adverse effect on the Company.

The Company has also indemnified certain lenders and underwriters in relation to certain debt and equity offerings and their respective affiliates and directors, officers, employees, shareholders, partners, advisers and agents and each other person, if any, controlling any of the underwriters or lenders or their affiliates against certain liabilities.

## FINANCIAL INSTRUMENTS

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The Company's financial instruments consist of cash, trade and other receivables, accounts payable and accrued liabilities, long-term debt, derivative financial instrument and other liabilities. The fair values of these financial instruments, except long-term debt and other liabilities, approximate carrying value because of their short-term nature. Financial assets measured at amortized cost include cash and trade and other receivables.

Financial liabilities measured at amortized cost include accounts payable and accrued liabilities, long-term debt and other liabilities. Amortization is recorded using the effective interest rate method.

The Company's financial instruments are exposed to certain financial risks including credit risk, liquidity risk, currency risk and interest rate risk. There have been no significant changes to those risks impacting the Company since December 31, 2018, nor has there been a significant change in the composition of its financial instruments since December 31, 2018.

## Profound Medical Corp.

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

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## RELATED PARTY TRANSACTIONS

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Key management includes the Company's directors and senior management team. Additional information on the senior management team can be found in the Company's AIF. The remuneration of directors and the senior management team were as follows:

	Three months ended	
	March 31, 2019	March 31, 2018
	\$	\$
Salaries and employee benefits	349,590	203,726
Termination benefits	-	114,750
Directors' fees	37,500	19,947
Share-based compensation	56,634	172,804
<b>Total</b>	<b>443,724</b>	<b>511,227</b>

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

## OUTSTANDING SHARES

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As at May 6, 2019, the date of this MD&A, the Company had the following securities outstanding:

	Number
Common Shares	108,054,939
Share purchase options	5,409,779
Warrants	22,571,714

## OFF BALANCE SHEET ARRANGEMENTS

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The Company has no off-balance sheet arrangements other than those disclosed in this MD&A.

## CRITICAL ACCOUNTING JUDGMENTS AND ESTIMATES

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The preparation of financial statements in conformity with IFRS requires management to make estimates and judgements that affect the reported amounts of assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the period. Actual results could differ from these estimates. As additional information becomes available or actual amounts are determinable, the recorded estimates are revised and reflected in operating results in the period in which they are determined.

### Critical accounting judgments

#### *Complex financial instruments and provisions*

The Company makes various judgments when determining the accounting for certain complex financial instruments. The Company has concluded that the contingent consideration in a business combination represents a financial liability measured at fair value through profit or loss.

## **Profound Medical Corp.**

### Management's Discussion and Analysis

For the three months ended March 31, 2019 and 2018

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#### **Critical accounting estimates**

##### *Impairment of non-financial assets*

The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

##### *Accounting for acquisitions and contingent consideration*

Areas of estimation include the determination and fair value measurement of the contingent consideration, which includes the Company developing its best estimate of projected revenue, the probability of the contingency being achieved and the discount rate. Management is also required to make estimates of the fair value of assets acquired and liabilities assumed.

##### *Clinical trial expenses*

Clinical trial expenses are accrued based on the services received and efforts expended pursuant to agreements with clinical trial sites and other vendors. In the normal course of business the Company contracts third parties to perform various clinical trial activities. The financial terms of these agreements vary from contract to contract, are subject to negotiation and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients or the completion of certain portions of a clinical trial. The Company determines the accrual by reviewing contracts, vendor agreements and through discussions with internal personnel and external clinical trial sites as to the progress or stage of completion of the clinical trial and the agreed-upon fees to be paid for such services. Actual costs and timing of the clinical trial is uncertain, subject to risks and may change depending on a number of factors.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

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### **Accounting standards recently adopted**

A number of new or amended standards became applicable for the current reporting period and the Company had to change its accounting policies as a result. The impact of the adoption of these standards are disclosed below.

