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**ONDINE BIOMEDICAL INC.**  
("Ondine Biomedical", "Ondine" or the "Company")

### **Topline Results Significant in Steriwave ICU Study**

#### **Steriwave Shows Significant Sustained ICU Pathogen Reduction in Royal Columbian Hospital Study Reinforcing Universal Nasal Decolonisation for Infection Control**

- Steriwave nasal decolonisation study proves pathogen reduction in ICU setting
- ICU market represents a multi billion-dollar opportunity for Ondine
- Nasal decolonisation is already Standard of Care in the USA using topical antibiotics
- ICU-acquired infections affect 12-13% of critical care patients, dramatically increasing mortality risk and adding significant costs from added length of stay

Ondine Biomedical Inc. (AIM: OBI) is pleased to announce that preliminary results from the Steriwave ICU Pilot Study at Royal Columbian Hospital (RCH) demonstrate that Steriwave<sup>®</sup> nasal photodisinfection, a non-antibiotic, topical and fast acting broad spectrum antimicrobial, significantly reduces harmful pathogens in critically ill Intensive Care Unit (ICU) patients. There was a significant reduction in nasal bacterial load over the course of the study ( $p < 0.05$ ) in the Steriwave group, but not in the control group. By day 8, the share of swabs positive for non-respiratory flora (opportunistic) pathogens was 22.4% (control) vs 4.5% (treatment), an 80% relative risk reduction in colonisation. This 4-fold colonisation reduction compared to controls is an impressively strong result in the ICU setting.

**Dr. Elizabeth Rohrs, RCH principal investigator and RCH Foundation Research Director, said:**

*"Preliminary results from the Steriwave ICU pilot study reinforce the potential of Steriwave as a practical, non-antibiotic infection-prevention tool in the ICU where reducing multidrug-resistant pathogens can save lives, shorten ICU stays, and significantly reduce healthcare costs. Reducing airway pathogens in vulnerable ICU patients can help lower high ICU infection and mortality rates. Gram-negative Pseudomonas aeruginosa is particularly concerning because of its multidrug resistance and its role in many hospital-acquired infections."*

#### **Study Design**

The crossover ICU study, the first photodisinfection study of its kind, was carried out with 249 critically ill patients who were resident for at least 48 hours. In the treatment arm, researchers applied Steriwave treatments to all ICU study participants every second day and took microbial assessments every fourth day to monitor treatment efficacy and pathogen dynamics. This pragmatic design ensured that all patients were decolonized in the treatment phase, reducing bioburden at the hospital unit level and thereby minimizing the potential for cross-contamination between patients.

#### **Study Findings**

Key findings showed that by Day 8 there was an absolute risk reduction in the carriage of pathogenic bacteria of 17.9% (from 22.4% to 4.5%), a 4-fold reduction compared to controls. These large absolute reductions over the controls, expanding over the course of the study, are consistent with strong on-target effect indicating efficacy of the treatment. Detailed assessments of carriage microflora showed a significant reduction in nasal bioburden (all species) in treated patients compared to controls, with 69% of swabs (treatment) showing no growth at day 8 compared to 26% (control) ( $p < 0.05$ ).

Overall results demonstrate strong on-target effect, with statistically significant outcomes on microbial load over time, faster bioburden reduction, and higher within-patient clearance in the treatment arm versus control. Access to patients proved slightly more limited than patients in the presurgical environment, with 70% of all planned decolonisation events completed mostly due to deferrals for patient instability or airway devices. Meticulous microbial surveillance was conducted in these patients, with over 97% compliance rate (of 797 planned swabs, only 18 were missed). Both treatment and control groups were broadly comparable at baseline, with no significant differences between treatment and control arms in age, ICU length of stay, mortality, Sequential Organ Failure Assessment score, gender, baseline community-acquired pneumonia / hospital-acquired pneumonia scores, and baseline blood-culture positivity. Overall, the study showed notable benefits for the treatment group: lower microbial loads, quicker reductions in bioburden, and higher rates of patient-level clearance compared with controls. No product related significant adverse events were noted, and the treatment was well tolerated.

The trial's success in demonstrating clinical non-antibiotic antimicrobial efficacy is particularly timely and relevant for healthcare systems across the globe. Antibiotic resistance is soaring, a crisis highlighted by the recent [WHO Global Antibiotic Resistance Surveillance Report 2025](#). This report found that a concerning one in six lab-confirmed bacterial infections worldwide was resistant to antibiotic treatment. Study results are particularly important given that mupirocin-an antibiotic derived from *Pseudomonas* bacteria-is often used for nasal decolonisation, causing rising levels of resistance (up to 63% of MRSA in some settings). By contrast, Steriwave photodisinfection kills microbes via a free-radical process, with no known resistance development. This offers a stewardship-friendly path to suppress *S. aureus*/MRSA carriage without adding antibiotic pressure.

