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## Welcome

More than ever, the world needs antimicrobials that are effective against superbugs and don't drive resistance.

Ondine Biomedical is leading the charge in breakthrough photodisinfection-based therapies to prevent and treat serious infections, including those caused by existing, emerging, and antimicrobial-resistant pathogens. We are focused on solutions that address significant needs, are easy to deploy, are environmentally safe, provide substantial public health benefits, and cost a fraction of the infections they target.

### **Purpose**

To provide simple solutions to complex infections

### **Mission**

Enabling worldwide access to the power of photodisinfection

### **Vision**

A world free from untreatable infections





## **Highlights**

## 2021 was an exceptional year of performance and record growth for Ondine.

In 2021, Ondine Biomedical substantially advanced its business and capabilities across clinical, regulatory, commercial, and manufacturing areas. We increased our customer base, strengthened our financial position, and expanded our Board, adding deep sector experience. We continued to demonstrate the unique capabilities and efficacy of our photodisinfection technology against pathogens of all kinds and were recognised with an Innovation Award of Excellence at the International Consortium for the Prevention and Infection Control (ICPIC), a world-leading infection control conference in Geneva, for the efficacy demonstrated against SARS-CoV-2.

### **Financial Highlights**

Unless otherwise specified, all financial figures throughout this annual report are in Canadian dollars See pages 35 to 36 for more information.

**\$37.7m** 

**Equity raise and listing on the AIM Market** 

Free cash flow for the year

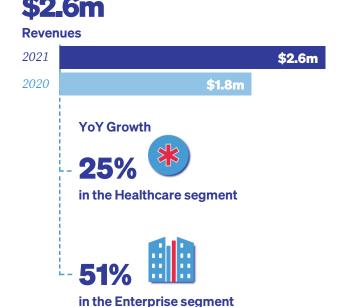
vs. -\$6.4m in 2020; primarily due to IPO costs

Cash balance at year-end





2021 \$34.1m 2020







**Highlights** Continued

## **Operational Highlights**



Initiated US FDA
Phase 2 clinical trial
for nasal photodisinfection



Completion of 4 studies demonstrating effectiveness vs.

SARS-CoV-2



Increased enterprise adoption of Steriwave™ for prevention of COVID-19



Additional Canadian hospital deployments of Steriwave for SSI suppression



4x increase in manufacturing capacity and output



Significantly enhanced Ondine's Board of Directors

### **ESG Highlights**



Ondine workforce = 56% women



New Board of Directors = 25% women



Board Members = 50% independent



Photodisinfection donations to help protect healthcareand essential workers during pandemic



Consistently meet/ exceed regulatory requirements



Fully audited Quality Management System





## Our Business at a Glance

Ondine Biomedical Inc. is a life sciences company at the forefront of development of photodisinfection-based therapies to address the large and growing need for solutions to a broad spectrum of infections.









We have created a novel, patented platform technology, called "photodisinfection", to help prevent and treat infections across many therapeutic areas in healthcare and industry settings. Our pipeline of products, in various stages of development, will collectively leverage clinical safety and efficacy experiences, key opinion leader relationships, and regulatory applications.

#### **Product Platform Overview**

Photodisinfection is a topical light-based antimicrobial technology that eliminates harmful pathogens, rapidly destroying bacteria, fungi and viruses - including superbugs and SARS-CoV-2 - in minutes.

### ONDINE'S PHOTODISINFECTION TECHNOLOGY One platform, many applications **Patented formulation Specific Light Dose** Applied via Delivered via Same methods and Swab Tip light-activated compound to Syringe Balloon treat multiple anatomical sites Fiber Bandage III Panel



#### **Our Business at a Glance** Continued

### Our lead product: Steriwave™ nasal photodisinfection

Steriwave nasal photodisinfection eliminates upper respiratory viruses, bacteria and fungi in minutes with a single, five-minute treatment, before these pathogens can cause serious healthcare-associated infections (HAIs).

#### **Regulatory Approvals**

- ✓ Canada
- ✓ Europe (CE Mark)
- ✓ Australia
- ✓ Philippines
- USA:
- ✓ QIDP designation
- √ Fast Track granted
- Phase 2 clinical trial underway



#### **Apply**

Using pre-saturated swabs, the nostrils are gently coated with the Steriwave photosensitiser formulation that adheres specifically to the pathogens.



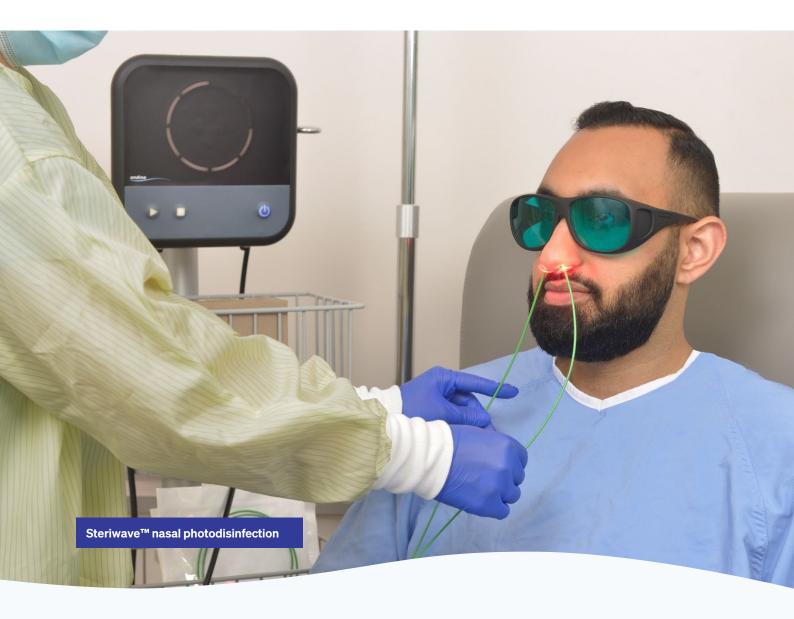
#### Illuminate

Light at a specific wavelength is used to activate the Steriwave photosensitiser in the nose.



#### **Destroy**

This reaction physically destroys the microbes without harming human cells. The pathogens are unable to adapt, eliminating the concern of antimicrobial resistance.

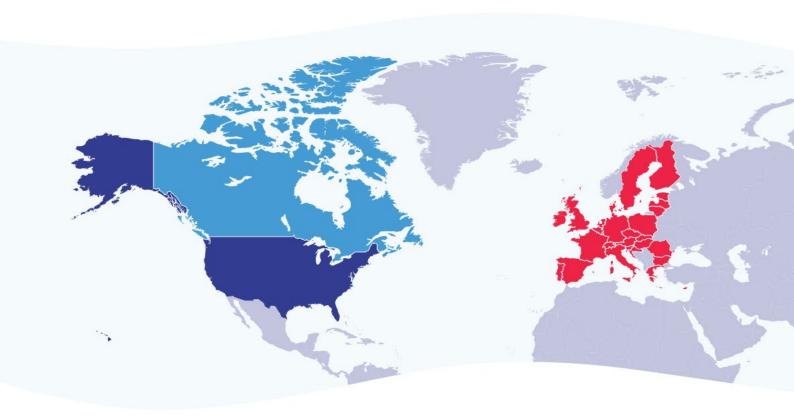






# **Key Markets**

## **Initial focus geographically**



#### **USA**

FDA Phase 2 clinical trial underway. Major commercial market opportunity upon FDA approval.

#### Canada

Creating and building commercialisation experience and marketing messaging ahead of US FDA approval

#### **UK and EU**

Building awareness with NHS and Europe-based key opinion leaders. Focus on opportunistic deployments.





## **Timeline**

### Ondine's strategic approach (in phases):

See pages 26 to 28 for more information.



#### Develo

The platform technology and individual product applications.



#### De-risl

Approval in Canada and long-term beta site hospital deployments to validate efficacy, protocols, safety, ease of use, workflow integration and business model. Build network of KOLs and



#### Deploy

Obtain regulatory approvals in additional jurisdictions and commercialise directly or through partners / licensing arrangements.

#### 2000

Photodisinfection platform technology.

Significant patent portfolio of over 70 patents covering the formulation, devices, and methods.

Pipeline of photodisinfection products for the prevention of healthcare associated infections and treatment of chronic infections.

Health Canada approval of nasal photodisinfection and several other pipeline products.

Validation of nasal photodisinfection safety, efficacy, protocols, and ease of adoption by nursing staff.

Publication of significant infection rate improvement (>40%) results at Vancouver General Hospital (VGH), a leading tertiary care and teaching hospital in Canada.

Strategic relationship formed with HCA Healthcare, the largest US private health system (2017).

Qualified Infectious Disease Product (QIDP) designation awarded (2018).

Fast Track granted (2019).

Nasal photodisinfection system rebranded to Steriwave™ (2020).

CE Mark granted (2020).

2016 -2017 -



### -

#### **Timeline** Continued







Released new, compact Steriwave laser with enhanced design for easier use and mobility and improved margins. (launched 2020). Substantial reduction in post-operative spine infections due to nasal photodisinfection announced (2019).

*In vitro* testing confirms efficacy against SARS-CoV-2 (2020)

Steriwave adopted into non-healthcare enterprises due to COVID-19 (2020).

2020 -

2021

New injection moulded nasal light illuminator assembly design (target Q4 2022 for release). US FDA Phase 2 trial commenced with HCA Healthcare (target to complete patient recruitment mid-year 2022).

Preparation for Phase 3 clinical trial underway.

4 new hospital and industrial deployments of Steriwave.

Received ICPIC Innovation Award of Excellence for photodisinfection efficacy results against SARS-CoV-2 variants.

Raised \$37.7 million IPO on AIM Market of London Stock Exchange.

2022







## **Investment Case**

Ondine Biomedical is a leading life sciences company that has developed a unique, patented platform technology to revolutionise infection control and address a broad spectrum of infections in healthcare and industry settings.



### **Huge addressable markets**

Healthcare-associated infections (HAIs), which affect 7% of hospital patients in high-income countries, cost c. US\$45 billion annually in the USA alone. Increasing antimicrobial resistance suggests these costs will rise significantly in the coming decades, driving significant demand for preventative solutions. In parallel to our US regulatory efforts, Ondine has begun to develop strategies for introducing Steriwave to the NHS and other facilities in the UK. Further initiatives have similarly started to approach hospital groups in the EU.



#### Patented and cost-effective technology

70+ patents and 20 years of development underpin an easy-to-use, cost-effective proprietary platform technology that kills over 99.99% of bacteria, viruses and fungi (MRSA, SARS-CoV-2), crucially without inducing antimicrobial resistance



#### Ready-for-market position

Lead product, Steriwave<sup>™</sup>, has been commercially tested and validated over the past ten years in Canada and has received regulatory approval in other major markets such as the UK and EU. Real-world data from treating over 80,000 patients in Canada demonstrates efficacy (up to 80% infection reduction) and safety (no serious adverse events reported), providing strong confidence for the US FDA Phase 2 and Phase 3 clinical trials. Steriwave's rapid single treatment saves healthcare systems time and money.



#### **Investment Case** Continued



### **Established partnerships**

Ondine has successful partnerships with a number of medical organisations and hospitals, including a decade-plus relationship with Vancouver General Hospital (VGH), one of Canada's largest tertiary hospitals. Since 2017, Ondine has a strategic partnership with HCA, the largest private hospital group in the USA and a leader in infection prevention efforts, to conduct Ondine's US clinical trials to bring nasal photodisinfection through the regulatory process and into the US market. Over the past year, Ondine has been forging key relationships within the NHS; discussions for the deployment of Steriwave within UK medical facilities are currently underway.



### Highly relevant for COVID-19 and other emerging upper-airway pathogen infections

Steriwave has a long track record of safety as well as efficacy. This experience provided us with the opportunity to explore expansion of use to include emerging pathogens such as Candida auris, a drugresistant yeast with a 30% mortality rate. During 2020-2021, Ondine was able to demonstrate in vitro and in vivo clinical efficacy against SARS-CoV-2, and the benefits of nasal photodisinfection for the prevention and treatment of upper respiratory disease, providing near-term opportunity with enterprise clients during the pandemic.



#### Further products in the pipeline to leverage the platform and installed base

Ondine has seven products at various stages of development built upon its photodisinfection platform technology. These products can leverage and benefit from real-world safety and efficacy data and long-term hospital deployments, key opinion leader endorsement, re-usable regulatory filings, product development and scale up expertise, as well as the certified production and supply chain capacity that Ondine has generated from its first product. Products under development target a number of chronic and acute infections with high clinically-unmet need.







## **Chairman's Statement**



"Making a profound difference to quality of life is at the heart of Ondine's mission and why I have personally supported the Company's efforts."

The Honourable Jean Charest Chairman

#### Dear shareholder,

The global devastation of COVID-19 was a sobering reminder of how vulnerable we are, as humans, to current and emerging microbial threats. The pandemic and the rapidly rising tide of antimicrobial resistance has highlighted the need for affordable solutions, such as those being created by Ondine, to treat infections by lethally resistant pathogens and help prevent millions of deaths.

The pandemic has strengthened our resolve to increase awareness of the many therapeutic areas where our photodisinfection technology is effective and to accelerate the commercialisation of the numerous antimicrobial therapies in our product pipeline.

The Company's IPO on AIM on 6 December 2021 was inspired by both of these missions.

## An ideal opportunity to showcase Ondine technology

Ondine proudly stepped up during the COVID-19 battle and contributed to the fight against this new viral threat. We accelerated our efforts to bring our unique solutions to light, with much of our production capacity in 2020 and 2021 directed towards enterprise sales and, in particular, protecting essential workers in Canadian meat processing plants.

The impressive outcomes – over 3 times reduction in COVID-19 rate and the co-morbidities associated with SARS-CoV-2 infection – of this pandemic-related deployment are being

submitted for peer review and publication. Our *in vitro* and clinical work demonstrating eradication of all known SARS-CoV-2 strains was recognised with an Innovation Award of Excellence at the International Conference of Prevention and Infection Control (ICPIC Geneva) in September 2021—the second such award for Ondine's photodisinfection technology.

## Rising antimicrobial resistance impacting healthcare associated infections

Despite our success in the COVID-19 arena, our focus remains on reducing healthcare-associated infections across the healthcare spectrum. The HAI rate is, alarmingly, accelerating as resistance to antibiotic drugs grows, and healthcare systems are under pressure from COVID-19. Recent studies confirm that the world is on pace to exceed the UK O'Neill Report's 2014 prediction of ten million AMR-related deaths annually by 2050.

This growing threat of AMR is well recognised by the world's leading hospital groups such as HCA Healthcare Corp., where we are carrying out our trials for FDA approval to reduce HAI. HAI are now costing healthcare systems tens of billions of dollars annually, causing massive surgical backlogs and staff shortages as well as seriously increasing the rate of fatalities. With few new antibiotics under development and new drugs costing billions of dollars to bring to market, there is a clear and urgent need for the disruptive, antimicrobial products that Ondine is developing in its pipeline.



## 8

#### Chairman's Statement Continued

# Over ten years of data in Canadian hospitals supporting safety, efficacy, and return on investment

We have spent a considerable amount of time and resources to demonstrate the benefits of nasal photodisinfection in reducing HAI and validating the technology, the product designs and business models to support success and long-term sustainability. We now have over a decade's worth of experience in Canadian hospital deployments, proving that we can reduce HAI by more than 70% without serious side effects. This impressive realworld data, safety, efficacy and return on investment data will help accelerate adoption rates in key markets.

### Recognised global leader in photodisinfectionbased medical devices to reduce hospital infections

With over 20 years' experience, Ondine has become a recognised leader in photodisinfection for the prevention and treatment of multidrugresistant infections. We believe that photodisinfection is poised to become the standard of care in topical disinfection due to its high efficacy, broad spectrum, rapid mechanism of action, safety, accessibility, and ease of use without the added effect of promoting of resistance. We are starting to build a sales and market access team which can rapidly be deployed as soon as Ondine achieves FDA approval.

#### Solid foundation supports a bright future

We have put in place a solid foundation for future growth through our unwavering commitment to quality and proven patient outcomes in Canadian hospitals and industrial settings. These outcomes continue to be published in peer reviewed journals and the expected results of current and upcoming clinical trials we believe will only add to this list of publications supporting the safety, efficacy, and accessibility of our patented photodisinfection technologies.

Our clinical successes are attracting a growing number of key supporters, including HCA Healthcare, our clinical trial partner for our US FDA studies. In the coming years, we look forward to building on this foundation, leveraging past successes and regulatory filings to accelerate new applications and product evolutions to help health professionals better serve their patients' needs.

Making a profound difference to quality of life is at the heart of Ondine's mission, and why I have personally supported the Company's efforts over the past four years. Bringing photodisinfection to global healthcare systems is our bold ambition, and we have every confidence in the efforts, talents, passion, and commitment of the Ondine team.

On behalf of the Board, I would like to extend my heartfelt thanks not only to the dedicated professionals – our employees, trusted suppliers, and client partners – for their extraordinary contributions and tireless efforts in 2021, but also to our shareholders who share our commitment and vision for the future of Ondine.

Sincerely, Jean Charest Chairman



## \*

## **Chief Executive's Review**



"Enabling worldwide access to the power of photodisinfection is our bold mission, and my confidence in the efforts, talents, passion and commitment of our team has never been higher."

Carolyn Cross
Chief Executive Officer

#### Performance overview

As we cross the threshold into the third year of the COVID-19 pandemic, all of us are humbled by the extraordinary challenges the global community has faced, and the enormous devastation and impact we have witnessed.

We are proud of the small but important role that Ondine played in defending Canadians against the virus and the comorbidities associated with SARS-CoV-2 infection alongside our focus on HAI and AMR.

#### **Phase 2 Clinical Trial Progress**

Our Phase 2 clinical trial at an HCA hospital is on target to complete patient recruitment by midyear, despite widespread continued operational challenges associated with COVID-19. Using this current clinical trial experience, we continue to work very closely with HCA to develop and optimise our multicentre Phase 3 study plans. We truly value and appreciate the extraordinary support we receive at every level from HCA, from top management to principal investigators, clinical research coordinators, monitors, and nursing staff.

## Clinical Trial Collaboration with HCA Healthcare Inc.

Our work with photodisinfection continues to be recognised internationally, and our ongoing success is attracting a growing number of key supporters, including HCA Healthcare, our clinical trial partner for our US clinical studies. HCA Healthcare was founded in 1968, employs 235,000 people and generates over \$51 billion in annual revenues. With 184 hospitals and approximately 2,000 sites of care—including

surgery centres, freestanding Ers, urgent care centres and physician clinics in 21 states, HCA is one of the largest hospital groups globally. For Ondine, HCA is an ideal clinical partner because of its recognised leadership in advancing patient safety protocols and dedication to 'giving people a healthier tomorrow'. We believe that Ondine's innovative photodisinfection technology fits that vision perfectly and, that together, we can significantly improve patient outcomes with photodisinfection-based treatment and prevention protocols.

### **Successfully Responding to COVID-19**

As the first wave of infections began to decimate populations all over the world, we took the collective knowledge gained by Ondine over a decade of Steriwave nasal photodisinfection development in Canadian hospitals and turned the technology towards the fight against COVID-19. First, we determined that our technology was highly effective against the virus in vitro, running test after test with viral surrogates and heat-killed wild-type strains available from the Centers for Disease Control and Prevention (the national public health agency of the United States). We published this work at a major infection control conference in Geneva, Switzerland and won an ICPIC 2021 Innovation Award of Excellence for the research.



## 8

#### **Chief Executive's Review** Continued

We showed that our photodisinfection rapidly destroyed the viral genome in less than 60 seconds of treatment, rendering the virus unable to replicate. Equally important, we showed that the technology also destroyed the spike protein and receptor binding domains of SARS-CoV-2, the key structural components used by the virus to target and lock onto human ACE2 receptors in the nose.

Building on this success, we teamed up with world-class scientists in Spain and Portugal to test the technology against wild-type virus directly isolated from patients and showed continued high efficacy against these targets. Finally, we tested the technology in human patients at Sunnybrook Health Sciences Centre in Toronto, Canada, and at the University of Navarra, in Pamplona, Spain. These researchers demonstrated that our potent, safe approach to broad-spectrum nasal photodisinfection was indeed effective against SARS-CoV-2 *in vivo*—producing over 90% reduction in infectivity of the virions located in the nose with only a single treatment, and substantially reducing COVID-19 symptoms and time to recovery. Our technology was subsequently deployed in patients, in healthcare workers and in commercial enterprises, bringing an additional measure of safety to Canadians overburdened by the pandemic.

#### **AMR Focus**

While the COVID-19 pandemic presented an immediate need for novel solutions, nevertheless the large and growing threat of AMR will exist long after the current pandemic has officially ended. Recent studies confirm that the world is well on track to exceed the UK O'Neill Report's 2014 prediction of 10 million AMR related deaths annually by 2050—an unimaginable figure almost 50% greater than all deaths caused by the novel coronavirus to date. More than 2.8 million antibiotic-resistant infections occur in the US each vear. One in five of all infections in the UK are now antibiotic-resistant. Worldwide, over five million people died of an antibiotic-resistant infection in 2019, the last year that such statistics were available before the pandemic.

