



PROFOUND MEDICAL CORP.

**MANAGEMENT'S DISCUSSION AND ANALYSIS
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017**

Profound Medical Corp.

Management's Discussion and Analysis

For the years ended December 31, 2018 and 2017

The following Management's Discussion and Analysis ("MD&A") prepared as of March 7, 2019 should be read in conjunction with the December 31, 2018 audited consolidated financial statements and related notes of Profound Medical Corp. ("Profound", the "Company", "us" or "our"). The audited 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"). 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

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, 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

Profound (TSX: PRN; OTCQX: PRFMF) develops, manufactures and markets a therapeutic platform that provides the precision of real-time magnetic resonance ("MR") imaging combined with the safety and accuracy of directional and focused ultrasound technology for incision and radiation free ablation of diseased tissue. Profound's TULSA-PRO[®] is a robotically controlled catheter based transurethral thermal ultrasound system that combines real time temperature monitoring by way of a continuous closed feedback loop via magnetic resonance imaging ("MRI") guidance and the Company's process control software for precise inside-out ablation of diseased prostate tissue; minimizing healthy tissue damage and the occurrence of disabling side effects. Additionally, the Company acquired the Sonalleve[®] focused ultrasound system in 2017 from Koninklijke Philips N.V. ("**Philips**") to create a MR-guided therapeutic ultrasound platform that can offer ablative therapies for use in the treatment of multiple other disease conditions, broadening the scope of the Company's long-term product offerings.

The Company's TULSA-PRO[®] technology is designed to provide a minimally invasive and precise ablation of the prostate while simultaneously reducing the risk of harming the critical surrounding anatomy from potential side effects. TULSA-PRO[®] provides the surgeons with the flexibility to personalize the treatment to the patient's specific anatomy and pathology thus enabling prostate ablation for patients with localized prostate cancer; in a whole gland to targeted (focal) approach, as well as ablative therapies for the treatment of 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 if successful, it is expected to support Profound's application to the U.S. Food and Drug Administration ("**FDA**") for clearance to market this technology in the United States. In May of 2018, initial data from the TACT Pivotal Clinical Trial was presented at the AUA conference, with median prostate-specific antigen ("**PSA**") reduction to-date reported as 95% (nadir 0.36 ng/ml), and 95% (109 out of 115) patients were reported to meet the PSA endpoint, of at least a 75% reduction in PSA. TULSA-PRO[®] is CE marked for ablation of targeted benign and malignant prostate tissue. 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. 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 incision-free, precise and customized procedures that are real-time MR-guided ultrasound ablations performed with the TULSA-PRO[®] and Sonalleve[®] systems. These incision-free flexible procedures offer surgeons the option of providing precise and customized procedures that further reduce invasiveness, offer the potential to improve clinical outcomes and further reduce hospital stays and patient recovery times.

TULSA-PRO[®] 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[®] 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[®] and Sonalleve[®] systems. The primary focus of the direct sales team is to cultivate adoption of the TULSA-PRO[®] technology, support clinical customers TULSA-PRO[®]

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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® 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® 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 21, 2018, Dr. Laurence Klotz presented preliminary results of the TACT Pivotal Clinical Trial across 13 research sites in the United States, Canada and Europe. The primary efficacy endpoint of the TACT Pivotal Clinical Trial is the proportion of patients achieving a post-treatment PSA reduction of no less than 75% of their pre-treatment baseline value. The Company's pre-established performance goal for the proportion successfully achieving the primary efficacy endpoint is 50% of patients. Based on a preliminary analysis performed by the Company, of the 115 evaluable patients, the median PSA reduction to-date was 95% and 95% (109 out of 115) of patients had achieved the PSA reduction success proportion. The primary safety endpoint is the frequency and severity of adverse events, with additional secondary endpoints focused on the disabling quality-of-life side effects commonly associated with current prostate cancer therapies, such as urinary incontinence, bowel dysfunction and erectile dysfunction. As the standard evaluation period for these side effects is 12 months post-treatment, the sample size of evaluable patients is not yet large enough to assess.

