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Nugen sets its sights on US and Mexican type 1 diabetes markets

By David Godkin, Staff Writer

A needle-free injection system for patients with diabetes developed by Nugen Medical Devices Inc. has been approved for use in 40 countries but until now has yet to crack the North American market. Nugen said it is now gearing up for FDA and Mexican approval of the Nugen MD needle-free injector following Health Canada's approval of the system less than a month after the Toronto med tech went public in late 2021.

"Part of our strategy was to begin with Health Canada because our investor base, our advisers and board members are in Canada," Nugen president and CEO Michael Wright told *BioWorld*. "We also intend to identify a strategic partner in the U.S. who would see a competitive advantage combining their drug with our device and securing a longer revenue stream for us."

Spring-loaded and virtually pain-free, the Nugen MD passes insulin through a hole at the end of the syringe about the size of a human hair to accelerate uptake of the life saving drug.

Fighting the fear

Most people with type 1 diabetes manage their blood sugar levels through daily administration of insulin, often three to four times per day – assuming they've accepted use of syringes as normal practice. In fact, daily use is far from assured. In a 2018 report published by the National Library of Medicine, nearly 33% of children aged 6-17 diagnosed with type 1 diabetes mellitus express deep fears about multiple daily injections of insulin.

More than one in five adults expressed similar worries, leading studies contained in that report to strongly suggest "needle procedure-related fear may result in increased avoidance behavior and attempts to eliminate any possible exposure to needles."

In addition to the dangers to patients who don't take their insulin is the risk to front line health workers from needle stick injuries, said Wright.

"Needle stick injuries have really been a significant factor globally with a reported incidence of 2,000 needle stick injuries each day in the U.S. alone. That's even after more than a decade's long use of safety needles."

A larger problem may be the biohazard that spent insulin needles pose to the public at large, said Wright. "A lot of needles are ending up in landfills, on beaches and in parks so that's a big concern." Meanwhile, the U.S. medical industry "disposes of close to 8 billion needles yearly."

The costs associated with non-compliance by patients and a massive, intractable biohazard make it clear why the virtually pain free, self-injectables industry sees so much opportunity here. Golden, Colo.-based Pharmajet Inc. offers needle-free injectors that penetrate the skin with a narrow stream of vaccine it says reduces needlestick Injuries, reuse and cross-contamination.

France's Crossjet Dijon SA is equally buoyant, but stresses speed when promoting its needle-free auto-injector Zeneo, a prefilled, single-use device which according to the company website "propels the medicine through the skin in less than a tenth of a second."

Wright cites both companies as competitors in the self-injectables market. However, he says Nugen MD has a significant edge over its competition in features such as "variable dosing."

"Using our product, you might measure your blood glucose level in the morning and find you need to take 0.4 ml of insulin, then

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later that day see this drop to 0.25 ml. Nugen MD allows you to provide different doses at different times of the day all on the same device."

Finding the path of least resistance

Wright said Nugen MD virtually eliminates pain by using a simple principle of skin immediately evident whenever we sweat: skin is porous. Accordingly, Nugen has nixed the "sharps," those subcutaneous insulin needle jabs in the arm, for a spring-loaded device Wright said "provides the path of last resistance" for insulin.

"We're pushing the medicine through a tiny hole at the end of the syringe about the size of a human hair. Once it enters the skin, the stream of insulin opens up into a spray like pattern that accelerates the uptake of the medicine."

Conventional needles produce a pooling effect, which means insulin takes longer to move through the body than the Nugen MD. Another benefit: the cost. A needle and syringe prices out at around C$0.50 (US$0.40) per injection, "where our device across 5,000 injections could cost as low as C$0.37 (US$0.29)," said Wright.

"We're talking about significant cost advantages, and I'm not including the cost of collecting and disposing of sharps or the cost of treating needle stick injuries, which can be up to $4,000 per incident in the U.S. alone."

No sharps underfoot for your children in the local park doesn't hurt either (literally) and gives the environment a break, added Wright. "The more times you're able to dispense medicine from a reusable device and recycle the disposable materials, the less impact you have on the landfill."

Nugen's reach also extends beyond diabetes, noting needle-free drug delivery technology to treat anemia, autoimmune rheumatoid arthritis, severe migraine, psoriasis and other chronic diseases.

Partners, please

In June 2020, Nugen Medical acquired Netherlands-based Mosadex Group NV, which developed the original Insujet needle-free injector at an investment cost of €15 million (US$17 million). Nugen Medical's task was to raise its own tranche of capital to commercialize the Nugen MD for North America.

"And that's one of the reasons we decided to go public," said Wright, raising C$6 million (US$4.7 million) in brokered financing through Canaccord Genuity Group Inc., "and concurrent with our going public on Nov. 8, 2021. This also allows us to explore other opportunities and targets that might complete our assets portfolio."

Ideally, this would include a strategic alliance with a biotech firm, pharma or generic drug company for long term commercial development of Nugen's technologies. On the tech side, data collection capabilities will be added to the working protype of the current device, Wright noted.

"This would be data on the amount and length of time medicinal treatment takes and the ability to report that back to the doctor and patient. We would measure the efficacy of the protocol treatment and patient adherence as well."