AMR has the potential to affect people at any stage of life, as well as the healthcare, veterinary, and agriculture industries. Pathogens do not have to be resistant to every antibiotic to be dangerous. Resistance to even one antibiotic can mean

serious problems. Resistance forces clinicians to turn to second- and third-line treatments which are more toxic, more costly, and can cause serious side effects in patients including microbiome disruption, anaphylactic shock, organ failure, and even death. The common requirement for prolonged care and recovery, sometimes for months, puts huge strain on healthcare systems and forces other patients onto ever-extending waiting lists. Hospital waiting lists in England are longer than at any time since records began, with over 6 million people queued for pre-planned NHS treatment in December 2021, more than one-tenth of the population. Healthcare systems simply cannot afford to readmit patients due to an avoidable healthcare-acquired infection.

AMR has become one of the world's most urgent public health problems. With few new antibiotics under development and new drugs costing billions of dollars to bring to market, there is a clear and urgent need for the non-antibiotic antimicrobial products that we have in our pipeline. Meeting this need is at the core of Ondine's mission, driving our people, our vision, and our company.

#### **Expanded Production Capacity**

Our success in treating COVID-19 patients as well as continued growth in our HAI business increased demand for our photodisinfection product, and we significantly expanded our manufacturing efforts at multiple subcontractors as well our own facilities in Bothell, WA. Along with so many companies across the globe, our supply chains were stretched to the maximum and beyond, and we had to rapidly innovate across all our operations to be able to keep producing our products for both legacy and new clients.

We learned important lessons in lean manufacturing, reducing our reliance on external resources and quadrupling throughput with our in-house production teams. Across the company, we hired exceptional people with superb industry experience and shared core values to join us. Our new team members are collectively buoyed by our life-saving mission and share the desire to exceed shareholder expectations. We reviewed and improved every aspect of our quality management system, from design and development all the way through post-market surveillance, lean six-sigma supplier management and successful MDSAP certification.



## 8

#### Chief Executive's Review Continued

#### **Enhanced Capabilities**

In 2021, we expanded our Board of Directors with extraordinary, experienced leaders who continue to motivate and inspire us. We are very pleased to have Ms. Jean Duvall (Lead Director), Dr. Junaid Bajwa, Mr. Michael Farrar, Dr. Simon Sinclair and Mr. Craig Tooman join our Board. With Hon. Jean Charest as Chairman, we have a Board whose collective experience and expertise are helping us continue to develop and execute on the right strategic plans. We carefully weighed our corporate governance policies, putting in place measures to ensure accountability, fairness, transparency, and equitable gender and diversity balance.

Halfway through the year, we accelerated our public offering plans, and together with our legal, financial and regulatory teams we listed Ondine on 6 December 2021 on the AIM Market of the London Stock Exchange, having raised \$37.7 million (AIM:OBI). With a strong balance sheet, the majority of proceeds from this public offering are targeted at completing our Phase 2 study, substantially advancing our Phase 3 study, and hiring the operational, manufacturing and engineering staff necessary to support these efforts.

## Sincere Appreciation of the Extraordinary Support of Our Many Stakeholders

Enabling worldwide access to the power of photodisinfection is our bold mission, and my confidence in the efforts, talents, passion and commitment of our team has never been higher. It takes an extraordinary effort to bring important, disruptive new technologies to light and I would like to extend my sincerest appreciation to the many dedicated professionals—both inside and outside of our company—for their immense contributions and tireless efforts in 2021 to bring photodisinfection-based products to the world. People are our greatest assets, and we are grateful for the contributions from so many committed supporters across many countries.

On behalf of the Board and the entire Ondine team, we would like to thank our stakeholders for their confidence and continued support of our company.

## Carolyn Cross Chief Executive Officer







## **Our Market**

## Growing global demand for novel, fast-acting antimicrobials amidst accelerating antimicrobial resistance, COVID-19 variants and other emerging pathogens.

There are significant adverse global healthcare trends on mankind's horizon that present growth opportunities for Ondine. An aging and growing population will result in greater human and financial resource strains on existing healthcare systems globally. The continued rise in antimicrobial resistance will only exacerbate this pressure. These two factors will result in larger numbers of surgeries along with higher levels of associated infections. The impact? Without potent alternative antimicrobials, the world faces significant negative socio-economic penalties, including increased loss of life, higher morbidity rates and accelerating healthcare costs.

#### 1. Rising costs and pressure on healthcare systems to reduce infections.

Healthcare spending in the US alone has more than doubled since 2006, reaching c.\$4.3 trillion in 2021 (c.19% of GDP)<sup>2</sup>. Direct costs of providing hospital services have also doubled during this period. Changing reimbursement plans in the US have shifted the financial burden of HAIs to hospitals, affecting profitability. Furthermore, hospitals with the worst HAI rates are now subject to costly penalties and reduced reimbursement. The need for safe, effective, and easy to implement infection prevention protocols is accelerating the world over. Ondine's photodisinfection is ideally suited to address this need.

#### Unprecedented global surgery backlogs increase scrutiny and need for rapid bed availability.

Clinic closures and surgery cancellations during the pandemic have increased surgery waitlists to historic levels. Since the start of the pandemic in March 2020, over 300,000 patients in the UK have had to wait more than a year for their surgeries, an increase from only 904 patients in 20193. This trend has been seen worldwide<sup>4</sup>. As hospitals seek to increase surgical throughput, focus will be on minimising patient length-ofstay and, critically, avoidance of infections, both of which Ondine's nasal photodisinfection has been demonstrated to achieve.

<sup>&</sup>lt;sup>4</sup> Health Care Wait Times by Country 2022.





<sup>&</sup>lt;sup>1</sup>The Wall Street Journal, 28 March 2022.

<sup>&</sup>lt;sup>2</sup> Bureau of Economic Analysis, 24 February 2022.

<sup>&</sup>lt;sup>3</sup> BBC News, 8 February 2022.

#### **Our Market** Continued

#### Accelerating antimicrobial resistance (AMR) driving interest in new, resistance-free alternatives.

AMR is considered by the World Health Organization (WHO) to be one of the top ten human health crises. The Center for Disease Control and Prevention (CDC) estimates more nearly 3 million people annually in the United States acquire serious antibiotic-resistant infections and more than 35,000 die as a result<sup>1</sup>. Globally, the annual AMR-related death rate is about 700,000 according to the 2016 O'Neil Report. Without new antimicrobials, global deaths from drug-resistant infections are projected to escalate to 10 million annually by 2050<sup>2</sup>. This increasing threat requires an alternative to prophylactic antibiotics, which are increasingly ineffective and contribute to AMR rising rates. Ondine's ambition is to replace ineffective antibiotic use with photodisinfection with its broad-spectrum efficacy, including against superbugs, and demonstrated lack of resistance formation.

#### 4. COVID-19 variants and concern over future threats have increased awareness and demand for upper airway infection control, adjunctive to current personal protection equipment (PPE)

SARS-CoV-2 variants, continued COVID-19 waves despite high vaccination rates, and concern over future pathogens have increased interest for accessible and effective infection control technologies both within the medical industry and outside of it. Ondine has proven Steriwave nasal photodisinfection efficacy for early prevention and treatment of those that have tested positive for SARS-CoV-2 (in vitro, ex vivo, and clinical trials with trial partners). By promoting the use of Steriwave in conjunction with PPE, Ondine can leverage these findings to promote nasal photodisinfection to help prevent outbreaks and provide peace of mind for individuals who feel at risk. This opens the available market to organisations outside of the medical industry, such as those with workers who operate in close proximity to each other. With more employees treated, the chance of outbreak is reduced, which can translate to higher productivity.

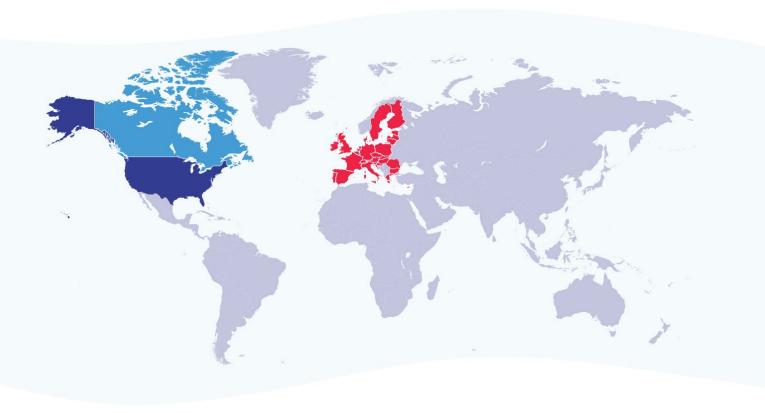
<sup>&</sup>lt;sup>2</sup> O'Neill report 2016.





<sup>&</sup>lt;sup>1</sup> Antibiotic Resistance Threats in the United States, 2019. CDC.

#### **Our Market** Continued



#### USA

- Over 1.7 million healthcare-associated infections ("HAI") in USA annually 1 (1 in 10 hospitalisations worldwide) <sup>2</sup>
- 35 million major surgeries 3
- 5 million ICU admissions <sup>4</sup>
- 18 million healthcare workers 5
- 6,000 hospitals <sup>6</sup> and 11,000 ambulatory surgery centres 7

#### EU

• EU HAI rate of 6.5% is significantly higher than the 3.2% rate in the USA 8

#### UK

- >8 million surgeries annually 9
- 6 million surgical backlog 10
- 2.3% mortality rate within 90 days from a procedure (one-third of deaths in UK national registers) 9

### **Global Impact**

- 10 million annual deaths from drug-resistant infections by 2050 vs. 700,000 in 2016 11
- \$100+ billion annual global cost with global GDP impact forecast at \$100 trillion by 2050 11
- <sup>1</sup>CDC
- <sup>2</sup> World Health Organization
- <sup>3</sup> CDC/NCHS National Hospital Discharge Survey, 2010.
- <sup>4</sup> Society of Critical Care Medicine.
- <sup>5</sup> National Institute for Occupational Safety and Health, CDC.
- <sup>6</sup> American Hospital Association.

- <sup>7</sup> Definitive Healthcare.
- <sup>8</sup> Burden of HAIs in European acute care hospitals.
- <sup>9</sup> British Journal of Anaesthesia, August 2017.
- <sup>10</sup> BBC News, 13 January 2022.
- <sup>11</sup> O'Neill report 2016.





## **Our Impact**

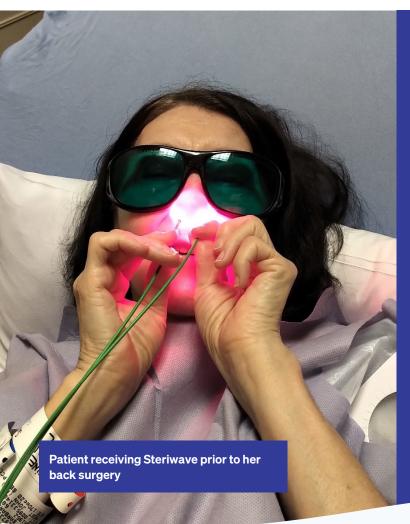
Ondine's nasal photodisinfection has had a marked and sustained impact across the care continuum.

#### **Patients:**

Faster recovery, better outcomes, and improved quality of life

Since implementation at Vancouver General Hospital (VGH):

- Patients have nearly four-times lower risk of post-surgical infection
- Over 140 patients each year avoid an SSI
- 53 fewer patients annually (avg.) suffer a serious infection after spine surgery
- Only 18 spine surgery patients need to be treated to prevent a single spine infection
- Patients are increasingly sensitive to infection risks and are attracted to VGH for superior infection control outcomes as a result of nasal photodisinfection



"In my opinion, there have been very few if any other initiatives that have had such a profound and lasting impact on the health of British Columbians in the past 10 years."

Dr. John Street, MD Associate Professor Spine Surgery Department Of Orthopaedics at University Of British Columbia

"I had the opportunity to have my surgery completed at an earlier time, however with the rising rate of infections, I wanted to be sure my hospital stay would be safe. Knowing the staff at VGH took infection prevention seriously was a major factor in why I chose Dr. Street."

VGH back surgery patient





#### **Our Impact** Continued

### **Healthcare professionals:**

### Less worry, better patient outcomes, and greater satisfaction and confidence

HAIs can be agonising not only for patients and their loved ones, but also for the healthcare professionals treating them. Surgical site infections are often hard to treat and can take a great deal of time to address. They can be demoralising for surgeons who have responsibility for patient outcomes, as well as for the nurses who need to treat the infected sites. Nasal photodisinfection provides a powerful, new tool in clinicians' infection-prevention arsenal.



"The nurses have been extremely excited about [nasal photodisinfection] because they've been doing something new, something innovative, we're improving outcomes. This program is working well and the infection rates have dropped precipitously."

#### Dr. Michel Hjelkrem, MD

Orthopaedic surgeon at Kootenay Boundary Hospital

"Having worked as an operating room nurse for over 40 years, post-surgical infections routinely occur causing additional stress to all of us. These infections are demoralizing for everyone involved and can be really hard to manage. I love that I can protect my patients from these awful infections with a simple 5-minute procedure."

#### Sharron Paulsen

Penticton Hospital Operating Room Nurse, Steriwave Trainer

"Using a procedure like nasal photodisinfection is very satisfying because you know you're making a difference; you know that you are cleaning the nose of any type of germs or bacteria that can pose a risk to the patient."

Shelagh Weatherill, BScN, MA

## **Hospitals:**

## Increased capacity, lower costs, improved reputation

See page 29 for more information.

Ondine nasal photodisinfection improves patient outcomes, reduces reliance on antibiotics, frees beds and resources to treat more patients, and has the potential to save billions of dollars in healthcare costs. Adding nasal photodisinfection to existing infection control measures has demonstrated:



#### **Infection rates**

\$ millions annually in infection cost avoidance



#### Readmissions

Ability to treat more patients and shorten waitlists



**High ROI** (\$10:1 savings-to-cost ratio) Improved resource utilisation and quality of care





## **Our Business Model**

#### **Better Technology Better Compliance Better Outcomes Better Care**

Clinicians and the patients they care for are at the heart of everything we do. They inspire us. They guide and help us validate our product designs and protocols, providing invaluable input and feedback through every stage of our business model. We are ever grateful for their support and are proud to bring our photodisinfection solutions to help them in their daily fight against infections.







#### **Our Business Model** Continued

## Our approach in action

At Ondine, our approach is to rigorously validate our products, protocols, value propositions, and pricing approaches on a small scale in Canada before investing substantial resources in commercialisation efforts. The long-term use, efficacy, safety, and pharmacoeconomic results seen in Canada build a network of key opinion leaders and give us high confidence of success in our efforts to bring the solutions to commercial availability across global markets.

### Stakeholder value creation

Stakeholder	Value	Evidence
Patients	Better health outcomes, including faster recovery and shorter hospital stays.	Nearly four-times lower infection risk
Clinicians	Peace of mind with easy-to-use patient protection that provides superior outcomes.  Reduction of adverse events experienced by patients and increased patient flow-through capacity.	"We did many things to improve our outcomes, but we did not decrease our infection rate to zero until we introduced nasal photodisinfection. Since we've started this technique, we've had no infections in the past year and a half. It's quick, it's easy, it's painless. The results are outstanding."  Dr. Michel Hjelkrem, Orthopaedic Surgeon at Kootenay Boundary Hospital
Healthcare Providers / hospitals	Significant pharmacoeconomic benefits through avoidance of costly infections and readmissions, as well as ability to treat more patients due to shorter hospital stays.	Average of 550+ bed-days saved and >\$4 million in infection costs avoided annually at Vancouver General Hospital in Canada
Employees	Ability to contribute, grow and make a direct and meaningful impact to health around the world as part of a dynamic, innovative and supportive team.	"I joined Ondine because I felt that I could be a part of something beneficial to humankind, something bigger than myself. Joining a team with a culture of collaboration makes me feel valued and that what I do every day matters and will make our world a healthier place."  Dawn Nguyen Director of Quality
Shareholders	High growth potential in the largest healthcare market upon US FDA approval.	Close collaboration with and interest from HCA Healthcare, largest non-government health system and a leader in patient safety protocols.



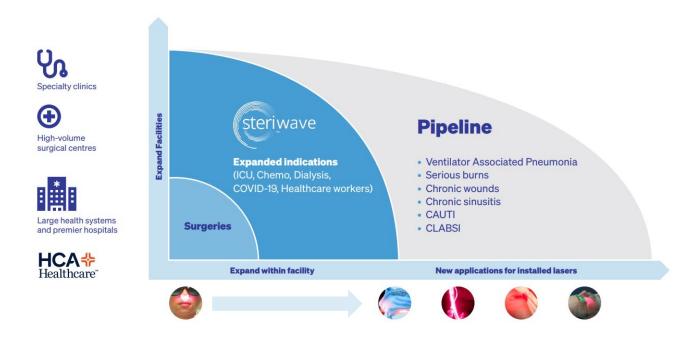


## **Our Strategy**

## Leverage the synergies across our photodisinfection pipeline for multidirectional growth

We are focused on making photodisinfection the first step in the prevention of HAIs. Our immediate commercial priority is on the large hospitals systems in the USA. Over time, we plan to grow by adding to our product offering, leveraging these initial installations and relationships, as well as by reaching out to more hospitals and surgical centres, including in other jurisdictions. Establishing a large installed base of light activating devices is our near-term commercial focus. Our Canadian experiences over the past ten years, we believe, will serve us well and provide us the foundation for rapid growth.

#### APPLICATIONS ACROSS HEALTHCARE DRIVE GROWTH







### **Our Strategy** Continued

Strategic Priorities	YoY Progress	2022 Goals		
US Market Entry and growth	Onboarded qualified FDA drug manufacturer to produce and package nasal photodisinfection formulation for the US.	Complete Phase 2 clinical trial.  Commence Phase 3 clinical trial.		
	Phase II clinical trial commenced. \$37.7 million equity raise and listing on AIM market IPO.	Hire head of US commercialisation.		
Scale Production Capabilities and Capacity	Expanded supply chain and internal manufacturing capability.  Increased production 389%.  Designed new injection moulded nasal light illuminator assembly design for high-volume, low-cost manufacturing (target Q4 2022 for release).	Implement formal Sales and Operational Planning processes.  Enhance Enterprise Requirement Planning (ERP) systems.  Increase production capacity and supply chain reliability.  Hire manufacturing excellence expertise and develop a flexible manufacturing workforce.		
Expand Market Opportunities	Nasal photodisinfection deployments implemented at four additional facilities across Canadian healthcare and meat-packing facilities.  Completion of four trials proving efficacy of nasal photodisinfection against the SARS-CoV-2 virus across variants and ability to prevent disease progression.  First regulatory approval obtained for expansion into Asian markets.  Added NHS experts to the Ondine Board of Directors and Advisory Board.  Results of nasal photodisinfection to prevent COVID-19 presented at Canadian Public Health Association Conference.	Expand nasal photodisinfection into ICU.  Introduce nasal photodisinfection into the NHS.  Publication of the SARS-CoV-2 trial results in peer-reviewed journals.  Clinical trial in partnership with leading university hospital demonstrating impact on clinical COVID-19 symptom progression.  Hire territory sales professional for Canadian region.		

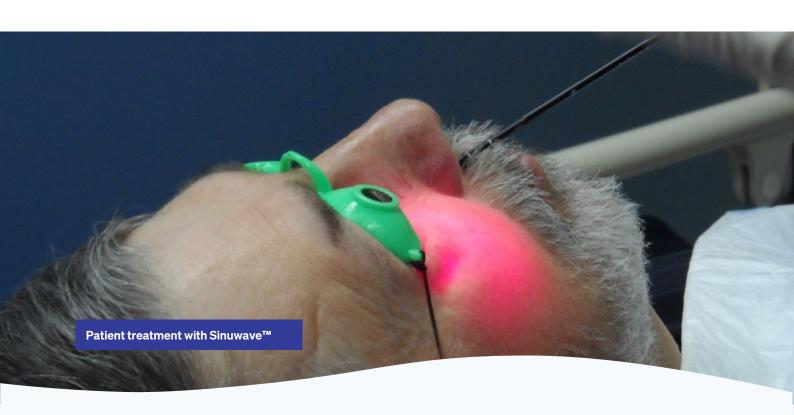


### **Our Strategy** Continued

### **OUR PIPELINE**

	Therapy Area	Development	<b>Human Trials</b>	A	pprove	ed
PREVENTION				(•)		#
Steriwave™	HAI (nasal decolonization)			<b>✓</b>	✓	*
	COVID-19 / Influenza (upper airway decolonization)					
OND1002	Ventilator-associated pneumonia (VAP) (endotracheal tube decolonization)					
OND1003	Burns (burns decolonization)					
Uriwave™	CAUTI (urinary catheter decolonization)					
TREATMENT						
Sinuwave™	For chronic sinusitis			$\checkmark$		
OND1004	For chronic wounds					
OND1005	For chronic ear infections					

<sup>\*</sup>Active IND with US FDA, granted QIDP and Fast Track status, undergoing US Phase II clinical trial.







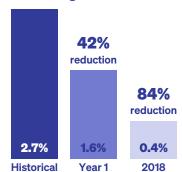
## **Strategy in Action**

# Compelling decade of results at one of Canada's largest hospitals

Vancouver General Hospital is one of Canada's largest acute care hospitals. In 2011, VGH conducted a one-year quality improvement pilot, adding Steriwave nasal photodisinfection to its presurgical infection prevention protocols.