If successful, the TACT Pivotal Clinical Trial is expected to support Profound's application to the FDA for approval to market the TULSA-PRO® system 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® system with the FDA as a Class II device.

In 2017, Profound made reimbursement progress in Germany for TULSA-PRO®. TULSA-PRO® 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.

Sonalleve® 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.

Sonalleve® 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 Sonalleve® MR-HIFU business (the "**Sonalleve® Transaction**"), establishing Profound as a market leader in MR-ultrasound ablation therapy.

Under the terms of the Agreement, Philips transferred its Sonalleve® 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 year ended December 31, 2018, 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 Sonalleve®, any subsequent, successor or next-generation product of which the treatment technology is primarily based on Sonalleve® and which utilizes intellectual property rights acquired under the Agreement or any future product that combines the technologies of Sonalleve® and TULSA-PRO® 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 Sonalleve® Transaction, Philips and Profound expanded their non-exclusive strategic sales relationship for Profound's TULSA-PRO® system to include distribution of Sonalleve®.

The Sonalleve® Transaction has expanded Profound's core competency in MR-ultrasound ablation therapy. Management believes that Profound is now the only Company to provide a therapeutic 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.

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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® and Sonalleve® systems are available through the Philips sales catalog. Similarly, as of April 1, 2018, TULSA-PRO® 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.

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 (insideout) 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.

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HIGHLIGHTS

- On December 14, 2018, Profound announced changes to commercial organization with the resignation of Ian Heynen, Senior Vice-President Sales & Marketing.
- On November 7, 2018, Profound presented at the Stifel 2018 Healthcare Conference.
- On September 19, 2018, Profound filed a final short form base shelf prospectus.
- On September 18, 2018, Profound press released 3-year clinical outcomes and BPH subgroup analysis of Profound's Phase I Clinical Trial to be included in a presentation at DGU 2018.
- On July 31, 2018, Profound issued a press release that the Company would present at the Canaccord Genuity 38th Annual Growth Conference.
- On July 30, 2018, Profound secured a term loan agreement with CIBC Innovation Banking (the "CIBC Loan").
- On July 11, 2018, Profound graduated to the Toronto Stock Exchange ("TSX").
- On June 14, 2018, Profound disclosed the annual meeting of shareholders voting results and welcomed two industry veterans, Dr. Arthur Rosenthal and Brian Ellacott, as independent Directors to its board.
- On May 21, 2018, Profound announced the initial data from the TACT Pivotal Clinical Trial presented at American Urological Association 2018.
- On May 9, 2018, Profound obtained the Chinese Food and Drug Administration approval for Sonalleve®.
- On May 1, 2018, Profound further strengthened the management team with the appointment of Aaron Davidson as Chief Financial Officer and Senior Vice-President of Corporate Development.
- On April 25, 2018, Profound press released that they would present at the 2018 Bloom Burton & Co. Healthcare Investor Conference.
- On April 23, 2018, Profound hired the accomplished international medical device industry executive, Ian Heynen, Senior Vice-President Sales & Marketing, to lead Profound Medical's sales and marketing function.
- On March 20, 2018, Profound completed a bought deal financing pursuant to a short form prospectus for total gross proceeds of \$34,500,000 including the exercise of the underwriters' over-allotment option.
- On February 28, 2018, Profound announced the upsizing of the \$20,000,000 bought deal offering to \$30,000,000.
- On February 27, 2018, Profound announced a \$20,000,000 bought deal financing.
- On February 26, 2018, Profound announced the participation in 2018 BTIG Healthcare Conference.
- On January 31, 2018, Profound announced the completion of patient enrollment in the TACT Pivotal Clinical Trial.

SELECTED FINANCIAL INFORMATION

The following selected financial information as at and for the year ended December 31, 2018, 2017, and 2016, have been derived from the audited financial statements and should be read in conjunction with those audited financial statements and related notes. The results of the acquisition is added from the date of completion.

