

ONDINE BIOMEDICAL INC.

("Ondine Biomedical", "Ondine", or the "Company")

Innovative light-activated antimicrobial treatment has potential to become first FDA-approved nasal decolonization treatment for prevention of surgical site infections

- Ondine's light-activated antimicrobial therapy for nasal decolonization would apply to more than 35 million major surgical procedures in the USA annually.
- Surgical site infections ("SSIs") account for 20% of all hospital-associated infections ("HAIs") and are linked with up to an 11-fold increase in the risk of mortality, with 75% of SSI-associated deaths directly attributable to the infection itself.^[1]
- HAI costs represent 6% of public sector health budgets in the EU.^[2] Significant SSI reductions would have immediate cost-saving benefits, reduce surgical waitlists, and provide better patient outcomes.

Ondine's innovative light-activated antimicrobial treatment has the potential to become the first FDA-approved nasal decolonization treatment for the prevention of surgical site infections. The treatment is presently undergoing a pivotal phase 3 trial (LANTERN) in US hospitals.

The most commonly used approach to combat *Staphylococcus aureus* in the nose is off-label use of the topical antibiotic mupirocin. However, mupirocin is associated with poor patient compliance due to its demanding regimen - patients are required to apply an oily compound into each nostril twice a day for 5 days prior to surgery. Difficulty with use has led to compliance rates as low as 39% in major studies, (which was demonstrated in the STOP-SSI study), and because the agent is an antibiotic, resistance rates as high as 81%.^[3]

Ondine intends to replace mupirocin and other nasal agents with a single 5-minute light based antimicrobial treatment just prior to surgery. In addition to rapid decolonization, which eliminates the requirement for at-home compliance with a 5-day regimen, Steriwave is effective against the numerous pathogens which inhabit the nose - fungi, viruses and bacteria (including Gram-negative bacteria). Administered by a healthcare professional prior to surgery, the process involves applying a proprietary photosensitive agent to each nostril with a swab, followed by exposure to a specific wavelength of red light. The light activates the photosensitive agent, triggering an oxidative burst that eradicates pathogens in a single treatment.

Dr Simon Sinclair, Ondine's Chief Medical Officer, commented:

"We have successfully treated over 200,000 patients in Canada and the UK, and as Steriwave kills more pathogens than just S. aureus, both patients and clinicians have embraced the added protection Steriwave provides against infection risks. Patients appreciate the reassurance of enhanced safety, while clinicians value having a fast, easy-to-implement solution to help prevent potentially devastating post-surgical infections. By seamlessly integrating into nursing workflows, Steriwave gives surgeons confidence that nasal decolonization has been achieved, significantly lowering the risk of surgical site infections."

There is a large unmet need for rapid, broad-spectrum nasal decolonization without contributing to antimicrobial resistance. According to the Centers for Disease Control and Prevention (CDC), surgical site infections remain a significant cause of morbidity, prolonged hospitalization, and mortality in the United States. SSIs account for 20% of all HAIs and are associated with a 2- to 11-fold increase in mortality, with 75% of SSI-related deaths directly attributed to the infection.¹ Moreover, SSIs are the most expensive type of HAI, costing the healthcare system an estimated US 3.3 billion annually, extending hospital stays by an average of 9.7 days, and increasing hospitalization costs by more than US 20,000 per admission.¹

Ondine's nasal photodisinfection has been in use in Canadian hospitals for the past ten years and is now being used in several UK NHS Trusts. Recently, Ondine announced its partnership with Mölnlycke Health Care, a global leader in

MedTech specialising in wound care and surgical solutions, to distribute its technology across the UK, EU, and Middle East markets.

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About Ondine Biomedical Inc.

Ondine Biomedical Inc. is a Canadian life sciences company and leader in light-activated antimicrobial therapies (also known as 'photo disinfection'). Based on its proprietary photo disinfection technology, Ondine has a pipeline of investigational products in various stages of development.

Ondine's nasal photodisinfection system has a CE mark in Europe and is approved in Canada 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.

[1] Centers for Disease Control and Prevention. Surgical Site Infection (SSI) Event. National Healthcare Safety Network (NHSN), n.d. ([link](#))

[2] Healthcare expenditure and financing. OECD.Stat. Accessed March 20, 2023.

[3] Poovelikunnel T, Gethin G, Humphreys H. Mupirocin resistance: clinical implications and potential alternatives for the eradication of MRSA. J Antimicrob Chemother. 2015;70(10):2681-2692. ([link](#))

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