The results were so compelling, the hospital increased its Steriwave use and has continued to see infection rates decline even further:

#### VGH overall surgical site infection rate 1



Before Steriwave | Year 1 (2011) | 2018

## ANNUAL PHARMACOECONOMIC IMPACTS\*





<sup>&</sup>lt;sup>1</sup> Bryce et al. J Hosp Inf 2014 Jun. and VGH presentation to ICPIC 2019. Historical = 4-years prior to study period. Study period (year 1) = Sept. 1, 2011 – Aug. 31, 2012.

<sup>\*</sup>Average of years 2011-2017.

#### **Strategy in Action** *Continued*

# **Extrapolating Canadian results** to US hospitals

The strong clinical and pharmacoeconomic results, high compliance and nursing support, and confirmed low impact to hospital workflow demonstrated in Canada over the many years at VGH, attracted the attention of HCA Healthcare and other institutions.

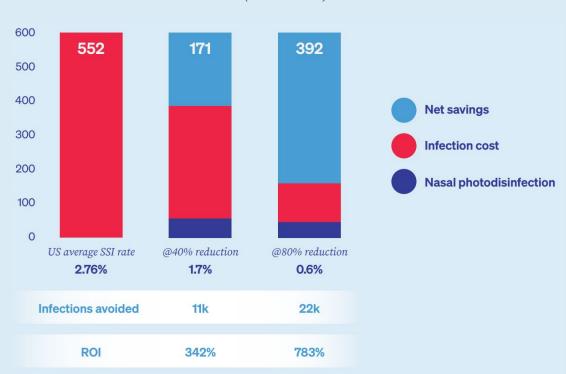
The potential to replicate the Canadian results across major surgeries in US hospitals represents millions of dollars of cost-saving opportunity, not to mention incremental revenue opportunity from the ability to treat more patients.

In the US, 276 of every 10,000 patients develop an SSI with an average cost \$20,000 each, representing over \$550 in preventable costs for every patient undergoing surgery. Reducing these surgical rate infections by half would result in \$225 savings per surgical patient, a savings that is significantly higher than the proposed nasal photodisinfection per patient cost.



#### **NET SAVINGS PER MILLION SURGERIES**

(USD millions)





<sup>&</sup>lt;sup>1</sup> Surgical Site Infection Guidelines, 2016 Update.



## **Sustainability**

As an emerging company, we launched and continued to develop several **ESG** initiatives within our business.

#### We are committed to:

- Making a positive impact globally
- Working hard to realise our vision of a world free from infections
- Improving the health of humanity through our photodisinfection therapies
- Championing diversity, equality and dignity
- Being socially and environmentally responsible









### **ESG** strategy

#### **Environmental**

At Ondine, we consider how our products can reduce environmental impact for patients, hospitals, communities and our company.

#### **Implementation**

When Steriwave is used we are reducing the risk of antimicrobial resistance.

The reduction of hospital readmission rates reduces resources used and bed capacity needed, which lessens waste and energy.

#### **Manufacturing**

Manufacturing requires minimal energy and resources and is optimised to reduce waste. Ondine devices are built with materials compliant with the EU Restriction of Hazardous Substances (RoHS) directive and follow WEEE regulations.

### **Health & Safety**

Ondine provides employees the facilities, personal protective equipment and procedures to ensure a safe workplace environment.

We follow local, state, and federal safety regulations for occupational safety, biohazard responses and hazardous waste disposal.

Ondine's commitment to safety has resulted in no workplace injury claims.



#### **Sustainability** Continued

#### Social

We are targeting two of the top twelve health challenges facing the world: infectious disease prevention and antimicrobial resistance.

Our technology can reduce the number of people with multidrug-resistant infections in hospitals, which in turn improves patient outcomes and saves time and money that can be used to treat more patients and freeing dollars to support universal healthcare.

With fewer people suffering from healthcareassociated infections and recovering more quickly from wounds and other surface infections, a positive impact on economic output and family stability is realized.

At Ondine, we hold ourselves and the people we work with to high standards of professional conduct. In addition, we have a number of policies to ensure we keep our employees safe.

#### **Our Core Values**

People are our greatest assets. Ondine's culture and mission are the glue that bind us together through the journey.

Equity	We create an inclusive environment where all can feel welcome, respected and valued for their contributions. Diversity of backgrounds, experiences, perspectives and ideas makes us stronger as a team.
Teamwork	We are a family as well as coworkers. We collaborate and support each other, inspiring personal and professional growth. Our teammates are enabled, informed and appreciated.
Reliability	Being innovative comes with uncertainty and risk. We aren't afraid of unexpected outcomes, knowing they can teach us as much as our successes and accelerate us on our path.
Quality	Excellence is in our makeup, and we pursue it in everything we do by delivering unparalleled service and products to all of our stakeholders.
Trust	We hold trust sacred. Reliability, integrity, privacy and transparency are integral to how we build trust with all our stakeholders.
Celebration	We believe that appreciation and gratitude are essential to our success. We celebrate wins, recognise efforts and milestones, and have passion for the work that we do.



## 8

#### **Sustainability** Continued

#### Governance

In 2021, Ondine made great process in enhancing both its board and its governance to align with best practices. The Board, half of whom are deemed Independent Directors, is very engaged and provides the Company with a diverse and rich set of experience. Our Directors' skillsets reflect our business needs, helping with effective oversight, independence, and guidance.

Ondine ensures ongoing dialogue between the Board and employees, which gives Board Members more insight into daily operations to support more effective oversight. Disclosure and reporting practices are comprehensive, covering a wide range of financial and nonfinancial metrics.

Financial disclosures are comprehensive and meet auditor and regulatory requirements.

#### ESG focus areas for 2021 and 2022

#### **Environmental**

- Expansion of biohazard recycling and waste disposal in an environmentally safe way
- Further reduced waste
- Packaging refinements to reduce landfill waste

Evaluate product and packaging designs to be more environmentally responsible

#### Social

- 100% of non-manufacturing team members provided with company laptops to enable remote and flexible work
- Strengthened flexible work initiatives, including work-from-home policies for relevant positions
- Diverse workforce including 56% women. Women represented 25% of board in 2021
- Donated equipment and photodisinfection treatment kits to help protect healthcare workers, essential workers and patients during the pandemic

Increase female representation on the Board to >30%

#### Governance

- Added five Directors with deep and diverse experience across healthcare, life sciences, and governance domains
- Adopted QCA standards
- Implemented independence of Board Committees: all chaired by non-executive directors and 2 of the 3 are chaired by independent directors
- Enhanced corporate reporting for transparency
- Completed successful audit and certification renewal of our top-quality management system

Identifying and addressing risks related to ESG factors to build organisational resilience





## **Stakeholder Engagement**

In order to operate effectively, companies must understand those resources and relationships that matter most to their success. In line with the requirements of the QCA Code, Ondine's Board will seek to ensure effective engagement with all stakeholders.

Stakeholder	Stakeholder Interests	Our Approach
Partners & Customers	<ul> <li>Quality products for clinical needs</li> <li>Improve patient safety</li> <li>Fair pricing, enabling accessibility</li> <li>Reliability of supply</li> <li>Clinical education, information, resources and support</li> <li>Patient privacy</li> </ul>	<ul> <li>Continuous communications with clinicians for input and feedback</li> <li>Long-term contracts, volume discounts</li> <li>ROI and health-economic analyses</li> <li>Multiple application platform technology</li> <li>Commitment to after-market support</li> <li>Adherence to patient privacy standards</li> </ul>
Employees	<ul> <li>Training and development</li> <li>Safe and healthy working conditions</li> <li>Ethical workplace practices</li> <li>Diverse and inclusive workplace</li> <li>Fair pay, benefits and equal opportunities</li> </ul>	<ul> <li>Open and regular informal dialogue</li> <li>Ongoing training and development</li> <li>Whistleblowing procedures</li> <li>Competitive employee benefits</li> <li>Formal annual reviews and goal setting</li> </ul>
Shareholders	<ul> <li>Return on investment</li> <li>Business sustainability</li> <li>High standard of governance</li> <li>Operational and financial transparency</li> <li>Corporate visibility</li> <li>Ethical behaviour</li> </ul>	<ul> <li>High growth business strategy</li> <li>Investor meetings, conferences, and online presentations</li> <li>Press releases on major developments</li> <li>Industry and general media coverage</li> <li>Corporate website and social media</li> <li>Annual General Meeting ('AGM') and Annual Report</li> </ul>
Suppliers	<ul> <li>Fair terms for trading and payments</li> <li>Positive environmental impact</li> <li>Collaboration on successes</li> <li>Long-term relationships</li> </ul>	<ul> <li>Performance management and feedback</li> <li>Regular communication with suppliers</li> <li>Annual audits of key suppliers</li> </ul>
Community & the Environment	<ul> <li>Community safety</li> <li>Sustainability</li> <li>Contribution to local community</li> <li>Charitable donations and practices</li> <li>Social responsibility</li> </ul>	<ul> <li>Where possible, we sourced locally to support our community</li> <li>Packaging designs to minimise waste</li> <li>Long-term supply chain relationships where possible with local suppliers</li> <li>Oversight of corporate social responsibility plans</li> </ul>





## **Financial Review**



"2021 was a pivotal year in our corporate history with the successful completion of our IPO, enabling us to continue on the path of operational growth and US regulatory approval."

Vipul Shah Chief Financial Officer

This past year was a challenging and immensely rewarding one for the company. Among the numerous achievements is the company's transition from a private to a publicly traded company at the end of 2021. Ondine's initial public offering and AIM listing on 6 December 2021 significantly enhanced the company's financial position enabling us to pursue our ambitious growth plans. Simultaneous to the public offering was the restructuring of all of the company's debt into equity which has put the company on a solid financial footing to tackle the next phase of its corporate development.

In response to the pandemic, the company dedicated a significant proportion of its resources and bandwidth to clinical studies and evaluations of photodisinfection for use in the battle to treat and prevent COVID-19. Successful clinical studies resulted in short-term sales growth to enterprise customers looking to protect their employees and maintain their operations.

#### Revenue

Revenue recognised for 2021 increased to \$2.6 million (2020: \$1.8 million), driven by the continued pandemic-related adoption of Steriwave in the Enterprise (non-healthcare) market.

The Enterprise market contributed 76% of revenue as hospitals concentrated on COVID-related incidents and substantially reduced overall surgery volumes. Ondine expects

Enterprise market growth to taper as the percentage of the population who have been vaccinated against COVID-19 increases.

#### Research and development expenditure

Research and development spend in the year increased by \$1.7 million to \$5.0 million (2020: \$3.3 million), primarily driven by an increase in third-party and personnel costs needed to support the advancement of Steriwave into clinical studies as well as new product development.

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

General and administration expenses increased by \$2.6 million to \$13.0 million for 2021 (2020: \$10.4 million), primarily driven by additional finance and legal costs associated with the IPO listing on the AIM market in December 2021.

#### **Marketing and sales expenses**

Marketing & Sales expenses decreased by \$1.2 million to \$0.4 million for 2021 (2020: \$1.6 million), as Ondine consolidated locations in the US in 2020.

#### Other losses/gains

Ondine recognised an expense of \$31.6 million for the year ended 31 December 2021 (2020 - \$nil) due to the settlement of the loans payable to related parties and convertible loan notes offset by gains related to the extinguishment of the convertible loan notes issued in 2017 and the embedded derivative component of the convertible loan notes issued in 2020.



## 8

#### **Financial Review** Continued

For the year ended 31 December 2021, Ondine incurred finance expense of \$1.2 million (2020: \$0.5m) of which \$0.6 million was related to the convertible loan notes, \$0.1 million was related to the preferred shares, and \$0.5 million was related to the loan payable to related parties.

Additionally, Ondine recognised an expense of \$0.4 million (2020: \$0.2 million) on the fair value of derivative contract, offset by a \$0.2 million (2020: \$0.1 million) foreign exchange gain resulting from revaluation of foreign currency denominated monetary items.

Ondine also recognised income of \$0.5 million (2020: \$nil) from the forgiveness of the grants it received under the Paycheck Protection Program in the US.

#### **Taxation**

Ondine does not expect to pay any income tax as it has non-capital loss carry forwards of \$82.4 million in Canada, US\$34.6 million in the US and US\$6.9 million in Barbados, all expiring between 2022 – 2040. These losses are available in the future to reduce taxable income in their respective jurisdictions.

#### Liquidity, cash and cash equivalents

The Group's cash and cash equivalents at year end totalled \$29.9 million (2020: \$0.6 million).

The cash flow from operating activities was \$12.5 million outflow (2020: \$6.3 million outflow) against an operating loss of \$17.5 million (2020: \$15.9 million). In 2021, due to the listing on the AIM markets, the company had financing proceeds of \$37.7 million.

The Directors have reviewed the working capital requirements of the Group for the twelve months from signing these financial statements and are confident that Ondine will have sufficient working capital to meet its needs for the next 12 months.

#### Other balance sheet items

Current trade and other payables decreased by \$32.4 million to \$3.4 million at the end of 2021 (2020: \$35.8 million). This was largely driven by the conversion of loan notes, preferred shares and related party loans to equity pursuant to the IPO.

#### Vipul Shah

Chief Financial Officer





# Risk Management

## The management of risk is a key responsibility of the Board of Directors.

The Board ensures risks are understood and that a robust risk management process is maintained to identify, quantify, minimise and manage important risks. The Board is also prepared to act swiftly to formulate contingency plans to manage the situation if any risk materialises.

### **Risk Trend**



**Increased risk** 



**Decreased risk** 



No change

#### **Description Principal Risks Mitigating Activities Trend** Personnel Risk that we cannot We rely on corporate culture and a competitive **Risks** recruit the right talent compensation scheme to attract and retain for the Company to key personnel. We have implemented a longterm incentive plan involving share options to meet our goals. retain key employees. Additionally, we have Risk of over-reliance on entered into employment and retention certain key executives contracts to reduce the risk of loss of key executives during the next few years. Employment contracts contain limited noncompetition provisions with key personnel. We have taken great steps over the last 12 months to implement new recruitment and onboarding processes to ensure rapid integration and productivity of new employees. We hired an external HR consultant to assist with human resources planning against our growth plans and to assist with implementing new HR processes We have engaged recruitment firms to assist with talent recruitment and employee engagement.





#### **Principal Risks Description Mitigating Activities Trend** 2 Clinical Trial Risk of undesirable or Our clinical trial protocols are based on 10 Risks unexpected clinical trial years of real-world experience including outcomes. clinical trial data from Canadian hospitals. We are partnering with HCA Healthcare to Risk of delays and cost conduct our key Phase 2 and Phase 3 studies. overruns. HCA is highly experienced with conducting large trials similar to ours and maintains large databases of digital health data from each of their hospitals and electronic medical record (EMR) systems. We will be working with CRO's, clinical trial monitors, patient recruitment experts, hospital integration experts and clinical trial consultants along with competitive recruitment protocols to keep to planned timelines. Prioritising high-risk surgical patients during the recruitment process can help to control budgets and timelines if needed. 3 Breach of Risk that the Company Our in-house Quality Assurance and Regulatory breaches legal or Regulatory teams are focused on meeting the and Legal regulatory regulatory requirements in key jurisdictions for Requirements requirements in local product development and clinical studies. jurisdictions which They are responsible for developing and could result in fines, maintaining the quality management system penalties and damage and related quality documentation to support to Ondine. all regulatory applications. Mock recalls are conducted annually or as Underestimating the often as required in order to ensure postregulatory market readiness across the organisation. requirements in key • We have Health Canada approval as well as the markets could result in CE mark for Steriwave nasal photodisinfection. We have over 10 years of commercial market access delays. experience and are EN ISO 13485:2016 and MDSAP certified.





#### **Description**

### **Mitigating Activities**

#### **Trend**

#### 4 Barriers to Market

Risk our products do not meet the necessary regulatory requirements for access to the key US market.

Risk our products are not competitively priced or do not provide sufficient value over competitor products.

Risk related to competitors.

Lack of resources to adequately scale into non-North American markets.

 Frequent communication with the FDA to support key clinical trial planning and regulatory submissions.

- Hiring experienced regulatory consultants to supplement the in-house team.
- Engagement with key opinion leaders and clinicians to gain their support and endorsement at FDA.
- Development of next-generation photodisinfection products utilising LED technology to reduce cost of goods and improve margins.
- Benchmarking prices of products in local markets.
- Prioritising largest European markets first, with lowest barriers to competitive entry, using experienced consultants to guide our efforts.
- Extensive IP portfolio to protect our technology in the market.
- Competitive products currently used for nasal decolonisation suffer from issues relating to patient compliance, resistance generation, lack of broad-spectrum efficacy and require multiple treatments over several days (higher labour costs).
- Developing pharmacoeconomic models with in-country specialist firms to provide hospital and clinic administrators with key data needed to make purchasing decisions.





#### **Description**

#### **Mitigating Activities**

#### **Trend**

#### Financial and **Going Concern** Risks

Risk that the Company does not have sufficient cashflow to meet its liabilities and is no longer a going concern.

Risk that we do not have sufficient working capital to pursue growth opportunities and profitable projects when they arise.

- The 2021 fundraise and debt conversions added significant strength to the balance sheet to allow Ondine to achieve its near-term objectives.
- The public listing on AIM provides greater financing access. We are taking measures to broaden corporate visibility and investor appeal.
- We work closely with a number of agencies and bodies to maximise the amount of grant funding that is available to assist with our technological development while minimising our spend.
- We are constantly talking to current and new investors about our commercial plan and opportunities and the funds those opportunities would require.
- Budgets are reviewed each month to ensure sufficient working capital to meet operational requirements.

#### **Operating Risks**

Risk that Ondine is impacted by supply chain issues, manufacturing delays or lack of manufacturing capacity, product defects, or supplier dependence.

COVID-19 related disruptions

- **Experienced Vice President of Operations** hired and in place to review and mitigate any supply chain risks.
- We have identified alternative suppliers and second sources to secure our supply chain, avoiding sole supplier vulnerabilities and reducing geopolitical risks. We prioritise onshore suppliers where possible.
- Outsourcing partners are identified and ready to operate, should demand require additional manufacturing capacity for laser and disposable production.

#### **Product Liability Risks**

Criminal or civil proceedings might be filed against the Company by study subjects, patients, the regulatory authorities, other companies and any other third-party using or marketing our products.

- Steriwave has obtained required approvals from regulatory bodies in selling jurisdictions.
- Clinical trial and product-liability insurance is maintained to manage risk of litigation by clinical trial subjects, customers, distributors or third parties.
- Our design processes, usability engineering, supplier qualifications, quality management procedures and post-market surveillance system adhere closely to recommendations by regulatory authorities, including risk-based approaches specified in ISO 14971.
- We prioritise voice of the customer and invite input from Key Opinion Leaders on key aspects of product design and development.







#### **Description**

#### **Mitigating Activities**

#### **Trend**

#### 8 Business **Disruption Risks**

COVID-19 or similar pandemic or other business disruption to business preventing normal operations.

Supply chain disruptions arising from COVID-19 continue to impact pricing and volumes.

- A disaster recovery plan has been developed.
- We maintain in-house COVID-19 testing capability for our personnel including rapidantigen and PCR testing; we have clearly defined protocols for responding rapidly to any outbreak on our workforce, including the requirement to test negative prior to returning to work; we provide ready access to vaccine in our manufacturing facility.
- We have increased inventory levels of critical and long-lead time components in order to bridge interruptions in supply.
- We have designed out components in our devices that are in short supply, replacing them with more generic and less expensive components in order to reduce our reliance on difficult to source inventory.
- We have entered into contract arrangements with multiple drug suppliers and packaging manufacturers to protect our photosensitiser supply.
- The Company property is well secured and we have taken reasonable steps to protect the contents.





#### **Description**

#### **Mitigating Activities**

#### **Trend**

#### 9 IP and Proprietary Technology Risks

We rely on a combination of patents, trade secrets and proprietary knowledge to establish and protect our proprietary IP rights.

It is costly for us to obtain, maintain, enforce and defend our intellectual property rights. Some markets are challenging to defend IP rights. Although there are no direct competitors, failure to obtain or protect these rights could adversely affect our business and our ability to compete in the long term.

Redomicile of the Company's IP may be warranted due to tax treaties and crossborder accounting principles.

- We have a long-standing track record of IP generation and successful applications.
- We have a long-standing relationship with our external patent lawyer who has a deep understanding of our technology and the medical device sector in general, and who advises us on the application and execution of patents.
- In managing the need to potentially move our IP domicile to another country, we have engaged experts in cross-border taxation and IP protection to minimise cost and maximise value of our portfolio.
- We maintain an ongoing review of terms and conditions of contracts and relationships with third parties to ensure that IP rights are retained and protected wherever possible.
- The Company has engaged professionals to determine an IP holding strategy in all patented jurisdictions and has invested in software which assists with patent valuations, patent term considerations, opportunities to invest in new IP, and potential purchase opportunities of third-party IP.



#### **Description**

#### **Mitigating Activities**

#### **Trend**

#### 10 IT and Cyber **Security Risks**

Industrial espionage and malicious hacking of sensitive information and/or with the intention of deliberate malice may result in disruption to the business.