	Year ended December 31,		
	2018	2017	2016
	\$	\$	\$
Revenue	2,602,278	4,904,550	-
Operating expenses	21,013,458	19,499,209	15,640,414
Finance costs	826,312	1,249,084	829,899
Net loss for the year	20,532,205	18,748,219	16,326,769
Basic and diluted loss per share	0.21	0.31	0.39
Total assets	46,549,872	27,879,379	23,692,843
Total non-current liabilities	12,044,178	3,121,999	3,909,489

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 year ended December 31, 2017 was the first year of commercial sales.

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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 year ended December 31, 2018 of \$20,532,205 compared to the net loss of \$18,748,219 for the comparable year in 2017 and \$16,326,769 in 2016 due to increased operations.

The Company reported total assets of \$46,549,872 as at December 31, 2018 as compared to \$27,879,379 as at December 31, 2017 and \$23,692,843 for year of 2016. The increase was related to the proceeds from the CIBC Loan, the build up of inventory and net proceeds from the 2018 Offering that was completed in the year. Inventory increased for the year ended December 31, 2018 compared to 2017 and 2016 because of purchases relating to the Sonalleve[®] business, which were not present in 2017. Total non-current liabilities were higher than in the comparable year of 2017 and 2016 due to the CIBC Loan, which was obtained in the third quarter of 2018. The year ended 2017 non-current liabilities was lower than 2016 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 December 31				Year ended December 31			
	2018	2017	Change		2018	2017	Change	
	\$	\$	\$	%	\$	\$	\$	%
Revenue	1,708,936	1,890,482	(181,546)	-10%	2,602,278	4,904,550	(2,302,272)	-47%
Cost of sales	1,180,481	1,063,950	116,531	11%	1,778,501	3,032,208	(1,253,707)	-41%
Gross profit	528,455	826,532	(298,077)	-36%	823,777	1,872,342	(1,048,565)	-56%
Expenses								
Research and development - net of investment tax credits	2,823,313	2,524,405	298,908	12%	10,265,388	9,638,190	627,198	7%
General and administrative	1,351,450	1,456,649	(105,199)	-7%	6,656,723	5,935,215	721,508	12%
Selling and distribution	1,135,168	1,174,369	(39,201)	-3%	4,091,347	3,925,804	165,543	4%
Total operating expenses	5,309,931	5,155,423	154,504	3%	21,013,458	19,499,209	1,514,249	8%
Finance costs	111,275	169,046	(57,771)	-34%	826,312	1,249,084	(422,772)	-34%
Finance income	(171,426)	(38,414)	(133,012)	346%	(483,788)	(127,732)	(356,056)	279%
Net finance costs	(60,151)	130,632	(190,783)	-146%	342,524	1,121,352	(778,828)	-69%
Loss before income taxes	4,721,325	4,459,523	261,802	6%	20,532,205	18,748,219	1,783,986	10%
Income tax expense	136,884	69,470	67,414	97%	230,784	74,123	156,661	211%
Net loss attributable to shareholders for the period	4,858,809	4,528,993	329,816	7%	20,762,989	18,822,342	1,940,647	10%
Other comprehensive loss								
Item that may be reclassified to profit or loss								
Foreign currency translation adjustment - net of tax	42,707	(83,767)	126,474	-151%	29,226	(69,245)	98,471	-142%
Net loss and comprehensive loss for the period	4,901,516	4,445,226	456,290	10%	20,792,215	18,753,097	2,039,118	11%
Basic and diluted net loss per common share	0.04	0.06	(0.02)	-33%	0.21	0.31	(0.10)	-32%

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Revenue

For the three months ended December 31, 2018, the Company recorded revenue totaling \$1,708,936 with \$1,628,358 from the sale of products and \$80,578 from installation and training services, related to the commercial sales of the systems and disposables. For the three months ended December 31, 2017, the Company recorded revenue \$1,890,482, with \$1,738,450 from sale of products and \$152,032 from installation and training services. The Company primarily sold the systems and disposables through its partnership agreements with Siemens and Philips. The decrease in revenue was the result of fewer new system and disposable sales in Q4 2018. 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.