#### **IFRS 16, Leases**

On January 13, 2016, the IASB published a new standard, *IFRS 16, Leases*. The new standard eliminates the distinction between operating and finance leases and brings most leases onto the consolidated balance sheet for lessees. The adoption of IFRS 16 from January 1, 2019 resulted in changes in accounting policies of the Company. As the Company has significant contractual obligations in the form of operating leases, there were material increases to both assets and liabilities on adoption of IFRS 16, and changes to the timing of recognition of expenses associated with the lease arrangements.

In accordance with the transitional provisions in IFRS 16, the Company has adopted the new rules on a modified retrospective transition method and accordingly the information presented for 2018 has not been restated. Further, the Company has elected to apply the practical expedient not to recognize right-of-use assets and lease liabilities for short-term leases that have a lease term of 12 months or less and leases of low-value assets.

## **DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING**

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Disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure.

The Chief Executive Officer and the Chief Financial Officer of the Company (collectively the "**Certifying Officers**") are responsible for establishing and maintaining disclosure controls and procedures ("**DC&P**") and internal control over financial reporting ("**ICFR**"), as those terms are defined in *National Instrument 52-109 Certification of Disclosure in Issuer's Annual and Interim Filings*, for the Company.



## **Profound Medical Corp.**

### **Management's Discussion and Analysis**

For the three months ended March 31, 2019 and 2018

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The Certifying Officers have concluded that as at March 31, 2019, the Company's DC&P has been designed effectively to provide reasonable assurance that (a) material information relating to the Company is made known to them by others, particularly during the period in which the annual filings are being prepared; and (b) information required to be disclosed by the Company in its annual filings, interim filings or other reports filed or submitted, recorded, processed, summarized and reported within the time periods specified in the securities legislation.

There have been no significant changes to the Company's ICFR for the period ended March 31, 2019, which have materially affected, or are reasonably likely to materially affect the Company's ICFR. Based on their evaluation of these controls for the period ended March 31, 2019, the Certifying Officers have also concluded that the Company's ICFR have been designed effectively to provide reasonable assurance regarding the reliability of the preparation and presentation of the financial statements for external purposes and that ICFR were effective as at March 31, 2019. The Company used the Committee of Sponsoring Organizations of the Treadway Commission control framework to evaluate DC&P and ICFR.

It should be noted that while the Company's Certifying Officers believe that the Company's DC&P provides a reasonable level of assurance that they are effective, they do not expect that the disclosure controls will prevent all errors and fraud. A control system, no matter how well conceived or operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met.

ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the interim financial statements for external reporting purposes in line with IFRS. Management is responsible for establishing and maintaining adequate internal controls over financial reporting appropriate to the nature and size of the Company. However, any system of internal control over financial reporting has inherent limitations and can only provide reasonable assurance with respect to interim financial statement preparation and presentation.

In conjunction with the transition to the new IFRS 16, Leases, the Company has determined that the adoption of these new accounting standards did not have a significant impact on its control environment.

## **RISK FACTORS**

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For a detailed description of risk factors associated with the Company, refer to the "Risk Factors" section of the AIF, which is available on SEDAR at [www.sedar.com](http://www.sedar.com).

In addition, the Company is exposed to a variety of financial risks in the normal course of operations, including risks relating to cash flows from operations, liquidity, capital reserves, market rate fluctuations and internal controls over financial reporting. Our overall risk management program and business practices seek to minimize any potential adverse effects on our consolidated financial performance. Financial risk management is carried out under practices approved by our audit committee. This includes reviewing and making recommendations to the board of directors regarding the adequacy of our risk management policies and procedures with regard to identification of the Company's principal risks, and implementation of appropriate systems and controls to manage these risks.

## **ADDITIONAL INFORMATION**

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Additional information relating to the Company, including the AIF, is available on SEDAR at [www.sedar.com](http://www.sedar.com). The Common Shares are listed for trading on the TSX under the symbol "PRN."