Unforeseen HIPAA or GDPR compliance breaches may result in liability to the Company, including fines from regulatory agencies.

- IT security responsibilities have been placed under our experienced VP Operations who has managed cyber-security risks for major corporations in the past.
- A comprehensive cyber-security strategy review was undertaken during 2021 and recommended actions are being implemented.
- Cyber-security awareness training as been implemented across the Company.
- An IT consultant firm has been engaged to help ensure that we minimise potential cybersecurity risks.
- Strong IT security measures, including offsite data storage and back up capabilities have been implemented and are reviewed annually. We have robust processes to manage information internally, and our IT system, virus protection and hardware and software firewalls are constantly updated and monitored.
- We conduct training in HIPAA compliance for all personnel involved in clinical trials, postmarket surveillance, complaint handling and reporting, and we include standard operating procedures for HIPAA compliance in our quality manual to ensure annual auditing of compliance.
- Prior to conducting any sales and marketing activity in the EU, we intend to become fully GDPR compliant as required by law, including the provision of a data protection officer and all required privacy by design features.







## **Board of Directors**



#### **Jean Charest Chairman**

Mr. Charest is the former Deputy Prime Minister of Canada and the former Premier of the Province of Quebec. With a public service career spanning almost 30 years, Mr. Charest is one of Canada's best-known political figures; he was first elected to the House of Commons in 1984 and, at age 28, became Canada's youngest cabinet minister as Minister of State for Youth. As a leader, Mr. Charest has been a strong supporter and promoter of women in politics. In 2006 his government voted legislation that requires gender parity on the boards of the 22 most important state-owned corporations, and in 2007, his 18-member cabinet had an equal number of men and women. Mr. Charest is a Partner with McCarthy Tetreault in Montréal. Mr. Charest has been a lecturer on political science at Concordia University, and he remains active in public policy and community activities. He obtained his law degree from the University of Sherbrooke in 1980 and was admitted to the Québec bar in 1981.

Appointed: January 30, 2018

Areas of Expertise: Corporate strategy, business development and governance Committees: Audit & Risk Member, Remuneration Member



### Jean Duvall Senior Independent Non-Executive Director

Ms. Duvall is Co-Founder and was Chair of cell and gene therapy specialist, Trizell Holding, an affiliate of Ferring Pharmaceuticals. Ms. Duvall co-initiated and drove Ferring's entry into gene and cell therapy with the acquisition of the assets and founding of Trizell. She grew the company from ~50 to 250 employees, and into a fully integrated group including R&D and manufacturing capabilities in Finland, UK and Switzerland. Ms. Duvall was previously Executive Vice President at Ferring Pharmaceuticals, where she was responsible for a number of functions on a global basis, including corporate development, legal and compliance. She also served also as the secretary to the board of directors. Prior to joining Ferring she was general counsel at Elan Corporation. Ms. Duvall has a Bachelor of Science degree from Case Western Reserve University and a Juris Doctor degree from Ohio State University.

Appointed: November 15, 2021

Areas of Expertise: Corporate development, Pharmaceutical research and

development, legal and compliance

Committees: Nominating & Governance Chair, Remuneration Member



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#### **Board of Directors** Continued



### **Carolyn Cross Chief Executive Officer and Founder**

Ms. Cross was one of the initial founders and financial supporters of Ondine Biomedical Inc. in 1999, and currently serves as Chief Executive Officer of the Company. Ms. Cross sits on the National Research Council (NRC) of Canada and on the NRC's Departmental Audit Committee. She serves on the board of Canadian Light Source (Canada's synchrotron) and is a board member and Treasurer of the International Photodynamic Association. She is a former board director of Canada Foundation for Innovation, a Canadian Crown Corporation. Ms. Cross has over 25 years' direct experience working with early-stage companies and 30 years' experience with public market securities. Earlier in her career, Ms. Cross was responsible for managing pension, pooled, mutual and private client funds as a Vice President with Royal Bank Investment Management Inc. Ms. Cross is a Chartered Financial Analyst (CFA) and has an MBA from York University and an HBA from the University of Western Ontario (Western University). In 2016, Ms. Cross was awarded the Meritorious Service Cross by the Governor General of Canada for her work developing photodisinfection technologies in Canada. She is also a recipient of the Queen Elizabeth II Diamond Jubilee Medal among other awards.

Appointed: March 31, 2004

Areas of Expertise: Leadership, global commercialisation, strategy, financing, business development and corporate finance



#### **Nicolas G. Loebel PhD President and Chief Technology Officer**

Dr. Loebel serves as President and Chief Technology Officer to the Company, specialising in product research and development, photochemistry, systems integration, and cross-functional team building. His research focus has centred on novel photochemistries, rheological modelling of periodontal disease and tooth mobility, fibre optic waveguide propagation theory, evanescent coupling and the applications of optical fibres to interferometric sensors. He has experience in dental and medical product development and manufacturing, corporate management and business development in public and private market environments. He has authored numerous publications and patents and lectures regularly on antimicrobial photodynamics around the world. Dr. Loebel was awarded the 2017 Clinical PDT Research Excellence Award by the International Photodynamic Association in Coimbra, Portugal.

Appointed: February 22, 2017

Areas of Expertise: Research and development, regulatory and medical affairs, commercialisation, and corporate strategy



#### **Board of Directors** Continued



#### **Junaid Bajwa Non-Executive Director**

Dr. Bajwa is the Chief Medical Scientist at Microsoft Research and a practising NHS physician. He was previously the Global Lead for Strategic Alliances and Solutions for the Global Digital Centre of excellence at Merck Sharp & Dohme, where he helped shape their global digital strategy, and also co-founded "VelocityHealth" as Europe's first prevention focused digital-health accelerator, in partnership with Telefonica. Previously, Dr. Bajwa worked across primary care, secondary care, and public health settings in addition to acting as a payor, and policy maker within the UK, where he specialised in informatics, digital transformation, and leadership. He has consulted for health care systems across the US, Australia, New Zealand, Singapore, and Europe, in addition to being seconded by the NHS to work with IBM. Dr. Bajwa completed his MBA at the Imperial College Business School in London and has studied health strategy and quality improvement at both Harvard and the Institute for Healthcare Improvement in Boston. He is a Clinical Associate Professor at University College London, and Visiting Scientist at the Harvard School of Public Health.

Appointed: November 15, 2021

Areas of Expertise: Research and development, clinical affairs, health strategy

and quality improvement

Committees: Audit & Risk Member, Nominating & Governance Member



#### **Michael Farrar Non-Executive Director**

Mr. Farrar is a management consultant with 13 years of CEO experience in the NHS, having stepped down as the Chief Executive of the NHS Confederation in September 2013. Since then, Mr. Farrar has worked as an independent consultant, with clients such as Celesio, Boston Scientific, Intuitive, NHS Quest, NHS Leadership Academy, Health Foundation, Medtronic, Novartis, Pfizer, CIPFA, as well as starting up a number of small companies aimed at promoting health innovations, and links between health and sport.

Mr. Farrar remains a prominent thought leader and consultant to the NHS, where he supports system wide leadership groups such as those in Greater Manchester, South Yorkshire, The Northwest Nottinghamshire, Humber Coast and Vale, North East and North Cumbria, Hereford and Worcestershire, Sussex, Cambridge and Peterborough and Bristol, along with work in a number of individual NHS organisations including Kings College Hospital, London, Homerton, and Liverpool. Mr. Farrar was also the Vice and Interim Chairperson of Sport England, and in August 2009 was appointed as National Tsar for Sport and Health. He was also awarded a CBE in 2005 for services to the NHS and is an Honorary Fellow of the Royal College of General Practitioners, the Royal College of Physicians and the University of Central Lancashire.

Appointed: November 15, 2021

Areas of Expertise: Health strategy and business development



#### **Board of Directors** Continued



#### **Simon Sinclair Non-Executive Director**

Dr. Sinclair is a senior executive physician scientist with over 15 years' pharma, medtech and consumer healthcare industry experience. He is currently Chief Safety Officer at Reckitt. Dr. Sinclair was previously at Johnson and Johnson Medical Devices, first as International Clinical Director, then leading Medical Affairs for its EMEA region. Prior to this, Dr. Sinclair led translational medicine efforts and the early clinical development of several drug candidates at Merck and Co (MSD) in the USA. Originally trained as an ophthalmologist, Dr. Sinclair holds a medical degree and a PhD in neural transplantation from the University of Cambridge.

Appointed: November 15, 2021

Areas of Expertise: Clinical development and health strategy

Committees: Audit & Risk Member, Remuneration Member, Nominating &

Governance Member



#### **Craig Tooman Non-Executive Director**

Mr. Tooman has more than 30 years of experience in the biopharmaceutical industry, including 15 years of experience as a public company CFO. He is currently President, CEO and Executive Director at Silence Therapeutics, and recently served as CFO at Silence Therapeutics, CFO and COO at Vyome Therapeutics. Prior to this Mr. Tooman was CFO and then CEO of Aratana Therapeutics where he successfully negotiated a merger with Elanco. Before Aratana, Mr. Tooman was the CFO of Enzon Pharmaceuticals until its acquisition by Sigma Tau, and prior to that led the \$1.1 billion M&A initiative and integration of ILEX Oncology and Genzyme Corporation. He also previously held key positions at Pharmacia and Upjohn, and currently serves on the Supervisory Board and Audit Committee of CureVac, which accomplished a highly successful IPO on Nasdaq in August of 2020. Mr. Tooman holds a BA in Economics from Kalamazoo College, and an MBA from the University of Chicago.

Appointed: November 15, 2021

Areas of Expertise: Corporate strategy and finance, M&A and financing

Committees: Audit & Risk Chair



# **Senior Leadership**



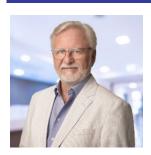
#### **Vipul Shah Chief Financial Officer**

Mr. Shah is the CFO of Ondine. He is a seasoned finance executive with over 30 years in senior leadership roles at a wide range of companies from biotech and technology start-ups to major financial and venture capital institutions. His experience spans corporate finance, evaluating and managing sizeable investment opportunities, driving financial and operational efficiencies, and maximising investment returns. He has led significant investment and asset acquisitions, leveraging his expertise in competitive and financial strategies to drive savings of over US\$75 million for his various organisations. Mr. Shah brings exceptional experience, financial discipline as well as a level-headed approach to strategy. Mr. Shah is a CPA and obtained his MBA and Master's in Professional Accounting from the University of Washington and is a member of a number of professional organisations.



#### **Tom Dawson Senior Vice President Corporate Development**

Mr. Dawson has over 35 years of experience developing and commercialising new products, implementing operational best practices, lean enterprise systems, and managing P&L responsibility for sensor & instrument, telecom, medical device, and electronics firms. Prior to joining Ondine, Mr. Dawson served as Vice President of Operations of DuxArea, Inc., President of Kistler-Morse Corporation, a subsidiary of Danaher Corporation, and Vice President and General Manager of Leviton Voice and Data, a division of Leviton Manufacturing Company. One of the original employees of the start-up business unit, he also held the position of Director of M&S, IT, Product Development, HR and Operations. He has managed multiple sites including in the US, Mexico and Europe. Mr. Dawson is a member of the Beta Gamma Sigma Honor Society, and lectures at various academic institutions and has served as an Entrepreneur In Residence at the University of Washington.



Dr. Roger Andersen, MD, MPH, RAC Vice President, Regulatory, Clinical & Medical Affairs

Dr. Roger Andersen develops Ondine's regulatory and clinical programs, working extensively with the FDA, Health Canada and the EU to obtain regulatory approvals. Prior to joining the company, he practiced as a physician and surgeon in Seattle and directed a clinical research organisation for pharmaceutical and medical device clinical trials. He has published numerous articles on photodisinfection and has participated in the clinical design of Ondine products. He has extensive experience with medical marketing, medical product development, clinical trial design and execution, and worldwide regulations relating to photodisinfection products.







#### **Jason Hickok Vice President, Clinical and Medical Affairs**

Mr. Hickok joined Ondine after fifteen years with HCA Healthcare, where he served as Assistant Vice President for Research and Patient Safety in the Clinical Services Group (CSG). Under his stewardship, HCA established CSG's Infection Prevention Department, successfully deployed multiple quality improvement toolkits, and conducted several large-scale public/private research studies in partnership with Center for Disease Control and Prevention, Harvard Pilgrim Health Care Institute, and the Agency for Healthcare Research and Quality. Mr. Hickok's clinical experiences include emergency department, critical care, case management and infection prevention. He is a member of APIC (Association for Professionals in Infection Control and Epidemiology), NAHQ (National Association for Healthcare Quality), NPSF (National Patient Safety Foundation), and Graduate Fellow of the NPSF Leadership Program.



#### **Bill Kanz Vice President, Engineering**

Bill Kanz has an impressive engineering background spanning 30+ years that includes providing design for manufacturability, process development, and design transfer services to medical device OEMs. His expertise includes electronic, mechanical and optical catheters, patient interface cables, and control consoles. He has helped numerous companies and held product development and project management roles at companies such as Planetary Power, EKOS Corporation (a BTG International Group company), Stratos Product Development, and Boston Scientific.



#### **Mike Long Vice President, Operations**

Mike has over 25 years of operations and IT experience in the medical device industry, including leadership of HR, IT, manufacturing, quality and service. Prior to joining Ondine, he served as Vice President of Operations for Ventec Life Systems, and held leadership roles in medical device startups in the areas of defibrillation, cortical stimulation, atherectomy, thrombectomy, pulmonary embolism and ventilation.



#### Charles (Chuck) Young Vice President, Sales & Marketing - North America

Chuck has over 30 years of sales and marketing experience in the introduction of new technologies to hospitals and clinics across the United States and Canada, with particular expertise in the field of prevention and treatment of infections. He was previously Vice President of Health Systems at Professional Disposables International (PDI), a market leader in the provision of Interventional Care, Environment of Care and Patient Care solutions designed to help reduce preventable infections. Prior to that, Chuck was Vice President, Corporate Accounts with Sage Products LLC, a leading manufacturer and distributor of patient care and employee health interventions that help prevent hospitalacquired infections, skin injuries and healthcare worker injury. He has administered annual budgets of over \$100 million.





# **QCA Governance Compliance**

The Board has adopted the Quoted Companies Alliance (QCA) Corporate Governance Code. Set out below is our Statement of Compliance with the key principles of the QCA Code.

	Governance Principle	Compliant	Explanation	Further reading
1	Establish a strategy and business model which promotes long- term value for shareholders	<b>√</b>	Our strategy is focused on positioning Ondine for future growth and creating long-term shareholder value by focusing on the development and broad commercialisation of the photodisinfection treatment platform across multiple applications.	See "Business Model" on pages 24 to 25
2	Seek to understand and meet shareholder needs and expectations	<b>√</b>	The Board recognises the importance of engaging with its institutional and private investors. The Chief Executive Officer communicates regularly with shareholders to ensure that matters raised are discussed at Board meetings. The AGM provides an opportunity for the Board to formally meet with shareholders.	https://ondinebio.com /investors/corporate- governance/#QCA
3	Take into account wider stakeholder and social responsibilities and their implications for long-term success	✓	We prioritise our corporate social responsibilities and understand that to fulfil them we need to develop and maintain long-term relationships with all our stakeholders.	See section Stakeholder Engagement on page 34
4	Embed effective risk management, considering both opportunities and threats, throughout the organisation	management, performed annually by the Chairman, and considering both formally discussed at the Board level. This register is reviewed quarterly and threats, throughout updated as needed. This is also shared		See section Risk Management on pages 37 to 43
5	Maintain the Board as a well-functioning, balanced team led by the Chair	✓	The Board is currently comprised of six non-executive directors and two executive Directors. Four non-executive Directors including the Chairman and the Senior Non-Executive Independent Director are independent.	See section Board of Directors on pages 45 to 48





## **QCA Governance Compliance** Continued

	Governance Principle	Compliant	Explanation	Further reading
6	Ensure that between them the Directors have the necessary up-to-date experience, skills and capabilities	<b>√</b>	The Board is satisfied that its current composition includes an appropriate balance of skills, experience and capabilities	See section Board of Directors on pages 45 to 48
7	Evaluate Board performance based on clear and relevant objectives, seeking continuous improvement	<b>√</b>	The Board carries out an annual mutual review of its own performance to identify areas for improvement. The assessment includes the effectiveness of identification and mitigation of risks, effective governing policies and composition of committees, compensation adequacy, Ondine's engagement with its stakeholders, etc.	See section Corporate Governance Report on page 53 to 56
8	Promote a corporate culture that is based on ethical values and behaviours	<b>√</b>	The Board's objective is to enable a culture of integrity, transparency, ethics, and high standards, and to ensure all of the Company's operations are conducted in accordance with these principles. These values are exhibited in the written policies and working practices adopted by all employees in Ondine.	https://ondinebio.com /investors/corporate- governance/#QCA
9	Maintain governance structures and processes that are fit for purpose and support good decision-making by the Board	<b>✓</b>	The Board has overall responsibility for promoting the success of Ondine. The Chief Executive Officer has day-to-day responsibility for the operational management of the Company's activities. The non-executive directors are responsible for bringing independent and objective judgment to all Board decisions.	https://ondinebio.com /investors/corporate- governance/#QCA
10	Communicate how the Company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders	<b>√</b>	We are focused on ensuring we keep open communication channels with our stakeholders, internal and external, and that we provide transparency and openness regarding our dealings. We connect with our investor community through the AGM along with the Investor Conference Call. Ondine's website is regularly updated, where financial reports, notices of general meetings, and other corporate documents are readily available.	https://ondinebio.com /investors/





# Corporate Governance Report

#### **Our Approach to Governance**

We are dedicated to maintaining the highest standards of corporate governance throughout our operations and to ensuring that all practices are conducted transparently, ethically and efficiently.

Ondine's Board of Directors (the "Board") and Senior Management continuously monitor the evolution of the business, understanding that the changing needs of the Company will require a systemic review and improvements to our internal controls and procedures in order to ensure long-term growth for all stakeholders.

As part of this assessment, and in compliance with the updated AIM Rules for Companies, we have chosen to formalise our governance policies by complying with the UK's Quoted Companies Alliance Corporate Governance Guidelines for Small and Mid-Size Quoted Companies (the "QCA Code").

#### **Board of Directors**

The Board of Directors is responsible for ensuring that Ondine provides long-term value to all of its stakeholders. The Board sets out the corporate strategy, provides oversight of senior management, and helps establish, approve, and monitor Ondine's objectives, budgets, and corporate strategy. By adopting the 10 principles of the QCA Code, the Board believes that we have established a governance foundation that will deliver long-term growth, while maintaining an agile management framework that empowers our team to collaboratively achieve results.

#### **Governance and Control Environment**

Mr. Craig Tooman, Ms. Jean Duvall, and Dr. Simon Sinclair chair Ondine's three key committees, and formally report to the Board Chairman. The committees are the Audit & Risk Oversight, Nominating & Governance and Remuneration. The Board meets are least four times a year and includes discussions and reports from its three committees as well as from key senior management, to ensure a holistic monitoring of

Ondine's operations, growth strategy, and business risks. The Chairman is confident that the current Board and its Committees have the correct mix of skillsets that match the Company's current stage of development.

We have established internal controls and processes as well as specific Committees in order to ensure that:

- the Board and its Committees have the right experience, skillsets, knowledge, and a balance of independence, to allow them to govern and enable long-term growth and stakeholder success
- Ondine is led by an effective and knowledgeable Board which is collectively responsible for the long-term success of the Company
- the Board establish a formal and transparent arrangement for considering how it applies the corporate reporting, risk management, and internal control principles and for maintaining an appropriate relationship with Ondine's auditors.

During the year, the Board comprised two
Executive Directors and the Non-executive
Chairman, who is independent, and five other Non-executive Directors, three of whom are
independent of management. A full list of the
Directors who served during the year, together





#### **Corporate Governance Report** Continued

with their skills and experience, is set out on page 45 to 48 of this Annual Report.

#### **Audit & Risk Oversight Committee**

The purpose of the Audit & Risk Oversight Committee is to monitor the integrity of Ondine's financial statements. Some of the Audit & Risk Oversight Committee's duties include:

- monitor the integrity of financial statements;
- reviewing the accounting policies and reports produced by internal and external audit functions;
- considering whether Ondine has followed appropriate accounting standards and made appropriate estimates and judgements, taking into account the views of the external auditor;
- reporting its views to the Board of Directors if it is not satisfied with any aspect of the proposed financial reporting by Ondine;
- reviewing the adequacy and effectiveness of Ondine's internal financial controls and internal
- overseeing the appointment of and the relationship with the external auditor.

The Audit & Risk Oversight Committee has four members, all of which are non-executive and three are independent directors. At least one member has recent and relevant financial experience. The members are Craig Tooman (Committee Chair), Simon Sinclair, Junaid Bajwa, and Jean Charest. The Audit & Risk Oversight Committee meets at least twice a year at appropriate intervals in the reporting and audit cycle and otherwise as agreed between the members of the committee or as required. The Audit & Risk Oversight Committee

also meets regularly with the Company's external auditor.