For the year ended December 31, 2018, the Company recorded revenue totaling \$2,602,278, with \$2,421,331 from the sale of products and \$180,947 from installation and training services, related to the commercial sales of the systems and disposables. For the year ended December 31, 2017, the Company recorded revenue totaling \$4,904,550, with \$4,663,986 from sale of products and \$240,564 from installation and training services. The Company primarily sold the systems through its partnership agreements with Siemens and Philips. The decrease in revenue was the result of fewer new system and disposable sales in 2018. As the Company is maintaining a limited European commercial effort and remains focused on US regulatory approval, revenues on a year over year basis are expected to fluctuate in the near term.

Gross Margin

For the three months ended December 31, 2018, the Company recorded a cost of sales of \$1,180,481, related to the commercial sale of systems and disposables, which reflects a 31% gross margin. For the three months ended December 31, 2017, the Company recorded a cost of sales of \$1,063,950, related to the commercial sale of systems and disposables, which reflects a 44% gross margin. Cost of sales include cost of finished goods, inventory provisions, royalties, warranty, freight and direct overhead expenses. The gross margin was lower in Q4 2018 due to increased overhead and costs of finished goods.

For the year ended December 31, 2018, the Company recorded a cost of sales of \$1,778,501, related to the commercial sale of the systems and disposables, which reflects a 32% gross margin. For the year ended December 31, 2017, the Company recorded a cost of sales of \$3,032,208, related to the commercial sale of systems and disposables, which reflects a 38% gross margin. Cost of sales include cost of finished goods, inventory provisions, royalties, warranty, freight and direct overhead expenses. The gross margin was lower in 2018 due to changes in the product mix as a result of the Sonalleve[®] Transaction and lower gross margin on disposables compared to the systems based on initial lower volumes.

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 December 31, 2018, R&D expenses were higher by \$298,908 compared to the three months ended December 31, 2017. Overall, the increase in R&D spending was attributed to new project initiatives. Materials, consulting fees, salaries and benefits, rent and other expenses increased by \$273,169, \$110,017, \$168,137, \$21,792 and \$129,545, respectively. These costs were higher due to new R&D projects, increased R&D personnel and occupancy costs. Offsetting these amounts was a decrease in clinical trial costs of \$402,414 because of the completion of the TACT Pivotal Clinical Trial enrollment initiatives.

For the year ended December 31, 2018, R&D expenses were higher by \$627,198 compared to the year ended December 31, 2017. Overall, the increase in R&D spending was attributed to the Sonalleve[®] Transaction, which occurred in Q3 2017. Materials, occupancy costs, salaries and benefits and other expenses increased by \$125,035, \$110,756, \$1,224,691 and \$177,625, respectively. These costs were higher compared to the year ended December 31, 2017, due to a higher number of R&D personnel, new initiatives with the Sonalleve[®] product and a new facility in Finland. Offsetting these amounts was a decrease in clinical trial costs, travel and share based compensation by \$1,544,191, \$26,194 and \$67,403, respectively, resulting from the completion of the TACT Pivotal Clinical Trial enrollment initiatives and the forfeiture of certain share options. Amortization of intangible assets increased by \$626,593 due to the Sonalleve[®] Transaction which represents 12 months amortization in 2018 versus 5 months amortization in 2017.

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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 December 31, 2018 were lower by \$105,199 compared to the three months ended December 31, 2017. Consulting fees, share-based compensation expense and office and other expense decreased by \$132,821, \$90,463 and \$50,583, respectively, due to issuance of stock options to Company executives and employees in 2017 and lower consulting costs due to less activity transpiring in Q4 2018. These costs were offset by an increase in salaries and benefits of \$179,082, due to increased G&A personnel, board members and overall salary increases.

