

Overview: Founded in 2012, Wintermute Biomedical Inc. (WBI) has developed and patented a novel chemistry platform technology that can be used to create antibacterial, anti-viral, and anti-fungal water-soluble micelles from unsaturated and saturated fatty acids. This creates a broad-spectrum, stable solution for antimicrobial applications in medicine, industry, and agriculture.

Problem: Shingles is the latent reactivation of the Varicella Zoster Virus (VZV) in peripheral nerves that typically migrates to the skin causing extreme pain. Despite the availability of an effective shingles vaccine, the incidence of shingles continues to grow year over year.

- Due to cost and vaccine hesitancy, only 34.5% of adults over 60 are vaccinated in the United States (2018; CDC).
- Globally, 1 in 3 adults over 30 will suffer from shingles.
- Current standard of care is oral antivirals but they must be given within 3 days after onset of skin lesions or they are ineffective. Typically, this is difficult to achieve and they do not reduce pain.
- Opioids can be given for the pain but are largely ineffective and not normally prescribed due to addiction potential.
- There is a clear unmet need for a topical therapy for shingles that relieves pain quickly and enhances lesion healing.

Solution: WBI has invented and patented a shingles topical therapy, GS-1, for pain relief and enhanced lesion healing in shingles patients.

- It was FDA registered and has demonstrated excellent efficacy against VZV-infected skin.
- It has been tested on 100 human subjects with no skin reactions or sensitization.
- In a 30-patient double blind placebo, Solexan produced rapid pain reduction at the lesion site.

Market Analysis:

- There is a clear unmet need to develop a topical therapy to treat unvaccinated shingles patients to relieve pain. Nothing currently exists.
- An effective topical prescription therapy would generate an estimated \$550M-3B/yr for 16 years (patent lifespan).
- No effective treatment available

Traction:

- Successfully completed a phase Ib clinical trial in 30 shingles patients that clearly demonstrated excellent safety and robust pain relief in shingles patients.
- Currently negotiating a license agreement with two pharmaceutical companies to license post-phase II.
- Excellent team made up of leading experts in shingles, business development and regulatory affairs

Next Steps:

- WBI is seeking \$15M in equity funding to support a phase IIa double-blind placebo-controlled clinical trial in 220 patients for the topical treatment of shingles to assess pain relief and enhanced lesion healing.
- The trial will be managed in Australia to take advantage of the 43.5% cash rebate on research activities. The multi-site trial is ready to execute upon acquisition of funding and is scheduled for 18 months total.