#### **Remuneration Committee**

The purpose of the Remuneration Committee is to determine and agree with the Board regarding the framework or broad policy for the remuneration of Ondine's Chairman and the Executive Directors.

Some of the Remuneration Committee's duties include:

- reviewing the compensation structure across the Company, including the Board
- approving targets and performance related pay schemes operated by Ondine

The Remuneration Committee has three members, all of whom are non-executive and independent directors. The members are Simon Sinclair (Committee Chair), Jean Charest, and Jean Duvall. The Remuneration Committee will meet at least twice a year and otherwise as agreed between the members of the committee or as required.

#### **Nominating & Governance Committee**

The purpose of the Nominating Committee is to advise on nominations for Committee members, senior management, and key advisors.

Some of the Nominating & Governance Committee's duties include:

regularly reviewing the structure, size, and composition (including the skills, knowledge, experience and diversity) of the Board and Committee members and make recommendations to the Board with regard to





#### **Corporate Governance Report** Continued

- any changes, succession planning and vacancies
- Review the structure of Ondine's senior management, assessing any necessary changes to its composition

The Nominating & Governance Committee has three members, all of whom are independent non-executive Directors. The members are Jean Duvall (Committee Chair), Junaid Bajwa, and Simon Sinclair. The Nomination & Governance Committee will meet at least twice a year and otherwise as agreed between the members of the committee or as required.

#### **Share Dealing Code**

The Board has adopted a code on dealings in relation to the securities in the Company. Directors and other relevant employees are required to comply with the Share Dealing Code and the Board takes proper and reasonable steps to secure compliance.

#### **Internal Control**

The Board is responsible for the effectiveness of the Company's internal control and is supplied with information to enable it to discharge its duties. Internal controls are designed to meet the particular needs of the Company and to manage rather than eliminate the risk of failure to meet business objectives and can only provide reasonable and not absolute assurance against material misstatement or loss. The internal control system includes controls covering financial, operational and regulatory compliance areas together with risk management. The principal risks and uncertainties for the Company are set out on pages 37 to 43.

The Audit Committee monitors the Company's internal control procedures, reviews the internal control process and risk management procedures and reports its conclusions and recommendations to the Board.

#### **Employment and Corporate Culture**

The Board's objective is to enable a culture of integrity, transparency, ethics, and high standards, and to ensure all of the Company's operations are conducted in accordance with these principles.

 Employees and contractors are remunerated in line with their skills and competencies which



are reviewed on an annual basis via an employee performance appraisal program.

- The Company's Policy & Procedures manual is in place which staff are given as part of their induction and can access at all times. Staff are made aware that they must adhere to these at all times and are encouraged to ask questions and seek clarification on anything they are unsure about.
- Anti-corruption & anti-bribery policy is in place and is readily available on the server.
- The Company's expectation of honest, fair and professional behaviour is reflected by this and there is zero tolerance for bribery and unethical behaviour by anyone relating to the business.
- A Whistleblowing policy is established with a 3rd party service provider, to enable staff to confidently raise any concerns directly with the Chairman, the Company Secretary or the group's Audit team. The Company considers it essential that all staff should be made to feel safe in their environment and therefore has the means available to freely discuss any issues that arise.

These values are exhibited in the written policies and working practices adopted by all employees in the Company. An open culture is encouraged within the Company, with feedback regarding process improvement and culture assessment sought out from all employees.



#### **Corporate Governance Report** Continued

As such, all employees are expected to conduct themselves in a manner that complies with these principles, to ask questions and raise concerns openly and promptly. The CEO and senior management team monitors the Company's cultural environment and seeks to address any concerns that may arise, escalating these to board level as necessary.

#### **Investor Relations**

The Board recognises the importance of engaging with its institutional and private investors. The Chief Executive Officer communicates regularly with shareholders to ensure that matters raised are discussed at Board meetings.

The ways in which the Company seeks to engage with shareholders include:

- The AGM, which provides an opportunity for the Board to formally meet with shareholders
- The Investor Conference Call, which provides feedback to investors and gives the opportunity for any questions or concerns that are raised to be addressed
- Through RNS announcements
- Through a regular flow of news announcements to business and trade media on Company and product developments

- An active investor section of the Company's website which will include all the required regulatory information, news flow and RNS announcements
- An external third party to assist with investor relations services and communications.

The Board tries to proactively manage shareholders expectations and seeks to understand the motivations behind shareholder voting decisions by engaging with the respective shareholders to gain insight into the reasons behind their actions and address any issues.

The people responsible for shareholder liaison and the points of contact for such matters are:

- The Chief Executive Officer
- Company Secretary
- Nomad and Broker
- PR Company

Details of the above people responsible for shareholder liaison can be found in the Investor Relations section of the Company website.





## **Remuneration Report**

## **Remuneration Committee Report**

"As people are our greatest assets, having the right remuneration strategy is critical to our success at attracting and growing the talent needed to execute on our ambitious growth strategies"

It is my pleasure to present the highlights of the Remuneration Committee Report for the 2021 calendar year.

Fundamental to the Board's duties is ensuring that the Company has the right business and related operating strategies executed by the right executive management team. In this highly competitive talent and skills acquisition environment, attracting and maintaining the talent needed to grow a successful business is becoming increasingly more challenging. Now more than ever, the talent shortages are felt globally and threaten the growth strategies of companies across most industries. Ours is no exception.

The growing trend for increased job flexibility accelerated by the pandemic has only accelerated the talent scarcity and competition as companies are competing for skills across a global platform rather than only regionally. Having the right remuneration strategies across the entire company has therefore become increasingly more important in recent years, and a key corporate

success factor. For a company transitioning from an R&D focused company to a high sales growth company, compensation strategies and adopting best practices will greatly influence future operating success.

The Remuneration Committee currently consists of 3 independent non-executive directors: Hon. Jean Charest, Ms. Jean Duvall and myself as the Chair. It is the responsibility of the Remuneration Committee to determine overall corporate compensation philosophy and strategies as well as to determine the remuneration of Ondine's Board. No director is involved in any decision as to his or her own remuneration. The overall Committee objective is to deliver a remuneration program which ensures that both short-term and long-term goals of the Company are achieved and to evolve this program over time to reflect the opportunities and challenges faced by the Company along its growth trajectory.

**Dr Simon Sinclair,**Chair of the Remuneration Committee

#### **Overview of Executive Directors' remuneration**

The main elements of the remuneration package for Executive Directors include base salary, annual cash bonuses and long-term incentives such as options and RSUs.

#### **Base salary**

The base salary is reviewed annually by the Remuneration Committee. In determining the base annual salary, the Remuneration Committee considers several factors, including the current position and development of the Company, individual contribution, as well as internal and external reference points including market salary for comparable organisations. Current Executive Directors are employed under contracts which may be terminated by either party on no more than 24 months' notice.

Salaries for the Executive Directors are US\$375,000 (Carolyn Cross, CEO) and US\$350,000 (Nicolas G. Loebel, President & Chief



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#### **Remuneration Report** Continued

Technology Officer). Across the Company, salaries were increased in cases linked to increased responsibility or promotions or as part of an overall benchmarked review.

#### **Annual bonus**

All Executive Directors are eligible for a discretionary annual bonus which is paid in accordance with a bonus scheme developed by the Remuneration Committee. Bonuses paid are based on an assessment of performance against defined annual operational, financial, personal goals and

corporate objectives. The bonus is capped at 75% of the base salary. Across the Company, senior managers are also eligible for discretionary bonus payments based on the delivery against personal and Company performance objectives. Compensation is set to incentivise for achieving corporate targets and key success factors relating to the advancement in People & Talent, Technology & Product Advancement, Finance, Quality & Production objectives.

In 2021, the performance weightings were assigned as follows:

Objectives	Weighting
People & Talent	30%
Talent Acquisition and Development	15%
Upgrade Corporate Governance and Enhance the Board of Directors	10%
Gain Visibility and Awareness – Build Social Engagement	5%
Technology & Product Advancement	20%
Successful Outcomes for COVID-19 Programs and Related Sales Growth	7%
Publications and Awards	5%
Product Pipeline Development	5%
Production Capacity & Improved Margins	3%
Finance	20%
Secure Financing with an IPO	20%
Quality & Production	30%
Pass MDSAP Audits	5%
Quality Assurance - Maintenance of Regulatory Requirements for Current Markets	5%
Production Acceleration and Ramp Up for COVID-19 Demand	20%

#### Long-term incentives

Long-term incentive awards are an important component of Executive Directors' remuneration aimed at promoting the long-term success of the Company in alignment with the interests of the Company's shareholders and broader group of stakeholders. On November 1, 2021, the Board of Directors approved and adopted an amended stock option plan for the Company which provides for the grant of stock options to directors, officers, employees and consultants subject to the specific provisions of the plan, and at such time and in such

amounts as determined by the Board of Directors of the Company at its sole discretion. The maximum number of options authorised for issuance is 20% of the issued and outstanding common shares at the time of grant of any option.

To ensure that the Company can attract, retain and inspire key talent, stock options are a key component to the Company's long term incentive plan (LTIP). Stock options are granted to all employees and used to reward for individual and overall corporate performance. Options are granted on an annual basis pursuant to the Company's Option Plan dated November 1, 2021. The Options which vest equally over 4 years are



#### **Remuneration Report** Continued

conditional upon continuance of service and have an exercise price equivalent to the close of the market on the day the options were granted.

During the year, shares options were awarded to all employees of the Company as well as to key advisors and consultants. Previous options held by these employees and consultants were simultaneously cancelled.

Performance awards are set at a maximum of 100% of base salary for the Chief Executive Officer and 75% for other Executive Directors. Performance awards to Executive Directors under the LTIP are detailed in the table below. Under certain circumstances, including misconduct and nonperformance, recovery and withholding of option provisions may be invoked.

#### **Other benefits**

Other benefits for Executive Directors include extended health, dental, disability, life insurance plans and income protection.

### **Remuneration of the Chairman and Nonexecutive Directors**

Recognising the importance of a strong Board of Directors, it is the Company's policy to provide fees that attract and retain skilled individuals with appropriate experience who can add value to the Board. Board fees are reviewed on an annual basis to ensure they remain competitive and adequately reflect the time commitments and overall contribution to the roles. Non-executive Directors, however, do not normally participate in the performance-related compensation programs. The Remuneration Committee is also responsible for making recommendations to the Board on the fees payable to the Chairman. The Board, however, is responsible for determining compensation payable to the Company's Non-executive Directors and for ensuring that the compensation is consistent with best practices for our industry and scale of operations. No director is involved in any decision as to his or her own remuneration.

The tables below detail Directors' remuneration for 2021, together with share and option interests

#### Director's remuneration for 2021

The remuneration of the Board of Directors of Ondine Biomedical Inc. during the 12-month period ending 31 December 2021 was:

(All figure CAD)	Salary	Benefits	Bonus	Share based payments	Director Fees	31 December 2021	31 December 2020
Executive:							
Carolyn Cross	360,999	5,333	316,950	15,681	-	698,963	342,710
Nicolas Loebel	388,579	31,111	325,910	977,680	-	1,723,281	1,229,110
Total executive	749,578	36,444	642,860	993,362	-	2,422,243	1,571,821
Non-Executive:							
Junaid Bajwa	-	-	-	-	7,639	7,639	-
Craig Tooman	-	-	-	164,497	6,967	171,464	-
Simon Sinclair	-	-	-	-	8,681	8,681	-
Jean Charest	-	-	-	9,391	27,292	36,683	25,000
Michael Farrar	-	-	-	164,497	3,473	167,969	-
Jean Duvall	-	-	-	-	8,333	8,333	-
Total non-executive	-	-	-	338,384	62,384	400,768	25,000
Total directors' renumeration	749,578	36,444	642,860	1,331,746	62,384	2,823,012	1,596,821



### **Remuneration Report** Continued

## Directors' shareholdings

The interests of the Directors holding office as at 31 December 2021 in the shares of the Company, were:

	Number of shares	%
Executive:		
Carolyn Cross	108,376,109	55.70%
Nicolas Loebel	2,633,334	1.35%
Total executive	111,009,443	57.05%
Non-Executive		
Junaid Bajwa	-	0%
Craig Tooman	-	0%
Simon Sinclair	-	0%
Jean Charest	353,356	0%
Michael Farrar	-	0%
Jean Duvall	-	0%
Total non-executive	353,356	0%
Total directors' shareholdings	111,362,799	57.23%

### Directors' interests in share options

Directors' interests in share options, granted under the Company's Stock Option Plan:

	December 31				December 31		
	2020			Cancelled /	2021		
	Number of	Granted	<b>Exercised</b>	<b>Forfeited</b>	Number of	Vested but	Exercise
	options	during year	during year	during year	options	unexercised	Price \$
Executive:							
Carolyn Cross	-	150,000	-	(75,000)	75,000	-	0.90
Nicolas Loebel	1,500,000	1,000,000	(650,000)	(925,000)	925,000	637,500	0.90
Total executive	1,500,000	1,150,000	(650,000)	(1,000,000)	1,000,000	637,500	
Non-Executive							
Junaid Bajwa	-	-	-	-	-	-	-
Craig Tooman	-	100,000	-	-	100,000	100,000	0.01
Simon Sinclair	-	-	-	-	-	-	-
Jean Charest	353,356	50,000	(353,356)	-	50,000	-	3.61
Michael Farrar	-	100,000	-	-	100,000	100,000	0.01
Jean Duvall	-	-	-	-	-	-	-
Total non-executive	353,356	250,000	(353,356)	-	250,000	200,000	
Total directors' options	1,853,356	1,400,000	(1,003,356)	(1,000,000)	1,250,000	837,500	

<sup>\*</sup> all current directors' options granted prior to AIM Admission on 6 December 2021







# Independent Auditor's Report



## Independent auditor's report

To the Shareholders of Ondine Biomedical Inc.

#### **Our opinion**

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the financial position of Ondine Biomedical Inc. and its subsidiaries (together, the Company) as at December 31, 2021 and 2020, and its financial performance and its cash flows for the years then ended in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board (IFRS).

#### What we have audited

The Company's consolidated financial statements comprise:

- the consolidated statements of financial position as at December 31, 2021 and 2020;
- the consolidated statements of loss and comprehensive loss for the years then ended;
- the consolidated statements of changes in equity for the years then ended;
- the consolidated statements of cash flows for the years then ended; and
- the notes to the consolidated financial statements, which include significant accounting policies and other explanatory information.

#### **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing. Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Independence

We are independent of the Company in accordance with the International Code of Ethics for Professional Accountants (including International Independence Standards) issued by the International Ethics Standards Board for Accountants (IESBA Code) and the ethical requirements that are relevant to our audit of the consolidated financial statements in Canada. We have fulfilled our other ethical responsibilities in accordance with these requirements.

PricewaterhouseCoopers LLP

Pricewaterhouse Coopers Place, 250 Howe Street, Suite 1400, Vancouver, British Columbia, Canada V6C 3S7 T:  $\pm$ 1 604 806 7000, F:  $\pm$ 1 604 806 7806

"PwC" refers to PricewaterhouseCoopers LLP, an Ontario limited liability partnership.



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#### **Independent Auditor's Report** Continued



### **Key audit matters**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements for the year ended December 31, 2021. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

#### Key audit matter

#### **Revenue Recognition**

Refer to note 2 (d) – Basis of preparation - use of estimates, assumptions and judgments and note 3 (m) – Significant accounting policies - revenue recognition to the consolidated financial statements.

For the year ended December 31, 2021, the Company recognized revenue from sales of products of \$2.6 million.

The Company generates revenues from sales of hardware and consumables. Hardware sales consist of lasers. Consumable sales consist of single use disposable treatment kits. The Company has contracts with customers to deliver both lasers and consumables as part of a single arrangement. Management exercises judgment to evaluate these arrangements to determine whether the lasers and single use disposable treatment kits (goods) are considered distinct performance obligations that should be accounted for separately from each other. A good is distinct if the customer can benefit from it on its own or together with other readily available resources and the Company's promise to transfer the good is separately identifiable from other promises in the contract. Management has determined that the goods are distinct performance obligations. Revenue is allocated to the goods based on relative transaction prices and is recognized as goods are delivered to the customer.

We considered this a key audit matter due to the judgment exercised by management to evaluate whether the goods are considered distinct

#### How our audit addressed the key audit matter

Our approach to addressing the matter included the following procedures, among others:

- Assessed whether the goods are distinct performance obligations by considering for a sample of contracts whether the customer can benefit from it on its own or together with other readily available resources and the Company's promise to transfer the goods are separately identifiable from other promises in the contract.
- Evaluated for a sample of contracts the reasonableness of the revenue allocation to each good by considering relative transaction prices per the contracts and the cost and expected gross margin of each good.
- Tested for a sample of revenue transactions whether revenue is recognized as goods are delivered to the customer by inspecting relevant customer invoices and shipping documents.



#### **Independent Auditor's Report** Continued



#### Key audit matter

How our audit addressed the key audit matter

performance obligations that should be accounted for separately in the arrangements. This in turn resulted in a high degree of auditor judgment and subjectivity in performing procedures.

#### Other information

Management is responsible for the other information. The other information comprises the information, other than the consolidated financial statements and our auditor's report thereon, included in the annual report, which is expected to be made available to us after the date of this auditor's report.

Our opinion on the consolidated financial statements does not cover the other information and we will not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information identified above when it becomes available and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

When we read the information, other than the consolidated financial statements and our auditor's report thereon, included in the annual report, if we conclude that there is a material misstatement therein, we are required to communicate the matter to those charged with governance.

### Responsibilities of management and those charged with governance for the consolidated financial statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with IFRS, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Company's financial reporting process.



#### **Independent Auditor's Report** Continued



#### Auditor's responsibilities for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with International Standards on Auditing will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with International Standards on Auditing, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements. whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Company to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.



#### **Independent Auditor's Report** Continued



We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

The engagement partner on the audit resulting in this independent auditor's report is Kevin Bromley.

#### /s/PricewaterhouseCoopers LLP

**Chartered Professional Accountants** 

Vancouver, British Columbia, Canada May 16, 2022





# **Consolidated Financial Statements**

## (In thousands of Canadian dollars)

	Note	December 31, 2021	December 31, 2020	
Assets				
Current assets				
Cash		\$ 30,365	\$ 626	
Accounts and other receivables	4	248	543	
Inventory	5	1,061	404	
Prepaid expenses and deposits	6	1,830	174	
		33,504	1,747	
Non-current assets				
Property and equipment	7	601	671	
Intangible assets	8	-	171	
Other assets	6	35	46	
		636	888	
		\$ 34,140	\$ 2,635	
Liabilities				
Current liabilities				
Cheques issued in excess of funds on deposit	20	\$ 497	\$ -	
Accounts payable and other liabilities	9	3,277	1,412	
Convertible loan notes	10	-	7,538	
Preferred shares	11	-	3,000	
Loans payable to related parties	17	-	23,610	
Current portion of lease liability	12	148	225	
		3,922	35,785	
Non-current liabilities				
Lease liability	12	94	85	
Other long-term liabilities	13	467	593	
		4,483	36,463	
Equity				
Share capital	14	235,037	119,529	
Contributed surplus	17	10,528	10,378	
Reserves		16,636	18,415	
Deficit		(232,544)	(182,136)	
Equity attributable to owners of the Company		29,657	(33,814)	
Equity attributable to non-controlling interest		-	(14)	
		29,657	(33,828)	
		\$ 34,140	\$ 2,635	

Commitments and contingencies - Note 18; Subsequent events - Note 25

## Approved on behalf of the Board:

"Carolyn Cross"

"Jean Charest"



## **Consolidated Statements of Loss and Comprehensive Loss**

(In thousands of Canadian dollars, except share and per share amounts)

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		rear ende	ea December 31,
	Note	2021	2020
Revenue	17,19	\$ 2,569	\$ 1,791
Cost of sales	5,7,17,21	(1,315)	(1,142)
Gross margin		1,254	649
Expenses	21		
General and administration		12,970	10,405
Research and development		4,982	3,309
Marketing and sales		364	1,634
Depreciation and amortisation	7,8	458	1,172
		18,774	16,520
Loss from operations		(17,520)	(15,871)
Other income (expense)			
Miscellaneous (loss) gain		(20)	173
Government loan forgiveness	13	518	-
Loss on debt settlement	10,17	(31,626)	-
Finance expense	10,11,17	(1,199)	(491)
Change in fair value of embedded derivative	10	(424)	(221)
Foreign exchange gain		186	139
		(32,565)	(400)
Net loss for the year		(50,085)	(16,271)
Other comprehensive loss			
Exchange differences on translation of foreign operations <sup>(1)</sup>		(12)	64
Total comprehensive loss		(50,097)	(16,207)
Total comprehensive loss attributable to:			
Equity holders of the Company		(50,097)	(16,205)
Non-controlling interest		-	(2)
Total comprehensive loss for the year		\$ (50,097)	\$ (16,207)
Net loss per share			
Basic and diluted		\$ (0.63)	\$ (0.23)
Weighted average number of shares outstanding			
Basic and diluted		79,637,956	70,671,262
Was a second strategy and the second		10,001,000	10,011,202

<sup>(1)</sup> May be reclassified to profit or loss in subsequent years.