G&A expenses for the year ended December 31, 2018 were higher by \$721,508 compared to the year ended December 31, 2017. Salaries and benefits, travel and office and other increased by \$885,846, \$60,982 and \$28,879, respectively, due to increased number of G&A personnel and board members, bonus payments, salary increases, the inclusion of Sonallevé® operations, increased insurance expenses and travel to customer sites. These costs were offset by a decrease in share-based compensation expense and occupancy costs by \$326,501 and \$106,427, respectively, on account of decreased share based compensation expense and lower utility bills and repairs to the facilities. Depreciation expense increased by \$167,970 primarily due to leasehold improvements for the new facility that was constructed in the latter part of 2017.

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 December 31, 2018 were lower by \$39,201 compared to the three months ended December 31, 2017. Salaries and benefits decreased by \$65,941 due to sales force turnover and a reduced revenue share obligation expense of \$239,212 related to the Siemens revenue share payments compared to the minimum amounts contractually stipulated. These costs were offset by an increase in consulting fees, marketing, travel and share based compensation by \$89,404, \$54,135, \$40,041 and \$70,528, respectively. The increase is attributable to additional sales consultants working and traveling overseas, stock awards issued to new employees, increased marketing-related efforts and product branding development.

Selling and distribution expenses for the year ended December 31, 2018 were higher by \$165,543 compared to the year ended December 31, 2017. Salaries and benefits, consulting fees, travel, marketing and share based compensation increased by \$400,470, \$175,152, \$77,295, \$138,644 and \$145,229, respectively, due to additional direct sales force personnel, awards issued to new employees, increased marketing-related efforts, product branding development and conference attendance. These costs were offset by a reduced revenue share obligation expense of \$787,858 related to the Siemens revenue share payments compared to the minimum amounts contractually stipulated.

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 (as defined herein) accreting to the principal amount repayable and its related interest expense; and (vii) the change in the fair value of the derivative liability warrants.

Finance costs for the three months ended December 31, 2018 were lower by \$57,771 compared to the three months ended December 31, 2017. During the three months ended December 31, 2018, the Company recognized \$95,441 of foreign exchange loss and a \$218,277 and \$25,349 gain on the change in fair value to the contingent consideration and the change in fair value of the derivative liability warrants, respectively. The Company recognized CIBC Loan interest and accretion expense of \$315,579.

Finance costs for the year ended December 31, 2018 were lower by \$422,772 compared to the year ended December 31, 2017. During the year ended December 31, 2018, the Company recognized \$214,226 of foreign exchange loss, a \$325,253 and \$96,619 gain on the change in fair value gain on the contingent consideration and the change in fair value of the derivative liability warrants, respectively. The Company recognized a decrease in the Health Technology Exchange Loan and Federal Economic Development Agency Loan and Knight Loan interest and accretion expense of \$57,149 and \$752,358, respectively and CIBC Loan interest and accretion expense of \$517,409.

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Income tax expense

During the three months and year ended December 31, 2018, the Company recorded an income tax expense of \$136,884 and \$230,784, respectively, primarily related to taxes in certain foreign jurisdictions.

Net loss

Net loss for the three months ended December 31, 2018 was \$4,858,809 or \$0.04 per Common Share, compared to a net loss of \$4,528,993 or \$0.06 per Common Share for the three months ended December 31, 2017. The increase in net loss was primarily attributed to an increase in R&D expenses of \$298,908 and a decrease in gross profit of \$298,077. These were partially offset by a decrease in G&A expenses of \$105,199, a decrease in selling and distribution expenses of \$39,201 and in net finance costs of \$190,783.

Net loss for the year ended December 31, 2018 was \$20,762,989 or \$0.21 per Common Share, compared to a net loss of \$18,822,342 or \$0.31 per Common Share for the year ended December 31, 2017. The increase in net loss was primarily attributed to an increase in R&D expenses of \$627,198, an increase in G&A expenses of \$721,508, an increase selling and distribution expenses of \$165,543, and a decrease in gross profit of \$1,048,565. These were offset by a decrease in net finance costs of \$778,828.