**Dr. Steven Reynolds, Executive Lead of the Advancing Innovations in Medicine (AIM) Institute, Associate Professor at Simon Fraser University and specialist in Infectious Diseases and Critical Care, stated:**

*"This single-center study was powered to detect microbial rather than clinical outcomes, an important finding because reducing a patient's bioburden remains a critical step in preventing ICU infections. The absence of known resistance to Steriwave, and its lack of contribution to further antimicrobial resistance, make it an appealing alternative to mupirocin. It's encouraging to see a potential new option for infection prevention that aligns with the principles of antimicrobial stewardship."*

**Carolyn Cross, CEO of Ondine Biomedical Inc commented:**

*"We would like to extend our sincere appreciation to RCH Foundation's Advancing Innovation in Medicine (AIM) Fund and to its commitment to advancing clinical innovation in Canada. Its vital support has been instrumental in enabling us to undertake this significant study within the Intensive Care Unit (ICU)."*

*We would also like to express our profound gratitude to Dr. Steven Reynolds, Dr. Elizabeth Rohrs, Jessica Wittman, and the exceptional RCH research team for their efforts and professionalism, as well as to the RCH ICU nurses for*

*their invaluable support throughout Steriwave's first ICU study. Their collective work sets a new standard for translational infection-control, conclusively demonstrating the utility of a rapid, point-of-care decolonisation method which eliminates all pathogens, not just Gram-positive species like MRSA. Reducing bioburden has been proven to reduce the rate of ICU infections, which in turn reduces mortality rates, antibiotic use and length of stay, thereby freeing up more capacity in overcrowded ICUs. We cannot thank Drs. Reynolds, Rohrs and colleagues enough for the perseverance and innovative spirit that powered Steriwave's first ICU study from concept to clinic.*

## **Infection Control in Critical Care**

Intensive Care Unit-acquired infections represent a critical challenge for healthcare systems, significantly raising both patient mortality risk and the cost of care. Infection control in critical care requires a comprehensive strategy, as patients are frequently immunocompromised and highly vulnerable to numerous ICU pathogens. These patients face increased risk of infection from various environmental and procedural factors present in ICU. Studies demonstrate that when a patient acquires an infection in the ICU, their risk of death rises markedly, and an infection can add an additional 7-14 extra days to an ICU patient's length of stay.

Respiratory infections, in particular, remain a major cause of morbidity and mortality in critical care settings. Many of these infections are caused by complex, multidrug-resistant bacteria such as *MRSA* and resistant Gram-negative bacilli including *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, and *Acinetobacter baumannii*, which are not effectively addressed by topical antibiotics. ICU infection-prevention should prioritize Gram-negative bacteria, which represent more than 50-70% of bacterial isolates and are responsible for the majority of ICU pneumonia cases and significantly contribute to ICU mortality rates. The increasing prevalence of such bacteria and rapid rise of antimicrobial resistance underscores the need for innovative, broad-spectrum solutions such as Steriwave.

## **About Steriwave® and its Mode of Action**

Steriwave nasal photodisinfection is a non-invasive and painless treatment that uses a proprietary light-activated photosensitive agent to destroy harmful bacteria, viruses, and fungi-including antibiotic-resistant strains-in the nasal passages. The procedure takes five minutes and, unlike antibiotics, is effective immediately and allows the normal nasal microbiome to recover quickly, without fostering antimicrobial resistance.

The two-step process involves applying the Steriwave formulation in the nostrils where it electrostatically binds to microbes rather than human cells. The area is then illuminated with safe red light to activate the formulation, triggering an oxidative burst that physically destroys all manner of pathogens within minutes. This rapid and overwhelming oxidative stress makes it extremely difficult for pathogens to develop resistance even across repeated applications. Steriwave is already being successfully used in hospitals across Canada and in the UK to decolonise the nose - a major pathogen reservoir - prior to surgery to reduce surgical site infections.

## **About the Royal Columbian Hospital, Royal Columbian Hospital Foundation (RCHF) and Advancing Innovation in Medicine (AIM)**

Royal Columbian Hospital (RCH) is a large tertiary care hospital in Fraser Health, one of Canada's largest health authorities. It has a legacy of care since 1862 and serves more than 2.2 million people with unparalleled expertise in cardiac, trauma, neurosciences, and high-risk maternity as a provincial referral centre, making it a vital lifeline for critical medical needs in British Columbia, Canada.

The hospital's foundation, a non-profit organization that supports RCH through public donations, is the largest external funder of research and innovation at RCH. Advancing Innovation in Medicine (AIM) is the research and innovation division of the Royal Columbian Hospital Foundation. AIM is dedicated to pioneering innovative clinical solutions that enhance patient outcomes, improve healthcare productivity, and create global impact through strategic partnerships. Find out more: [www.rchfoundation.com/aiminstitute](http://www.rchfoundation.com/aiminstitute)

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## **About Ondine Biomedical Inc.**

Ondine Biomedical Inc. is a Canadian life sciences company and leader in light-activated antimicrobial therapies ('photodisinfection') for the prevention and treatment of infections, including those caused by multidrug-resistant organisms. Ondine has a pipeline of investigational products, based on its proprietary photodisinfection technology, in various stages of development.

Ondine's nasal photodisinfection system is CE-marked in Europe and is approved for nasal decolonisation in Canada, UK, Australia, Mexico, and several other countries under the name Steriwave®. In the US, it has been granted Qualified Infectious Disease Product designation and Fast Track status by the FDA and is currently undergoing clinical trials for regulatory approval. Products beyond nasal photodisinfection include therapies for a variety of medical indications such as chronic sinusitis, ventilator-associated pneumonia, burns and other indications.

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