## **Consolidated Statements of Changes in Equity**

(In thousands of Canadian dollars, except share amounts)

	Number of common shares (Note 14)	Number of preferred shares (Note 14)	Share capital	ributed surplus	Share-based payment reserve	trar	urrency nslation reserve	Deficit	Non- rolling nterest	Equity
Balance, January 1, 2020	70,671,262	-	\$ 119,529	\$ 10,078	\$ 10,649	\$	(450)	(165,867)	\$ (12)	\$ (26,073)
Services received at no charge - Note 14	-	-	-	300	-		-	-	-	300
Issuance of preferred shares	-	3,000,000	-	-	-		-	-	-	-
Share-based payments – Note 15	-	-	-	-	8,152		-	-	-	8,152
Total comprehensive loss for the year	-	-	-	-	-		64	(16,269)	(2)	(16,207)
Balance, December 31, 2020	70,671,262	3,000,000	119,529	10,378	18,801		(386)	(182,136)	(14)	(33,828)
Balance, January 1, 2021	70,671,262	3,000,000	119,529	10,378	18,801		(386)	(182,136)	(14)	(33,828)
Services received at no charge – Note 17	-	-	-	150	-		-	-	-	150
Issuance of share capital on debt settlement	78,211,095	-	70,759	-	-		-	-	-	70,759
Issuance of share capital on conversion of preferred shares	3,336,345	(3,000,000)	3,000	-	-		-	-	-	3,000
Issuance of share capital upon initial public offering	41,668,716	-	37,723	-	-		-	-	-	37,723
Issuance of share capital for shares of Sinuwave Technologies Corporation	343,750	-	309	-	-		-	(323)	14	0
Issuance of share capital on exercise of stock options	1,231,131	-	5,682	-	(5,680)		-	-	-	2
Shares bought back into treasury	(877,775)	-	(799)	-	-		-	-	-	(799)
Share issuance costs	-	-	(1,167)	-	-		-	-	-	(1,167)
Share-based payments – Note 15	-	-	-	-	3,913		-	-	-	3,913
Total comprehensive loss for the year	-	-	-	-	-		(12)	(50,085)	-	(50,097)
Balance, December 31, 2021	194,584,524	-	\$ 235,037	\$ 10,528	\$ 17,034	\$	(398)	\$ (232,544)	\$ -	\$ 29,657





## **Consolidated Statements of Cash Flows**

(In thousands of Canadian dollars)

	Note	2021	2020
Cash flows from (used in) operating activities			
Net loss for the year		\$ (50,085)	\$ (16,271)
Adjustments for non-cash items:			
Depreciation and amortisation	7,8	514	1,220
Finance expense	10,11,17	1,199	491
Non-cash salary compensation	17	150	300
Share-based payments	15	3,913	8,152
Unrealised foreign exchange gain (loss)		90	(225)
Change in fair value of financial instruments	10	424	221
Government loan forgiveness	13	(518)	-
Loss on debt settlement	10,11,17	31,626	173
Other		16	41
Changes in non-cash working capital	22	131	(361)
Net cash used in operating activities		(12,540)	(6,259)
Cash flows from (used in) financing activities			
Loan proceeds from related parties	17	2,827	2,604
Loan repayments to related parties	17	(652)	-
Convertible loan notes proceeds	10	3,840	843
Convertible loan notes repayments	10	(30)	-
Interest paid		-	(72)
Payment of lease obligations	12	(256)	(259)
Government loans proceeds	13	414	638
Preference shares proceeds	11	-	3,000
Proceeds from issuance of common shares	14	37,727	-
Repurchase of common shares		(799)	-
Share issuance costs	14	(1,167)	-
Net cash from financing activities		41,904	6,754





## **Consolidated Statements of Cash Flows**

(In thousands of Canadian dollars)

	Note	2021	2020
Cash flows used in investing activities			
Purchase of property and equipment	7	(77)	(99)
Net cash used in investing activities		(77)	(99)
Effect of foreign exchange rate change on cash and cash equivalents		(45)	(76)
Net increase in cash and cash equivalents		\$ 29,242	\$ 320
Cash and cash equivalents, beginning of year		626	306
Cash and cash equivalents, end of year	24	\$ 29,868	\$ 626
Supplemental cash flow information	22		

## Cash and cash equivalents are comprised of:

		2021	2020
Cash		\$ 30,365	\$ 626
Cheques issued in excess of funds on deposit		(497)	-
Cash and cash equivalents, end of year	24	\$ 29,868	\$ 626



# Notes to the Consolidated Financial Statements

## Year ended December 31, 2021 and 2020

(In thousands of Canadian dollars, except as otherwise indicated)

#### 1. Nature of operations and liquidity risk

Ondine Biomedical Inc. (the "Company") was incorporated under the British Columbia Business Corporations Act on September 9, 1996. The Company is a biotechnology company engaged in the development and commercialisation of innovative anti-infective therapies covering a broad spectrum of bacterial, fungal and viral infections primarily using antimicrobial photodynamic therapy ("aPDT") as a platform technology for its products, which are used as an alternative to the use of antibiotics. The Company's aPDT products employ laser-based activation of proprietary compounds to treat a wide range of medical infections. The address of the Company's corporate office is 888-1100 Melville Street, Vancouver, BC, Canada. The common shares of the Company are listed on the AIM Market of the London Stock Exchange under the symbol "OBI.L" (Note 13).

In March 2020, the World Health Organization declared a global pandemic related to the coronavirus known as COVID-19. The expected impacts on global commerce are anticipated to be far reaching. To date the movement of people and goods has become restricted. Management is actively monitoring the situation and is taking appropriate steps as needed to ensure minimal disruption to the Company's operations. As a consequence, the Company has experienced delays in its Steriwave U.S. Food and Drug Administration ("FDA") Phase 2 clinical trials.

On December 6, 2021, the Company completed its initial public offering ("IPO"), in which the Company issued 41,668,716 common shares at £0.53 (\$0.90) per share for total gross proceeds net of the impact of foreign exchange recorded in the consolidated statements of loss and comprehensive loss of \$37,723.

The Company has a history of incurring significant losses and as at December 31, 2021, had an accumulated deficit of \$232,544 (2020 - \$182,136). Also, as at December 31, 2021, the Company had a cash and cash equivalents balance of \$29,868 (2020 - \$626) and a working capital of \$29,582 (2020 - negative \$34,038). In the year ended December 31, 2021, cash used in operations totaled \$12,540 (2020 - \$6,259).

The Company's ability to continue as a going concern is dependent on its ability to develop profitable operations and/or to continue to obtain the necessary financing to meet its corporate expenditures and discharge its liabilities in the normal course of business. Management believes the Company's cash and cash equivalents will provide sufficient liquidity to meet its working capital requirements for at least twelve months from December 31, 2021. The Company will need to raise funds through public or private equity and/or debt financing in 2023 and beyond to advance its operations. Although the Company has been successful in obtaining financing in the past, there can be no assurance that it will be able to obtain such financing in the future, or that such financing will be on terms advantageous to the Company, and it may be dilutive to shareholder interests.

#### 2. Basis of preparation

### (a) Statement of compliance

These consolidated financial statements have been presented in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB').

Certain comparative figures have been reclassified to conform to the current year's presentation. The reclassifications have no effect on the previously reported assets, liabilities and previously reported net loss for the year ended December 31, 2020.



The consolidated financial statements were approved and authorised for issue by the Board of Directors on May 16, 2022.

#### (b) Basis of measurement

The consolidated financial statements have been prepared on a going concern basis under the historical cost basis as stated in the accounting policies. The expenses within the consolidated statements of loss and comprehensive loss are presented by function. Refer to Note 21 for details of expenses by nature.

## (c) Functional and presentation currency

These consolidated financial statements are presented in Canadian dollars. The parent company's functional currency is Canadian dollars while the functional currency of the Company's subsidiaries are their respective local currencies, except Ondine International Holdings Ltd whose functional currency is United States dollars.

## (d) Use of estimates, assumptions and judgments

The preparation of consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the amounts reported in the consolidated financial statements and accompanying disclosures. Although these estimates are based on management's knowledge of current events and actions the Company may undertake in the future, actual results may differ from the estimates and the differences may be material.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates, if any, are recognised in the year in which the estimates are revised and in any future years affected. Significant judgments, estimates and assumptions used in applying the Company's accounting policies that have the most significant effects on the amounts in the consolidated financial statements are summarised below.

### **Significant judgments:**

#### Going concern

Management applied judgment in determining that there are no material uncertainties related to events or conditions that may cast significant doubt upon the entity's ability to continue as a going concern. The assessment of the Company's ability to continue as a going concern and to raise sufficient funds to pay for its ongoing corporate expenditures, discharge its liabilities for the ensuing year, and to fund planned development and commercialisation of its products, involves significant judgment based on historical experience and other factors including expectation of future events that are believed to be reasonable under the circumstances.

## Convertible financial instruments

Convertible loan notes are hybrid financial instruments which are accounted for separately by their components. The financial liability components have been initially measured at fair value and will subsequently be measured at amortised cost. The identification of convertible notes components is based on interpretations of the contractual arrangement and therefore requires judgment from management. The separation of the components affects the initial recognition of the convertible debenture at issuance and the subsequent recognition of interest. The determination of the fair value of the liability is also based on a number of assumptions, including contractual future cash flows, discount rates and the presence of any derivative financial instruments.



## Revenue recognition

Determining whether the goods are considered distinct performance obligations requires judgment. Management exercises judgment to evaluate these arrangements to determine whether the goods are considered distinct performance obligations that should be accounted for separately from each other. A good is distinct if the customer can benefit from it on its own or together with other readily available resources and the Company's promise to transfer the good is separately identifiable from other promises in the contract. Management has determined that the goods are distinct performance obligations. Where a contract consists of more than one performance obligation, revenue is allocated to each based on their standalone selling price.

#### **Estimates and assumptions:**

#### Provision for excess and obsolete inventory

A significant estimate for the Company is its allowance for excess and obsolete inventory. The allowance is based upon management's assessment of a variety of factors, including, among other things, expected selling prices, technological change, product obsolescence, regulatory clearance timeframes, and the demand for the Company's products in the market as compared to the number of units currently on hand.

#### Fair value of embedded derivatives

The Company is required to determine the fair value of embedded derivatives, such as the conversion features, separate from the convertible loan notes, and the Company is required to determine the classification of the embedded derivative as either a financial liability or an equity instrument. Fair values for embedded derivatives are determined using valuation techniques and require estimates of most likely conversion scenarios, per share fair value, redemption dates, and volatility at the balance sheet date as the financial instruments are not traded in an active market.

## Share-based payments

Share-based payment charges are determined using the Black-Scholes option pricing model ("Black-Scholes model") based on estimated fair values of all share-based awards at the date of grant and are expensed to the statement of loss and comprehensive loss over each awards' vesting period. The Black Scholes model utilises subjective assumptions such as expected fair value of shares, volatility, expected life of the options, risk free interest rate, forfeiture rates and applicable future performance conditions and exercise patterns.

Share-based compensation provided to a consultant takes into account the number of warrants expected to vest based on achieving different milestones in relation to regulatory approval. It is reasonably possible that future estimates of the actual outcome and timing may be different than assumptions used in the preparation of these consolidated financial statements and a material change in share-based compensation reflected in the consolidated statement of loss and comprehensive loss may occur.

### **Income taxes**

The Company's operations are conducted in multiple jurisdictions with complex tax laws and regulations that can require significant interpretation. As such is the case, the Company and the tax authorities could disagree on tax filing positions and any reassessment of the Company's filing positions could result in material adjustments to tax expense, taxes payable and deferred income taxes.





#### **Significant accounting policies**

The accounting policies below have been applied consistently by the Company and all of its subsidiaries.

#### (a) Basis of consolidation

The consolidated financial statements include the accounts of the Company and its principal subsidiaries:

Name	Place of incorporation	Functional currency	Percentage of ownership
Ondine Research Laboratories	Washington, United States	USD	100%
Ondine Biomedical U.S., Inc.	Washington, United States	USD	100%
Champion ENT Products, Inc.	Wyoming, United States	USD	100%
Advanced Photodynamic Technologies, Inc.	Minnesota, United States	USD	100%
Sinuwave Technologies Corporation	Nevada, United States	USD	99.96%
Ondine Biomedical Limited	United Kingdom	GBP	100%
Ondine International Holdings Ltd.	Barbados	USD	100%
Ondine Bio Inc.	Canada	CAD	100%

On October 24, 2021, the Company acquired 1,031,250 shares of Sinuwave Technologies Corporation in exchange for issuing 343,750 shares of the Company, which increased the Company's interest of Sinuwave Technologies Corporation to 99.96% (2020 - 98.20%). Due to the increase in the Company's ownership, the fair value of the consideration paid of \$309 and the cumulative balance in non-controlling interest of \$323 has been allocated to deficit.

Subsidiaries are entities controlled by the Company. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns though its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Intercompany balances and transactions are eliminated in the consolidated financial statements.

Non-controlling interests ("NCI") in the net assets of consolidated subsidiaries are identified separately from the Company's equity therein. NCI consists of the amount of those interests at the date of the original business combination and the non-controlling shareholder's share of changes in equity since the date of the combination. Losses applicable to the non-controlling shareholders in excess of the non-controlling shareholders' share of changes in equity are allocated to the non-controlling shareholders.

## (b) Foreign currency

The consolidated financial statements are presented in Canadian dollars.

#### Foreign currency transactions

Transactions in foreign currencies are translated to the respective functional currencies of the Company's subsidiaries at exchange rates as at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated to the functional currency at the exchange rates in effect at the reporting date. Non-monetary assets and liabilities that are measured at fair value in a foreign currency are translated to the functional currency at the exchange rate in effect when the fair value was determined. Foreign currency differences are generally recognised in net income/(loss). Non-monetary items that are





measured based on historical cost in a foreign currency are translated to the functional currency using the exchange rate in effect at the date of the transaction giving rise to the item.

#### Foreign operations

The assets and liabilities of foreign operations are translated to the presentation currency using exchange rates at the reporting date. The income and expenses of foreign operations are translated to the presentation currency using the monthly average exchange rates. Foreign currency differences are recognised in other comprehensive income/(loss).

#### (c) Cash

Cash includes cash on hand.

## (d) Inventory

Inventory cost includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories, cost includes an appropriate share of production under normal operating capacity.

Raw materials are recorded at the lower of cost, determined on a specific item basis, and replacement cost. Finished goods are recorded at the lower of weighted average cost and net realisable value. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs necessary to make the sale. The Company assesses the net realisable value of inventory at each reporting date.

## (e) Financial instruments

#### (i) Non-derivative financial assets

All financial assets are initially recorded at fair value and upon initial recognition are classified as; those to be measured subsequently at fair value (either through other comprehensive income ("FVOCI") or profit or loss ("FVTPL")) or those to be measured at amortised cost. The classification of financial assets is generally based on the business model in which a financial asset is managed and its contractual cash flow characteristics. Derivatives embedded in contracts where the host is a financial asset in the scope of the standard are never separated. Instead, the hybrid financial instrument as a whole is assessed for classification.

Financial assets classified as amortised cost are measured using the effective interest method less any allowance for impairment. The effective interest method is a method of calculating the amortised cost of a financial asset and of allocating interest income over the relevant period.

Financial assets classified as FVOCI are measured at fair value with unrealised gains and losses recognised in other comprehensive income (loss) except for losses in value that are considered other than temporary or a significant or prolonged decline in the fair value of that investment below its cost. Such losses are recorded in the consolidated statements of loss and comprehensive loss. The Company does not have any financial assets classified as FVOCI.

Transaction costs associated with FVTPL financial assets are expensed as incurred while transaction costs associated with all other financial assets are included in the initial carrying amount of the asset and amortised to profit or loss as part of the application of the effective interest method.

In accordance with IFRS 9, Financial Instruments ("IFRS 9"), all of the Company's financial assets, which consist primarily of cash and accounts receivable, are categorised at amortised cost.

#### (ii) Non-derivative financial liabilities

All financial liabilities are initially recorded at fair value and upon initial recognition are either designated as FVTPL or classified as amortised cost.





Financial liabilities classified as amortised cost are initially recognised at fair value less directly attributable transaction costs and, after initial recognition, are subsequently measured at amortised cost using the effective interest method. Financial liabilities designated as FVTPL include financial liabilities designated upon initial recognition as FVTPL. Derivatives are also classified as FVTPL unless they are designated as effective hedging instruments. Transaction costs on financial liabilities designated as FVTPL are expensed as incurred. Fair value changes on financial liabilities designated as FVTPL are recognised through profit or

#### (iii) Compound instruments

The component parts of compound instruments issued by the Company are classified separately as financial liabilities and equity in accordance with the substance of the contractual arrangement.

If the conversion feature meets the definition of equity, the fair value of the liability component is estimated at the date of issue of the instrument using the prevailing market interest rate for a similar non-convertible instrument. This amount is recorded as a liability on an amortised cost basis using the effective interest method until extinguished upon conversion or at the instrument's maturity date. The equity component is determined by deducting the amount of the liability component from the fair value of the compound instrument as a whole. This is recognised and included in equity, net of income tax effects, and is not subsequently remeasured.

If the conversion feature of a convertible loan note issued does not meet the definition of an equity instrument, it is classified as an embedded derivative and measured accordingly. The debt component of the instrument is determined by deducting the fair value of the equity conversion option at inception from the fair value of the consideration received for the instrument as a whole. This amount (the debt component) is recorded as a liability on an amortised cost basis using the effective interest rate method until extinguished upon conversion or at the instrument's maturity date.

## (iv) Embedded derivatives

Derivatives embedded in financial instruments or other host contracts are treated as separate derivatives when their risks and characteristics are not closely related to those of the host contracts and the host contracts are not measured at FVTPL.

#### (v) Derivative financial instruments

Derivatives are initially recognised at fair value at the date a derivative contract is entered into and are subsequently remeasured to their fair value at the end of the reporting date. The resulting gain or loss is recognised in profit or loss immediately.

## (vi) Derecognition of financial assets and liabilities

Financial assets are derecognised when the rights to receive cash flows from the assets expire or the financial assets are transferred and the Company has transferred substantially all the risks and rewards of ownership of the financial assets. On derecognition of a financial asset, the difference between the asset's carrying amount and the sum of the consideration received and receivable and the cumulative gain or loss that had been recognised directly in equity is recognised in profit or loss.

Financial liabilities are derecognised when the obligation specified in the relevant contract is discharged, cancelled or expired. The difference between the carrying amount of the financial liability derecognised and the consideration paid and payable is recognised in profit or loss.

#### (vii) Preferred shares

Preferred shares are financial instruments accounted for as either a financial liability or an equity instrument. As the preferred shares issued by the Company are redeemable by the holder, they have been assessed to be financial liabilities and have been initially measured at fair value and subsequently measured at amortised cost.





## (f) Property and equipment

Items of property and equipment are measured at historical cost less accumulated depreciation and accumulated impairment losses. Historical cost includes any expenditure that is directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in a manner intended by management. Gains and losses on the disposal of an item of property and equipment are determined by comparing the proceeds from disposal with the carrying amount of property and equipment.

Depreciation is calculated on a declining balance basis except for leasehold improvements, demonstration equipment and right of use assets which are on a straight-line basis over their useful lives and are generally recognised in profit or loss.

## Estimated useful lives of property and equipment are as follows:

Computer equipment	3 years
Laboratory and office equipment	3 years
Furniture and fixtures	5 years
Manufacturing equipment and tools	5 years
Demonstration equipment	5 years
Leasehold improvements	Term of lease
Right-of-use assets	Term of lease

Depreciation methods, useful lives and residual values are reviewed at the reporting date and adjusted as appropriate.

## (g) Intangible assets

Intangible assets consist of technology licenses, patents and trademarks and are recorded at cost less amortisation and accumulated impairment losses. Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortisation and accumulated impairment losses. Internally generated intangibles, excluding capitalised development costs, are not capitalised and the related expenditure is reflected in profit or loss in the year in which the expenditure is incurred.

The useful lives of intangible assets are assessed as either finite or indefinite. Intangible assets with finite lives are amortised over the estimated useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at the end of each reporting date.

Changes in the expected useful life or the expected pattern of consumption of future economic benefits embodied in the asset are considered to modify the amortisation period or method, as appropriate, and are treated as changes in accounting estimates. The amortisation expense on intangible assets with finite lives is recognised in profit or loss in the expense category that is consistent with the function of the intangible assets.

Intangible assets with indefinite useful lives are not amortised, however they are tested for impairment at each reporting date either individually or at the cash-generating unit level. The assessment of indefinite life is reviewed each reporting date to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.



Gains or losses arising from derecognition of an intangible asset are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognised in profit or loss when the asset is derecognised.

## (h) Impairment

## (i) Impairment of financial assets

An expected credit loss ("ECL") model applies to financial assets measured at amortised cost and debt investments at FVOCI, but not to investments in equity instruments. The Company's financial assets measured at amortised cost and subject to the ECL model consist primarily of accounts receivable.

The Company measures the loss allowance on accounts receivable at an amount equal to the lifetime ECL. To measure ECL on a collective basis, trade receivables are grouped based on similar credit risk and aging. The expected loss rates are based on the Company's historical credit losses experienced and are updated to reflect the effects of the current conditions and forecasts of future conditions that did not affect the period on which the historical data is based.

Accounts receivable are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to make contractual payments for a period of greater than 90 days past due.