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.

	2018				2017			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue	1,708,936	303,664	213,343	376,335	1,890,482	1,465,412	957,139	591,517
Cost of Sales	1,180,481	240,686	126,259	231,075	1,063,950	1,185,674	471,359	311,225
Gross profit	528,455	62,978	87,084	145,260	826,532	279,738	485,780	280,292
Operating expenses	5,309,931	5,238,977	5,697,663	4,766,887	5,155,423	5,148,434	5,043,710	4,151,642
Net finance costs	(60,151)	(73,733)	196,249	280,159	130,632	651,378	98,207	241,135
Loss before income taxes	4,721,325	5,102,266	5,806,828	4,901,786	4,459,523	5,520,074	4,656,137	4,112,485
Income tax expense	136,884	32,700	24,200	36,400	69,470	-	2,356	2,297
Net loss for the period	4,858,809	5,134,966	5,831,028	4,938,186	4,528,993	5,520,074	4,658,493	4,114,782
Loss per common share								
Basic and diluted	0.04	0.05	0.05	0.06	0.06	0.09	0.08	0.07

The first quarter of 2017 was the initial pilot launch of The TULSA-PRO[®] system after receiving CE Certificate of Conformity from its notified body in the European Union.

The third quarter of 2017 was impacted by the Sonalleve[®] 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 net finance costs were lower due to a gain on the change in fair value of contingent consideration and share warrants. Revenue increased compared to previous quarters due to increased commercial sales of systems.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2018, the Company had cash of \$30,687,183 compared to \$11,103,223 at December 31, 2017.

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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 and year ended December 31, 2018, the Company revised the fair value of the royalty, using future revenue forecasts for the term of the Knight Loan.

CIBC Loan

On July 30, 2018, the Company signed a term loan agreement with CIBC Innovation Banking ("**CIBC**") to provide a secured loan for total initial gross proceeds of \$12,500,000 maturing on July 29, 2022 with an interest rate based on prime plus 2.5%. The Company is required to make interest only payments until October 31, 2019 and monthly repayments of the principal of \$378,788 plus accrued interest will commence on October 31, 2019. All obligations of the Company under the term loan agreement are guaranteed by current and future subsidiaries of the Company and include security of first priority interests in the assets of the Company and its subsidiaries. The Company has the ability to draw an additional \$6,250,000 subject to the achievement of certain financing and product development milestones. In connection with this term loan agreement, the Company also issued 321,714 Common Share 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 term 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 July 31, 2018 and December 31, 2018 was \$194,822 and \$98,203, respectively. As at December 31, 2018, the principal balance outstanding on the CIBC Loan was \$12,500,000.

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.

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

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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		Year ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
	\$	\$	\$	\$
Cash provided by (used in) operating activities	(4,370,359)	(4,579,490)	(18,294,636)	(14,854,460)
Cash provided by (used in) in investing activities	-	168,368	-	(997,428)
Cash provided by (used in) financing activities	(154,727)	(793,083)	37,878,596	6,122,050
Net increase (decrease) in cash	(4,525,086)	(5,204,205)	19,583,960	(9,729,838)

Net cash provided by (used in) operating activities for the three months ended December 31, 2018 was \$4,370,359 versus \$4,579,490 for the three months ended December 31, 2017. The principal increased use of the operating cash flows during this period related to increased workforce costs.

Net cash provided by (used in) operating activities for the year ended December 31, 2018 was \$18,294,636 versus \$14,854,460 for the year ended December 31, 2017. The principal increased use of the operating cash flows during this year related to additional costs associated with Sonallevé® that were only present for 5 months in 2017 and increased workforce costs.

Net cash provided by (used in) investing activities for the three months ended December 31, 2018 was \$nil versus \$168,368 for the three months ended December 31, 2017. This change related to the fact that there were no purchases of property and equipment during the three months ended December 31, 2018.

Net cash provided by (used in) investing activities for the year ended December 31, 2018 was \$nil versus \$997,428 for the year ended December 31, 2017. This change related to the fact that there were no purchases of property and equipment and intangible assets during the year ended December 31, 2018.

Net cash provided by (used in) financing activities for the three months ended December 31, 2018 were \$154,727 versus \$793,083 for the three months ended December 31, 2017. These cash flows related to the CIBC Loan interest payments in 2018 versus the Federal Economic Development Agency Loan and the Knight Loan interest payments in 2017.

Net cash provided by (used in) financing activities for the year ended December 31, 2018 were \$37,878,596 versus \$6,122,050 for the year ended December 31, 2017. These cash flows related to the CIBC Loan, 2018 Offering proceeds less cash transactions costs paid offset by debt repayments of the Health Technology Exchange Loan, Federal Economic Development Agency Loan and the Knight Loan.

Contractual obligations

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

	December 31, 2018				
	Carrying amount	Future cash flows	Less than 1 Year	Between 1 year and 5 years	Greater than 5 years
	\$	\$	\$	\$	\$
Accounts payables and accrued liabilities	3,912,350	3,912,350	3,912,350	-	-
Long-term debt	11,955,245	14,497,042	1,936,455	12,560,587	-
Other liabilities	1,275,394	1,365,217	429,426	935,791	-
Total	17,142,989	19,774,609	6,278,231	13,496,378	-

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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 December 31, 2018, by which time the proceeds from the 2018 Offering were partially expended.

	Estimated per 2018 Offering	Total spending as at December 31, 2018
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	\$921,000
Increased personnel requirements and employee travel expenses related to support of the clinical procedures for patients	\$1,200,000 to \$1,500,000	\$1,467,000
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	\$1,504,000
Sonalleve® MR-HIFU sales and marketing activities	\$2,000,000 to \$2,200,000	\$1,494,000
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	\$5,398,000
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	\$4,566,000
General working capital purposes	\$2,000,000 to \$2,200,000	\$1,021,000
Totals		\$22,353,000

Although it is intended the remainder of the net proceeds from the 2018 Offering of \$9,674,502 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 in order 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.

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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 December 31, 2018 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 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.

	December 31, 2018	December 31, 2017
	\$	\$
Current assets	37,919,789	17,602,066
Less: Current liabilities	7,879,360	10,616,241
Working capital	30,040,429	6,985,825
Add back: Deferred revenue	312,558	132,364
Net working capital	30,352,987	7,118,189

Working capital has increased by \$23,234,798 to a surplus of \$30,352,987 at December 31, 2018 compared to the surplus of \$7,118,189 at December 31, 2017. The change in working capital is due to a decrease in current liabilities of \$2,736,881, which was primarily the result of the full repayment of the Health Technology Exchange Loan, Federal Economic Development Agency Loan and Knight Loan. Accounts payable and accrued liabilities decreased by \$1,169,354 due to the timing of payments made to certain vendors. The increase in working capital correlates to the increased cash balance of \$30,687,183 resulting from the 2018 Offering for net cash proceeds of \$32,027,502 and the CIBC Loan for net cash proceeds of \$11,764,302.

COMMITMENTS & CONTINGENCIES

The Company has commitments under operating leases for the rental of office space. On March 28, 2016, the Company signed a lease for office space and took possession of this office space effective July 1, 2016. Included in prepaid expenses and deposits at December 31, 2018 is an amount of \$210,000 related to prepaid rent for this lease that is drawn down at \$10,000 per month starting October 1, 2016. The future minimum obligation are as follows:

	\$
No later than 1 year	452,574
Later than 1 year and no later than 5 years	1,775,583
Later than 5 years	1,085,135
	<u>3,313,292</u>

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

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.

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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, 2017, nor has there been a significant change in the composition of its financial instruments since December 31, 2017.