#### (ii) Impairment of non-financial assets

Non-financial assets are subject to impairment tests whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. Where the carrying value of an asset exceeds its recoverable amount, which is the higher of value in use and fair value less costs of disposal, the asset is written down to its recoverable amount. An impairment loss is charged to profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but only so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset in prior years. A reversal of an impairment loss is recognised immediately in profit or loss.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows ("cash generating units" or "CGU"s). These are typically individual properties or projects.

## (i) Share capital

Financial instruments issued by the Company are treated as equity only to the extent that they do not meet the definition of a financial liability. Common shares are classified as equity instruments. Costs incurred to issue shares are deferred until the shares are issued, at which time these costs are charged against share capital.

## (i) Share-based payments

The Company grants stock options and warrants to employees, directors, officers and consultants pursuant to the stock option plan described in Note 15. The fair value method of accounting for share-based compensation transactions is used.

For graded vested share options, IFRS 2, Share-based Payment ("IFRS 2") requires the use of the attribution method, which requires that the Company treat each installment as a separate share option grant with a different fair value.

The fair value of share-based payments to non-employees is based on the fair value of the goods or services received, when these can be measured reliably. In the event that no reliable measurement can be made, the fair value of the options and warrants granted will be used.



#### (k) Income taxes

Income tax expense comprises current and deferred tax. Current tax and deferred tax are recognised in profit or loss except to the extent that it relates to items recognised directly in equity or in other comprehensive income (loss).

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years.

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date. Deferred tax assets and liabilities are offset if there is a legally enforceable right to offset current tax liabilities and assets, and they relate to income taxes levied by the same tax authority on the same taxable entity, or on different tax entities, but they intend to settle current tax liabilities and assets on a net basis or their tax assets and liabilities will be realised simultaneously.

A deferred tax asset is recognised for unused tax losses, tax credits and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilised. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realised.

#### (1) Provisions

Provisions are recognised if, as a result of a past event, the Company has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of resources will be required to settle the obligation. Provisions are determined by discounting the expected future cash outflows at a pretax rate that reflects current market assessments of the time value of money and the risks specific to the liability. Management uses judgment to estimate the amount, timing and probability of the liability based on facts known at the reporting date. The unwinding of the discount is recognised as a finance cost.

## (m) Revenue recognition

The Company generates revenues from sales of hardware and consumables. Hardware sales consist of lasers. Consumable sales consist of single use disposable treatment kits. Product revenues are derived primarily from standard direct order product sales. The Company has contracts with customers to deliver both lasers and consumables as part of a single arrangement.

Revenue is allocated to the respective performance obligation based on relative transaction prices and is recognised as goods are delivered to the customer. Revenue is measured as the amount of consideration expected to be received in exchange for the goods transferred.

Revenue from the sale of products in the normal course of activities is measured at the fair value of the consideration received or receivable, net of returns and trade discounts. The Company recognises revenue when customers obtain control of the product, which is when transfer of title of ownership of goods have passed and when there is a present right to payment. Invoices are generated and revenue is recognised at that point in time.

## (n) Government grants and subsidies

Government grants related to income are presented as part of profit or loss as incurred, either as other income or deducted from the related expense. A forgivable loan from the government is treated as a government grant when there is reasonable assurance that the entity will meet the terms for forgiveness of the loan. When the criteria for forgiveness has been satisfied and forgiveness can be reasonably assured, the loan balance is released to the consolidated statement of comprehensive income.



## (o) Research and development

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in the Company's consolidated statements of loss and comprehensive loss as incurred.

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditure is capitalised only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. The expenditure capitalised will include the cost of materials, direct labor and overhead costs that are directly attributable to preparing the asset for its intended use. Other development expenditures are expensed as incurred. Capitalised development expenditures will be measured at cost less accumulated amortisation and accumulated impairment losses.

To date, all of the research and development ("R&D") costs have been expensed as all of the criteria for capitalisation have not yet been met.

## (p) Finance income/(expense)

Finance income/(expense) comprises interest expense on convertible debentures, the accretion of the discount on the conversion of convertible debentures into common shares or other equity of the Company and the subsequent recovery of the discount.

## (q) Loss per share

Basic loss per share is calculated by dividing the loss for the year attributable to common shareholders by the weighted average number of shares outstanding during the year. Diluted earnings per share reflects the potential dilution of securities that could share in earnings of an entity. For years, where the issue of shares upon the exercise of stock options and/or warrants would be anti-dilutive, diluted loss per common share is the equivalent to basic loss per common share.

## **Accounts and other receivables**

	December 31, 2021	December 31, 2020
Trade receivables	\$ 158	\$ 536
Other receivables	90	7
	\$ 248	\$ 543

The following table reflects the loss allowance for trade receivables balance:

	Dece	ember 31, 2021		December 31, 2020
Gross carrying value	\$	1,022	\$	1,400
Expected credit loss allowance		(864)		(864)
Trade receivables - net	\$	158	\$	536



The following table reflects the movement in the allowance for expected credit losses balance:

	2021	2020
Opening balance, January 1	\$ 864	\$ 910
Additions to allowance	-	-
Receivables written-off	-	(46)
Closing balance, Dec 31	\$ 864	\$ 864

## 5. Inventory

	December 31, 2021	December 31, 2020
Raw materials	\$ 561	\$ 205
Finished goods	500	199
	\$ 1,061	\$ 404

During the year ended December 31, 2021, raw materials and finished goods included in cost of sales amounted to \$1,257 (2020 - \$940). During the year ended December 31, 2021 and 2020, inventory valued at \$3 and \$157, respectively was written off and reflected within cost of sales.

## 6. Prepaids and deposits, and non-current assets

	December 31, 2021	D	December 31, 2020		
Prepaid insurances	\$ 391	\$	28		
Deposits	35		35		
Other prepaid costs	1,439		146		
Other non-current assets	-		11		
	\$ 1,865	\$	220		
Less: Current portion of prepaid expenses and deposits	\$ 1,830	\$	174		
Other non-current assets	\$ 35	\$	46		





## 7. Property and equipment

The Company's property and equipment gross carrying amounts and accumulated depreciation were as follows:

	nputer pment	ture and fixtures	Lab office pment	Leas improve	sehold ments	eturing pment d tools	Demo oment	Right-	of-use	Total
Cost										_
Balance, January 1, 2020	\$ 380	\$ 250	\$ 367	\$	283	\$ 465	\$ 279	\$	820	\$ 2,844
Additions	7	-	36		-	56	122		-	221
Disposals	(178)	(25)	(11)		-	-	(23)		(47)	(284)
Exchange adjustment	(16)	-	(10)		(4)	(8)	-		(11)	(49)
Balance, December 31, 2020	\$ 193	\$ 225	\$ 382	\$	279	\$ 513	\$ 378	\$	762	\$ 2,732
Additions	21	-	-		-	57	20		178	276
Disposals, derecognition and other	-	-	-		-	-	(20)		(139)	(159)
Exchange adjustment	-	(1)	-		(1)	1	-		(4)	(5)
Balance, December 31, 2021	\$ 214	\$ 224	\$ 382	\$	278	\$ 571	\$ 378	\$	797	\$ 2,844
Accumulated depreciation										
Balance, January 1, 2020	\$ 307	\$ 225	\$ 353	\$	283	\$ 427	\$ 131	\$	269	\$ 1,995
Additions	18	4	10		-	11	45		260	348
Disposals, derecognition and other	(169)	(9)	(5)		-	-	(16)		(47)	(246)
Exchange adjustment	(5)	(1)	(8)		(4)	(5)			(13)	(36)
Balance, December 31, 2020	\$ 151	\$ 219	\$ 350	\$	279	\$ 433	\$ 160	\$	469	\$ 2,061
Additions	19	1	10		-	22	57		234	343
Disposals	-	-	-		-	-	(20)		(139)	(159)
Exchange adjustment	1	-	-		(1)	2	(4)		-	(2)
Balance, December 31, 2021	\$ 171	\$ 220	\$ 360	\$	278	\$ 457	\$ 193	\$	564	\$ 2,243
Net book value										
December 31, 2020	\$ 42	\$ 6	\$ 32	\$	-	\$ 80	\$ 218	\$	293	\$ 671
December 31, 2021	\$ 43	\$ 4	\$ 22	\$	-	\$ 114	\$ 185	\$	233	\$ 601

During the year-ended December 31, 2021, depreciation of \$55 (2020 – \$45) was allocated to cost of sales.



## 8. Intangible assets

The Company's intangible assets, gross carrying amounts and accumulated amortisation were as follows:

	L	icenses	Patents	Other	Total
Cost					
Balance, January 1, 2020	\$	387	\$ 2,107	\$ 691	\$ 3,185
Exchange adjustment		(7)	(42)	(13)	(62)
Balance, December 31, 2020	\$	380	\$ 2,065	\$ 678	\$ 3,123
Exchange adjustment		(2)	(9)	(3)	(14)
Balance, December 31, 2021	\$	378	\$ 2,056	\$ 675	\$ 3,109
Accumulated amortisation					
Balance, January 1, 2020	\$	387	\$ 1,343	\$ 441	\$ 2,171
Amortisation		-	658	214	872
Exchange adjustment		(7)	(65)	(19)	(91)
Balance, December 31, 2020	\$	380	\$ 1,936	\$ 636	\$ 2,952
Amortisation		-	129	42	171
Exchange adjustment		(2)	(9)	(3)	(14)
Balance, December 31, 2021	\$	378	\$ 2,056	\$ 675	\$ 3,109
Net book value					
December 31, 2020	\$	-	\$ 129	\$ 42	\$ 171
December 31, 2021	\$	-	\$ -	\$ -	\$ -

The remaining useful life of the intangible assets as at December 31, 2021 is nil (2020 – 3 months).

## 9. Accounts payable and other liabilities

	December 31, 2021	December 31, 2020		
Accounts payable	\$ 1,202	\$ 237		
Accrued liabilities	556	285		
Employee related payables	1,424	163		
Accrued interest	95	641		
Deferred revenue	-	86		
	\$ 3,277	\$ 1,412		



#### 10. Convertible loan notes

	 nvertible bentures	Embedded d comp convertible de	Total	
Balance, January 1, 2020	\$ 6,468	\$	-	\$ 6,468
Issued	844		156	1,000
Issuance costs	(22)		-	(22)
Principal repaid	(135)		-	(135)
Coupon interest expense	(38)		-	(38)
Accretion	165		-	165
Change in fair value of embedded derivative	-		221	221
Foreign exchange adjustment	(121)		-	(121)
Balance, December 31, 2020	\$ 7,161	\$	377	\$ 7,538
Issued	3,840		-	3,840
Extinguishment of existing convertible debenture due to debt amendment	(6,202)		-	(6,202)
Recognition of convertible debenture due to debt amendment	7,061		-	7,061
Principal repaid	(12,053)		-	(12,053)
Interest expense	101		-	101
Change in fair value of embedded derivative	-		424	424
Extinguishment of embedded derivative component	-		(801)	(801)
Foreign exchange adjustment	92		-	92
Balance, December 31, 2021	\$ -	\$	-	\$ -

#### **2021 Notes**

The Company issued United States dollars ("US\$") denominated convertible loan notes at various dates from September through October 2021 (the "2021 Notes") for cash proceeds totaling US\$3,050 (\$3,840).

The principal amount of the 2021 Notes plus all accrued unpaid interest were payable upon the 2021 Notes' maturity date, December 31, 2023. The 2021 Notes accrued interest at 6% per annum compounded annually from the date of issuance and for as long as the 2021 Notes qualified as outstanding.

The 2021 Notes automatically converted into common shares of the Company ("Common Shares") immediately prior to the Company's Initial Public Offering ("IPO") at a conversion price equal to a 45% discount to the IPO admission price per Common Share (the "Conversion Price").

The Company had the right to convert the 2021 Notes into Common Shares upon a private equity financing of the Company at a conversion price equal to a 45% discount of the Private Financing Price per Common Share.

On December 6, 2021, upon the Company's IPO, the aggregate principal balance of the 2021 Notes and accrued interest of \$3,994 were converted into 7,803,979 Common Shares of the Company at a conversion price of \$0.29 (\$0.50) per Common Share. Due to the lower conversion price offered to the note holders, there was a loss on extinguishment of \$3,076 recorded through net loss.

## **2020 Notes**

The Company issued convertible loan notes in May 2020 (the "2020 Notes") totaling \$1,000 for cash proceeds of \$250 from a related party, \$250 from the Company's CEO and of \$500 from an accredited



investor. Issue costs for the 2020 Notes totaled \$20 and have been netted against the principal amount of the debt.

The principal amount of the 2020 Notes plus all accrued unpaid interest will be payable upon the Notes maturity date, 18 months after issuance. The Company and Noteholder may mutually agree to extend the maturity date for an additional six months. If a Qualified Financing (as defined in the agreement) occurs prior to the maturity date, the amount due and payable shall be automatically converted into Financing Securities at a price per share equal to the lower of (a) 90% of the price of the Financing Securities or (b) a price per share that reflects a pre-money valuation prior to the Qualified Financing in the amount of the Valuation Cap (as defined in the agreement). If a financing that is not a Qualified Financing occurs prior to the maturity date, the Noteholder may elect to convert the amount due and payable into equity sold in the non-Qualified Financing at a price per share equal to the lower of (a) 90% of the price of the Financing Securities or (b) a price per share that reflects a pre-money valuation in the amount of the Valuation Cap (as defined in the agreement). If the Company completes either a sale of substantially all of its assets, merges or consolidates with another entity, change in control or liquidation, prior to conversion or repayment of the Notes, the Noteholders have the option to convert the Notes plus all accrued interest into shares of the Company or to receive cash payment for the amount outstanding.

The 2020 Notes accrued interest at 6% from the date of issue, until the earlier of the Notes maturity date or the date of a Redemption.

The 2020 Notes were classified as a financial liability with an embedded derivative, as the number of shares is not the same under all conversion scenarios. The embedded derivative was required to be carried separately at fair value. The fair value of the derivative at the date of grant was estimated with the Black-Scholes model, the estimation of the assumptions are as described in Note 20.

On December 6, 2021, upon the Company's IPO, the aggregate principal balance of the 2020 Notes and accrued interest of \$1,090 were converted into 1,186,481 Common Shares of the Company at a conversion price of \$0.92 per Common Share. There was a gain on extinguishment of \$817 recorded through net loss.

As at December 31, 2021, there was additional interest that was not settled at conversion of \$4 (December 31, 2020 – \$38) included in accounts payable and other liabilities.

#### **2017 Notes**

The Company issued United States dollars ("US\$") denominated convertible loan notes at various dates from July through November 2017 (the "2017 Notes") totaling US\$5,000 (\$6,345) as follows: i) for cash proceeds of US\$1,215 (\$1,562) from a related party; ii) as settlement of loans payable totaling US\$1,272 (\$1,590) with a related party; iii) as settlement of loans payable totaling US\$673 (\$841) with the controlling shareholder of the Company; and v) US\$1,840 (\$2,352) as partial consideration paid for the acquisition of intellectual property by a wholly-owned subsidiary. Issue costs for the 2017 Notes totaled \$45 and have been netted against the principal amount of the debt.

The 2017 Notes automatically converted into common shares of the Company ("Common Shares") immediately prior to the Company's Initial Public Offering ("IPO") at a conversion price equal to a 30% discount to the IPO admission price per Common Share (the "Conversion Price").

The principal amount of the 2017 Notes plus all accrued unpaid interest became payable upon the Notes Maturity Date, December 31, 2018. The 2017 Notes accrue interest: i) at 5% per annum compounded annually from the specific date of issue to the earlier of the first anniversary date thereafter or to the date of either a Redemption or Automatic Conversion event, and ii) at 10% per annum compounded annually from the anniversary date until the earlier of the Notes Maturity Date or the date of a Redemption. Interest was payable on May 31 and November 30 annually.

On September 22, 2021, the Company and the majority noteholders of the 2017 Notes executed an amendment to revise certain terms and conditions of the 2017 Notes in which the maturity date was



extended from December 31, 2018 to March 31, 2022. Management determined that this should be accounted for as a debt extinguishment and therefore a gain on extinguishment of \$28 was calculated from recognising the new liability at fair value was recorded through the consolidated statement of loss and comprehensive loss.

On December 6, 2021, upon the Company's IPO, the aggregate principal balance of the 2017 Notes and accrued interest of \$7,056 were converted into 10,998,598 Common Shares of the Company at a conversion price of £0.37 (\$0.63) per Common Share. Due to the lower conversion price, there was a loss on extinguishment of \$2,897 recorded through net loss.

As at December 31, 2021, there was additional interest that was not settled at conversion of US\$69 (\$88) (December 31, 2020 – US\$471 (\$600)) and included in accounts payable and other liabilities in which the majority of the Noteholders are either related or associated parties.

The 2017, 2020, and 2021 Notes are senior, unsecured, unsubordinated and unconditional obligations of the Company. Except as under limited conditions, payment obligations shall rank at least equally with all of the Company's other present and future senior, unsecured, unsubordinated and unconditional obligations.

## 11. Preferred shares

On July 24, 2020, 3,000,000 fixed-value preferred shares were issued to the controlling shareholder in consideration for a held for sale asset that was subsequently sold on July 31, 2020, for \$3,000. The preferred shares are redeemable and retractable at \$1 per share, have voting rights equivalent to one vote per share and are entitled to a non-cumulative dividend of 6%.

On December 6, 2021, upon the Company's IPO, the aggregate balance of the preferred shares of \$3,000 was settled by the issuance of 3,336,345 Common Shares of the Company at a fair value of £0.53 (\$0.90).

For the year ended December 31, 2021, there were \$135 of dividends declared (2020 - \$nil) included in accounts payable and other liabilities.

## 12. Lease obligations

	December 31, 2021	December 31, 2020
Current portion	\$ 148	\$ 225
Non-current	94	85
Total lease obligations	\$ 242	\$ 310

The Company's leases are for office space and a laboratory property. Interest expense on lease obligations for the year ended December 31, 2021 was \$13 (2020 - \$25). The expense relating to variable lease payments not included in the measurement of lease obligations was \$129 (2020 - \$132). This consists of variable lease payments for operating costs and property taxes. Total cash outflow for leases was \$381 (2020 - \$402), including \$243 (2020 - \$259) of principal payments on lease obligations.

As at December 31, 2021, the minimum annual payments under these leases, including an estimate of operational costs for its office premises based on current costs, is provided below.

2022	\$ 231
2023	113
Thereafter	74
	\$ 418



#### 13. Other long-term liabilities

Other long-term liabilities represent government guaranteed loans received. The balances of the government loans are as follows:

		December 31, 2021	December 31, 2020
Canadian Emergency Wage Subsidy	\$	60	\$ 40
Paycheck Protection Program	a	394	540
Other		13	13
Total other long-term liabilities	\$	467	\$ 593

## (a) Paycheck Protection Program

In 2020 and 2021, Ondine Research Laboratories, Inc. and Ondine Biomedical U.S., Inc., subsidiaries of the Company received an unsecured advance of US\$735 (\$932) under the Paycheck Protection Program ("PPP"), which is guaranteed by the Small Business Administration ("US SBA"), pursuant to the Coronavirus Aid, Relief and Economic Security Act. The loan bears interest at 1% per annum and is repayable, in blended payments, over a two year term. Subject to the satisfaction of certain conditions, the loan may be forgiven if the proceeds are used to fund qualifying expenditures such as payroll and benefits costs, rent, and utilities costs over an elected coverage period. In 2021, the Company filed a loan forgiveness application for the advance received in 2020, and the Company was granted full loan forgiveness by the US SBA in 2021 of US\$424 (\$518) (2020 - \$nil) and this portion of the loan balance was released to the consolidated statement of comprehensive income. As at December 31, 2021, the remaining loan balance was US\$311 (\$394). As at December 31, 2021, the loan of US\$311(\$394) (2020 - US\$424 (\$540)) was recorded as part of "other long-term liabilities" in the consolidated statement of financial position.

## 14. Share capital

#### (a) Common Stock

On December 6, 2021, the Company completed its initial public offering ("IPO"), in which the Company issued 41,668,716 common shares at £0.53 (\$0.90) per share for gross proceeds of \$37,502. As a result of changes in exchange rates from the date of the IPO to the dates of cash receipts, a foreign exchange gain of \$221 was recorded to the statement of loss and comprehensive loss on translation and settlement of the receivable, bringing the net cash received to \$37,723. The common shares of the Company are listed on the AIM Market of the London Stock Exchange under the symbol "OBI.L".

As part of the IPO, the Company received net cash proceeds of \$32,613, after commission costs of \$2,230, other expenses including disbursements of \$1,623, and prepayment of expenses of \$1,257.

The Company incurred accounting, legal, advisory, and disbursement costs of \$5,875 directly related to the completion of the IPO as of December 31, 2021. The costs incurred were allocated to the consolidated statements of loss and comprehensive loss and consolidated statement of financial position based on the percentage of newly issued common shares of the Company compared to the total number of issued and outstanding common shares of the Company. Of the costs incurred, \$4,708 has been recorded in general and administrative expenses for the year ended December 31, 2021. \$1,167 has been recorded in equity.

#### **Authorised**

An unlimited number of common shares without par value.