RELATED PARTY TRANSACTIONS

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		Year ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
	\$	\$	\$	\$
Salaries and employee benefits	419,587	234,765	1,746,024	1,021,568
Termination benefits	-	-	114,750	138,125
Directors' fees	37,500	26,503	113,132	88,232
Share-based compensation	300,485	323,452	959,234	1,220,655
Total	757,572	584,720	2,933,140	2,468,580

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

OUTSTANDING SHARES

As at March 7, 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

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

CRITICAL ACCOUNTING JUDGMENTS AND ESTIMATES

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.

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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. The revenue share obligation represents an executory contract and is accounted for as a best estimate provision.

Accounting for acquisitions

The Company assesses whether an acquisition should be accounted for as an asset acquisition or a business combination under IFRS 3. This assessment requires management to assess whether the assets acquired and liabilities assumed constitute a business as defined in IFRS 3 and if the integrated set of activities, including inputs and processes acquired, is capable of being conducted and managed as a business and the Company obtains control of the business. The Company's acquisition has been accounted for as a business combination.

Critical accounting estimates

Revenue share obligation

The Company has certain minimum amounts payable under a revenue sharing agreement. The provision was determined using the following assumptions:

- estimated probability of a new agreement being signed based on the facts and circumstances in place as at December 31, 2018 that eliminated these minimum amounts payable;
- future revenue forecasts related to the revenue share agreement; and
- a discount rate of 11%.

The amount has been included in selling and distribution expenses in the consolidated statements of loss and comprehensive loss.

Subsequent to year-end the Company replaced the original co-marketing and co-selling agreement with Siemens with a new agreement. Under the new 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 agreement.

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.

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RECENT ACCOUNTING PRONOUNCEMENTS

Accounting standards issued but not yet adopted

IFRS 16, Leases

On January 13, 2016, the IASB published a new standard, IFRS 16. The new standard will eliminate the distinction between operating and finance leases and will bring most leases onto the consolidated balance sheet for lessees. This standard is effective for annual reporting periods beginning on or after January 1, 2019. The Company intends to adopt IFRS 16 in its consolidated financial statements for the annual period beginning January 1, 2019. As the Company has significant contractual obligations in the form of operating leases under current IFRS, there will be a material increase to both assets and liabilities on adoption of IFRS 16, and changes to the timing of recognition of expenses associated with the lease arrangements. The Company is analyzing the new standard to determine its impact on the Company's consolidated balance sheets and consolidated statements of loss and comprehensive loss. The Company expects to adopt IFRS 16 using the modified retrospective transition method. Further, the Company currently expects to apply the following practical expedients: (i) grandfather the assessment of which transactions are leases; (ii) recognition exemption of short-term leases; and (iii) recognition exemption leases of low-value items.

IFRIC 23, Uncertainty over Income Tax Treatments

In June 2017, the IASB issued IFRIC 23, Uncertainty over Income Tax Treatments ("IFRIC 23"), with a mandatory effective date of January 1, 2019. The interpretations provide guidance on how to value uncertain income tax positions based on the probability of whether the relevant tax authorities will accept the Company's tax treatments. A company is to assume that a taxation authority with the right to examine any amounts reported to it will examine those amounts and will have full knowledge of all relevant information when doing so. IFRIC 23 is to be applied by recognizing the cumulative effect of initially applying these guidelines in opening deficit without adjusting comparative information. The company currently expects no impact in applying the new standard.

DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROLS OVER FINANCIAL REPORTING

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.

The Certifying Officers have concluded that as at December 31, 2018, 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 year ended December 31, 2018, which have materially affected, or are reasonably likely to materially affect the Company's ICFR. Based on their evaluation of these controls for the year ended December 31, 2018, 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 December 31, 2018. 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.

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ICFR is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the annual 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 annual financial statement preparation and presentation.

In conjunction with the transition to the new IFRS 9, Financial Instruments and IFRS 15, Revenue from Contracts with Customers, the Company has determined that the adoption of these new accounting standards did not have a significant impact on its control environment.

RISK FACTORS

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.

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

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