### Issued

As at December 31, 2021, the Company's issued share capital comprised of 194,584,524 common shares (2020 – 70,671,262).



## (b) Preferred Stock

#### **Authorised**

An unlimited number of fixed-value, voting, preferred shares, entitled to a non-cumulative dividend of 6% per annum, redeemable and retractable at \$1/share.

#### Issued

As at December 31, 2021, the Company's issued preferred share capital comprised of nil preferred shares (2020 – 3,000,000). During the year ended December 31, 2021, 3,000,000 preferred shares were converted to common shares as part of the initial public offering.

#### 15. Share-based payments

## (a) Stock Option Plan

On November 1, 2021, the Board of Directors approved and adopted an amended stock option plan for the Company which provides for the grant of stock options to directors, officers, employees and consultants from time to time at the discretion of the directors. Under the terms of the amended stock option plan, the maximum number of options authorised for issuance is 10% of the issued and outstanding common shares in any 10-year period for any Employee' share scheme and the maximum number of options authorised for issuance is 5% of the issued and outstanding common shares in any 10-year period for any executive share scheme. As at December 31, 2021, the maximum number of total options that can be outstanding are 19,458,452.

A summary of the status of the stock options outstanding is as follows:

	December 31, 2021 December 31, 2021		Decem	ber 31, 2020		
	Number of options	Weighted exerc	average ise price	Number of options	Weighted a exerci	average se price
Outstanding, beginning of year	9,203,356	\$	1.98	9,361,712	\$	1.87
Options granted	7,337,994		1.76	320,000		3.30
Options exercised	(2,328,356)		0.43	-		-
Options forfeited	(1,282,500)		1.77	(93,750)		2.70
Options cancelled	(6,097,494)		2.98	(384,606)		0.23
Outstanding, end of year	6,833,000	\$	1.42	9,203,356	\$	1.98
Exercisable, end of year	4,233,748	\$	1.33	3,529,606	\$	2.44

Share-based payments expense for the year ended December 31, 2021, in the amount of \$2,571 (2020 – \$3,471) was recorded.

The outstanding options for the year ended December 31, 2021 is as follows:

Exercise price	Number of options	Remaining life (years)
\$ 0.01	200,000	4.75
\$ 0.50	165,000	1.91
\$ 0.90	4,555,000	2.47
\$ 2.70	1,015,000	1.94
\$ 3.00	800,000	4.65
\$ 3.61	98,000	4.28
\$ 1.42	6,833,000	2.73



The fair value of stock options granted during the year were estimated with the Black-Scholes model using the following assumptions at the time of grant:

	Year ended December 31	
	2021	2020
Dividend yield	0%	0%
Annualised volatility	70% - 80%	70%
Risk-free interest rate	0.87% - 1.38%	0.45%
Expected life of options (years)	1.1 - 5.0	5.0
Forfeiture rate	15%	15%

Volatility was estimated by using the historical volatility of other companies that the Company considers comparable that have trading history and volatility history. The share price was estimated using previously completed transactions and future discounted cashflows. The expected life in years represents the period of time that options granted are expected to be outstanding. The risk-free interest rate is based on Canadian government benchmark bonds with a term equal to or a remaining term that approximates the expected life of the options.

The weighted average fair value of stock options granted during the year ended December 31, 2021, was \$0.56 per option (2020 - \$1.89). As at December 31, 2021, stock options outstanding had a remaining contractual life of 2.73 years (2020- 2.92 years).

## (b) Options issued under separate agreements

On December 15, 2020, the Company granted options entitling the holders to acquire common shares of the Company. A summary of the status of the options outstanding is as follows:

	December 31, 2021 Number of options	December 31, 2020 Number of options
Outstanding, beginning of year	13,036,024	-
Options granted	-	13,036,024
Options expired	(13,036,024)	-
Outstanding, end of year	-	13,036,024
Exercisable, end of year	-	13,036,024

The fair value of options granted during the year were estimated with the Black-Scholes model with the following assumptions: risk-free weighted-average interest of 0.25%, expected dividend yield of nil, average expected volatility of 62% and expected life term of 6 months.

The expense for the year ended December 31, 2021 was \$nil (2020 – \$4,246). The estimation of the assumptions is as described in Note 15(a).

As at December 31, 2021, options outstanding had a remaining contractual life of nil months (2020 – 5.5 months).



## (c) Warrants

On May 30, 2020, and December 23, 2020, the Company granted warrants entitling the holders to acquire common shares of the Company as consideration for ongoing consulting and advisory services. A summary of the status of the warrants outstanding is as follows:

	<b>December 31, 2021</b>			<b>December 31, 2020</b>		
	Number of warrants	Weighted exerc	average sise price	Number of warrants	Weighted exerc	average ise price
Outstanding, beginning of year	1,350,000	\$	2.33	-	\$	-
Warrants granted	1,945,845		0.92	1,350,000		2.33
Warrants cancelled	(500,000)		1.92	-		-
Outstanding, end of year	2,795,845	\$	1.42	1,350,000	\$	2.33
Exercisable, end of year	2,795,845	\$	1.42	850,000	\$	2.57

The fair value of warrants granted during the year were estimated with the Black-Scholes model using the following assumptions at the time of grant:

Year ended December 31,

	2021	2020
Annualised volatility	70% - 80%	70% - 80%
Risk-free interest rate	0.23% - 0.92%	0.23% - 0.28%
Expected life of options (years)	2-5	2-5
Forfeiture rate	0% - 15%	0%

The expense for the year ended December 31, 2021 was \$724 (2020 –\$434). As at December 31, 2021, warrants outstanding had a remaining contractual life of nil years (2020 – 2.80 years).

## (d) Shares to be issued for services provided

On December 15, 2020, the Company entered into an agreement to provide shares in exchange for services provided. As at December 31, 2021, the Company recognised a charge of \$618 (2020 - \$nil) to accrue for the share based payments.

#### 16. Income taxes

Income tax expense differs from the amount that would be computed by applying the federal and provincial statutory tax rates to the earnings before income taxes. A reconciliation to the effective tax is as follows:

Years ended December 31,

	2021	2020
Loss before income taxes	\$ (50,086)	\$ (16,271)
Statutory income tax rate	27%	27%
Income tax (recovery)	\$ (13,523)	\$ (4,393)
Non-deductible expenses	1,268	2,888
Tax rate differences	270	328
Other differences	(552)	(38)
Foreign exchange differences	(57)	(38)
Change in unrecognised deferred tax assets	12,594	1,253
Income tax (recovery)	\$ -	\$ -



Deferred income tax assets are only recognised to the extent that the realisation of tax loss carry-forwards is determined to be probable. As at December 31, 2021, the Company has not recognised any income tax assets.

Effective January 1, 2019, the Canadian federal and British Columbia provincial corporate tax rates are 15% and 12%, respectively. All deferred tax assets and liabilities are measured at the combined 27% tax rate. As a result of tax legislation enacted in the U.S. at the end of 2017, the federal U.S. corporate tax rate applicable to years subsequent to 2017 was substantially reduced.

The Company has unrecognised deferred tax assets and liabilities as follows:

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Tax losses carried forward	\$ 34,473	\$ 22,987
General Business Credit	1,608	2,059
Other	11	29
Share issue costs	1,277	2
Equipment and leasehold improvements	121	56
Intangible assets	481	478
Total deferred tax assets	37,971	25,611
Deferred tax liabilities:		
Fair value of financial instruments	(452)	(686)
Total deferred tax liabilities	(452)	(686)
Unrecognised deferred tax asset	(37,519)	(24,925)
Net deferred tax assets	\$ -	\$ -

The Company has non-capital loss carryforwards in Canada of \$82,398, in the United States of US\$34,606 (\$43,873), in Barbados of US\$6,853 (\$8,688) and in the United Kingdom of GBP£26 (\$45), all expiring between 2022 – 2040. The losses are available to reduce taxable income in Canada, the US, Barbados and UK respectively. As at December 31, 2021, the non-capital loss carryforwards that expire on December 31 of each respective year are as follows:

Expiry date	Amount
Pre-2031	\$ 35,614
2031	4,792
2032	6,333
2033	7,281
2034	6,791
2035	3,598
Thereafter until 2040	70,595
	\$ 135,004



#### 17. Related party transactions

## (a) Revenues, product shipments and expenses

	Year ended December 3		
	2021		2020
Product sales (i)	\$ -	\$	1
Consulting fee expense (ii)	\$ -	\$	31

- (i) Product sales for the year ended December 31, 2020 were to a related company. The revenue associated with product shipments was not recognised due to revenue recognition conditions not being met, and the cost of the product shipped to a related company was included in cost of goods sold. The revenue associated with product shipments will be recognised in a subsequent year(s) upon invoice payment. For the year-ended December 31, 2021, there was \$16 (2020 \$32) of products shipped to a related party company for which revenue was not recognised.
- (ii) Expenses incurred for consulting services provided by companies under the control of an officer and a related party to an officer of the Company.

## (b) Compensation of key management personnel

The Company's key management personnel have the authority and responsibility for planning, directing and controlling activities of the Company and consists of the Company's executive officers and directors.

Year ended December 31,

	2021	2020
Compensation and other short-term benefits	\$ 1,852	\$ 1,435
Directors' fees	179	166
Share-based payments	1,950	1,416
	\$ 3,981	\$ 3,017

The CEO and controlling shareholder of the Company provided her services to the Company without salary compensation, thereby waiving her right to receive a monthly salary as set out in her employment contract for the six months ended June 30, 2021. For December 31, 2021 year-end reporting purposes, and included above, a notional expense of \$150 (2020 – \$300) has been recorded to 'contributed surplus' in the consolidated statements of loss and comprehensive loss and charged to reserves in the consolidated statements of changes in equity. The cumulative notional expense is \$10,528 (2020 - \$10,378). During the year ended December 31, 2021, the CEO and controlling shareholder of the Company had her salary compensation reinstated per the employment contract and no notional expense was recorded subsequent to June 30, 2021.

During the year-ended December 31, 2021, key management personnel exercised 1,403,356 stock options for common shares (2020 – nil), and the Company repurchased 466,665 common shares from key management at fair value for \$426 (2020 – nil).

## (c) Related party balances

	December 31, 2021		December 31, 2020	
Loans payable to related parties	\$	-	\$	23,610
Included in accounts payable and other liabilities	\$	1,015	\$	_

Loans payable to related parties are due to the personal holding company of the Company's controlling shareholder. The loans payable to related parties are unsecured. No amount payable was in respect of services provided.



On November 19, 2021, the Company and the lenders entered into a repayment agreement in which the aggregate balance of the loan of US\$20,546 (\$25,682) and accrued interest of US\$395 (\$494) will be repaid by the Company issuing Common Shares at a conversion price of US\$0.36 (\$0.45).

On December 6, 2021, upon the Company's IPO, the aggregate balance including accrued interest of US\$20,941 (\$26,176) was converted into Common Shares of the Company. Due to the lower conversion price, there was a loss on extinguishment of \$26,498 recorded through net loss.

#### 18. Commitments and contingencies

Open purchase order commitments as at December 31, 2021 were \$1,508 (2020 – \$1,330) for the purchase of inventory and contracted development and clinical services.

The Company has the following contingencies at December 31, 2021:

- (i) The Company's Barbadian subsidiary holds intellectual property in Barbados. As a result of the Barbados Companies (Economic Substance) Act passed in 2019, the Barbadian subsidiary must comply with economic substance requirements set out in the legislation. If the Barbadian subsidiary cannot establish economic substance in Barbados, the Barbadian subsidiary could be subject to additional financial penalties and/or could be struck from the register of companies. Any of the foregoing could have a material impact on the financial position and operating results of the Company.
- (ii) The Company and certain of its affiliates have also been named as defendants in certain legal actions in the normal course of business, none of which management believes singularly or cumulatively, will have a material impact on the results of operations and financial position of the Company.

#### 19. Segmented information

Management has determined that the Company has one reportable operating segment, aPDT products. This segment accounts for all of the Company's revenue, cost of sales and operating expenses. Determination of the operating segment was based on the level of financial reporting to the Company's chief operating decision makers. Revenues are attributed to the geographic area where the customer is located.

	Year ended December 3		
	2021		2020
Product revenue			
Canada	\$ 2,501	\$	1,754
Other	68		37
	\$ 2,569	\$	1,791

Revenue from significant customers are as follows:

	Year ended Decembe		
	2021		2020
Customer 1	\$ 1,128	\$	1,251
Customer 2	727		-
Customer 3	422		274
Other	292		266
	\$ 2,569	\$	1,791



A summary of non-current assets (excluding other assets) by geographical area based on the location of the asset is as follows:

	December 31, 2021	Dece	ember 31, 2020
Canada	\$ 353	\$	273
United States	248		569
	\$ 601	\$	842

#### 20. Financial risk management and financial instruments

#### (a) Fair value of financial instruments

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 Unadjusted quoted market prices in active markets for identical assets or liabilities;

**Level 2** Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable; and

**Level 3** Valuation techniques for which the lowest level input that is significant to the fair value measurement is not based on observable market data.

As at December 31, 2021, the carrying values of cash, cheques issued in excess of funds in deposit, accounts and other receivables, bank indebtedness, and accounts payable and other liabilities approximate their fair values because of their nature, relatively short maturity dates.

## (b) Management of risks arising from financial instruments

The overall responsibility for the establishment and oversight of the Company's risk management policies resides with the Board of Directors. The Company's risk management policies are established to identify, analyse and manage the risks faced by the Company and to implement appropriate procedures to monitor risks and adherence to established controls. Risk management policies and systems are reviewed periodically in response to the Company's activities and to ensure applicability. The Company, through its financial assets and liabilities, is exposed to certain risks as follows:

## **Credit risk**

The Company is exposed to credit risk arising from the possibility that cash held, receivables and amounts due from related parties are non-recoverable. However, the Company believes that its exposure to credit risk in relation to the cash and receivables is low. All of the cash held by the Company and its subsidiaries was held with reputable financial institutions. The Company has evaluated accounts receivable and determined an expected credit loss allowance of \$864 for the year ended December 31, 2021 (2020 – \$864). During the year ended December 31, 2021, the Company recorded a bad debt expense of \$nil (2020– \$nil).

### Foreign currency risk

The results of the Company's operations are subject to currency transaction and translation risks. The fair value of future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Company operates in Canada, the United States and the United Kingdom and is exposed to foreign exchange risk due to fluctuations in the US\$ and GBP against the Canadian dollar. Foreign exchange risk arises from financial assets and liabilities denominated in currencies other than the functional currency of the respective entities. The Company's primary risk is associated with fluctuations between the US\$ and Canadian dollar, and the GBP and Canadian dollar.



The Company has determined that the effect of a 10% increase or decrease in the US\$ and GBP against the Canadian dollar on net financial assets and liabilities, as at December 31, 2021, including cash, cheques issued in excess of funds in deposit, accounts receivables, accounts payable and other liabilities denominated in US\$ and GBP, would result in an increase or decrease of approximately \$2,811 (2020 – \$702) in the consolidated statements of loss and comprehensive loss for the year ended December 31, 2021.

#### Interest rate risk

Interest rate risk is the risk that the fair values and future cash flows of the Company will fluctuate because of changes in market interest rates. The Company was not exposed to fluctuations in interest rates during the years presented as the interest rate on the Company's convertible loan notes and preferred shares is fixed. The Company did not incur or have any other interest-bearing assets or liabilities.

## Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its obligations as they fall due. The Company ensures that there is sufficient liquidity to meet its short-term business requirements, taking into account its anticipated cash flows from operations and its holdings of cash. The Company's principal sources of liquidity are cash provided by operations, including advance payments from customers, related party loans, debt and equity issuances. The Company projects and monitors its cash requirements to accommodate changes in liquidity needs.

In addition to the commitments in Note 9 and Note 18, the Company has the following contractual financial liabilities as at December 31, 2021:

	Carrying amount	Contractual cash flows	Less than one year	More than one year
Financial liabilities				
Cheques issued in excess of funds in deposit	\$ 497	\$ 497	\$ 497	\$ -
Accounts payable and other liabilities	3,277	3,277	3,277	-
Other long-term liabilities	467	467	-	467
	\$ 4,241	\$ 4,241	\$ 3,774	\$ 467

## 21. Expenses by nature

Cost of goods sold and operating expenses are comprised of the following expenses by nature:

		_	
Year	ended	Decem	ber 31.

	20	2020
Salaries and benefits	\$ 8,	<b>218</b> \$ 7,911
Consulting and professional fees	8,	<b>199</b> 6,118
Office and laboratory supplies	1,3	1,034
Travel	3	<b>332</b> 120
Materials consumed	1,3	<b>378</b> 1,097
Variable lease payment – Note 12		132
Depreciation and amortisation	!	<b>513</b> 1,220
Licensing		<b>13</b> 30
	\$ 20,0	<b>989</b> \$ 17,662



#### 22. Supplementary cash flow information

	Year ended December 3		
	2021		2020
Changes in non-cash working capital items			
Accounts and other receivables	\$ 296	\$	(520)
Due from related parties	-		14
Inventory	(673)		86
Prepaid expenses and deposits	(1,656)		2
Accounts payable and other liabilities	2,153		257
Deposit payable	-		(200)
Other long-term liabilities	11		_
	\$ 131	\$	(361)

## 23. Ultimate controlling party

The Company's CEO is the ultimate controlling party of the Company, personally owning and/or controlling through her personal holding company a total of 55.7% of the issued common shares of the Company as at December 31, 2021 (2020 – 72.6%).

## 24. Capital management

The Company's objectives when managing capital are to ensure sufficient liquidity for operations and adequate funding for growth and capital expenditures while maintaining an efficient balance between debt and equity. The capital structure of the Company consists of credit facilities and shareholders' equity.

The Company's capital is comprised of the following:

		_		
Year	ended	Decem	her 31	ı

	2021	2020
Total indebtedness <sup>1</sup>	709	35,051
Less: Cash and cash equivalents <sup>2</sup>	29,868	626
Net debt	30,577	35,677
Shareholders' equity	28,252	(33,814)
	58,829	1,863

Indebtedness includes convertible loan notes, government loans, lease liabilities, loans payable to related parties and preferred shares <sup>2</sup> Cash and cash equivalents includes cash net of cheques issued in excess of funds on deposit

In order to facilitate the management of capital, the Company prepares annual expenditure budgets that are updated as necessary and dependent on various factors, including successful deployment of capital and industry conditions. The annual budgets are approved by the Board of Directors. The Company is not subject to any externally imposed capital requirements.

Management believes that existing cash resources, together with cash generated through operations, will generate sufficient liquidity to meet operating cash requirements for at least the next twelve months.



#### 25. Subsequent events

Subsequent to December 31, 2021, the following transactions have occurred:

- 1. On February 17, 2022, the Company granted 1,160,000 stock options to its employees at an exercise price of £0.54, in accordance with the Company's stock option plan. The stock options are exercisable for a period of 5 years and must meet certain vesting criteria.
- 2. On February 17, 2022, the Company cancelled 950,000 stock options formerly granted to its consultants.
- 3. On February 17, 2022, the Company granted 950,000 stock options to its consultants at an exercise price of £0.54, in accordance with the Company's stock option plan. The stock options are exercisable for a period of 5 years and must meet certain vesting criteria.
- 4. On March 18, 2022, the Company signed a lease extension for its office and manufacturing facility in Bothell, Washington, United States. The term is for 3 years with a tenant option to renew for an additional 2 years. The minimum lease payments for base rent are US\$517.
- 5. On April 8, 2022, the Company entered into a data subscription agreement with Definitive Healthcare, LLC.
- 6. On April 26, 2022, further to the announcements by Arden Partners plc on April 11 and 14, 2022, regarding the loss of its nominated adviser status upon the completion of its recommended takeover, the Company has appointed Strand Hanson Limited as its nominated adviser and financial adviser. Arden Partners plc will continue to act as Broker to the Company.



# **Glossary**

AIM	Alternative Investment Market
AMR	Antimicrobial Resistance
CDC	Centers for Disease Control and Prevention
Ex vivo	Experimentation or measurements done in or on tissue from an organism in an external environment
In vitro	Performed or taking place in a test tube, culture dish, or elsewhere outside a living organism
FCF	Free Cash Flow; cash used in operating activities less cash used to invest in capital assets
FDA	US Food and Drug Administration
HAI	Healthcare Associated Infection
HCA	HCA Healthcare, the largest privately owned hospital group in North America
MDSAP	Medical Device Single Audit Program
NRC	National Research Council of Canada
QIDP	Qualified Infectious Disease Product
SSI	Surgical Site Infection
VGH	Vancouver General Hospital
WHO	World Health Organization



## **Shareholder Information**

# Company Secretary

## Registered Office

Mr. Nikita Parkhaev

Ondine Biomedical Inc. 888 – 1100 Melville Street, Vancouver, British Columbia V6E 4A6

## Company Number BC0526736

#### Website

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#### **Nominated Adviser**

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## **Solicitors to the Company**

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Dentons US LLP (as to US law) 1900 K Street, NW Washington, DC 2006 United States

Dentons Delany (as to Barbadian law) Burnham Court, Bishop's Court Hill, Upper Collymore Rock, St. Michael, Barbados

#### Broker

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## Patent Attorney to the Company

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## **Reporting Accountant**

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## **Auditor to the Company**

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