

Needle-Free Injection Devices: Fast, Safe and Easy to Use. Eliminating the Fear of Needles.



Ron Lowy
Chairman and Chief Executive Officer
PharmaJet
www.pharmajet.com

Contact:
Nancy Lillie
1-888-900-4321 Option 3
Nancy.Lillie@pharmajet.com

Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: Mr. Lowy, what is the idea behind PharmaJet?

Mr. Lowy: PharmaJet's mission is worldwide acceptance of PharmaJet Needle-Free devices as a standard of care in the vaccine delivery market. We offer a portfolio of needle-free delivery devices that can be used across a host of liquid pharmaceuticals, including those that are currently on the market such as vaccines, as well as others that are under development.

CEOCFO: Why the need for a variety of devices that work with vaccines, as opposed to just one that works with all?

Mr. Lowy: Most vaccines are delivered by needle and syringe. In contrast, our devices do not use a needle at all and each needle-free Syringe is calibrated for a specific vaccine volume, either 0.5mL or 0.1mL dose. The devices are fast, safe and easy to use, and most people are trained in less than 20 minutes. Needle-free injection addresses a host of different issues surrounding needles. For example, there are about 800,000 needle stick injuries annually in the US, and this is an even bigger issue internationally. Not all needle sticks are associated with vaccinations, but it's important to note that once someone gets stuck with a needle, they usually have to go through a host of tests, because they can pick up diseases. Therefore, not having a needle is really a good thing. In terms of costs, sometimes the cost of disposing the needle is as expensive as the cost of the needle. We believe our devices not only solve many of these needle issues, but also address a fair number of people that are needle phobic. For example, less than half of the people that should get an influenza shot in the US today actually get one. Many cite fear of needles as a reason for not getting their flu shot.

CEOCFO: How does your Stratis® product work? How do you provide needle-free vaccinations?

Mr. Lowy: The spring-powered Injector uses a narrow stream of fluid that goes through the skin in about 1/10th of a second. There is no power or electricity needed. The Stratis device is used for intramuscular or subcutaneous delivery, depending on the technique needed. We also offer Tropis® which is an intradermal device that delivers liquid medicines directly into the dermis or skin.

CEOCFO: Does where the vaccine needs to be delivered determine which method is used?

Mr. Lowy: Yes. Vaccines are designed for introduction into certain tissue depths of the body. An intramuscular injection delivers into the muscle, a subcutaneous injection delivers below the dermis level and an intradermal injection delivers right into the dermis level. One of the benefits of our technology is consistent delivery. A needle injection is largely dependent upon the provider's technique, which can have a wide variation in terms of accuracy and injection speeds.

CEOFCO: *What has been the reaction in the marketplace?*

Mr. Lowy: Very positive. In the US, market surveys have shown amazingly similar results regardless of the venue, with 80% to 90% of those getting the needle-free injection liking it and saying they would get the injection again with our device. In addition, 80% to 90% of the providers also like our technology. These results have been consistent whether we survey in a pharmacy, in the military or in a flu clinic.

CEOFCO: *It would seem like a no-brainer from a patient point of view?*

Mr. Lowy: Yes, we agree. We believe it is an important breakthrough technology for the market.

CEOFCO: *What would cause the uptake to be slower than the way people would like?*

Mr. Lowy: The medical community tends to absorb new technology relatively slowly, although we had a very good first year in the market. Internationally, we are seeing much more activity. We recently had a major breakthrough with our receipt of a large order from the World Health Organization for our intradermal device Tropis, for the delivery of polio vaccine. As background, the polio vaccine used to be offered orally. Remember the sugar cube? However, over the years, mutation of the virus itself caused some “wild” types of polio. This led to the development of an injectable polio vaccine. The problem is that the volume of injectable polio vaccine required is enormous, and the capacity to produce it is about half of what is needed. To address these issues, the World Health Organization and the Gates Foundation conducted studies with our Tropis needle-free device, which concluded that two intradermal injections, using 60% less vaccine, were more effective than one full dose vaccination with a needle. This was quite a breakthrough. Additionally, intradermal injections with a needle and syringe are difficult to administer. On our website (pharmajet.com) we have some videos demonstrating the comparison of an intradermal injection with a needle and our device. The difficulty with using a needle for an intradermal injection is that the needle itself has to be at a very tight angle to create a bleb on the skin. It is a pretty difficult technique to master, and particularly difficult with a squirming baby. In contrast, the PharmaJet device is very easy to use. You simply push it up against the injection site at a 90-degree angle, click it and the injection is done in about one tenth of a second. These benefits really caught the attention of the World Health Organization.

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CEOFCO: *With so much opportunity, how have you decided where to focus?*

Mr. Lowy: Very good question. That is a big problem for small companies. Out of all the opportunities out there, how do you pick the ones that are most important? Our strategy consists of three main focus areas that we adhere to, because opportunities come to us daily. At a very basic level, we are looking at how to get as many devices out into the marketplace as possible. Next, we are interested in increasing the number of indications, meaning the number of vaccines and drugs that can be administered with the device. Lastly, we are interested in what we call “novel” pharmaceuticals or those that would use our device as part of the development of new pharmaceuticals. Using these strategic guidelines, our tactical focus is on three areas: (1) the US influenza market, where both a Trivalent and a Quadrivalent influenza vaccine have our needle-free device approved on label, (2) additional vaccines in the rest of the world including influenza, measles, mumps, rubella and polio, and (3) novel pharmaceuticals which include new development programs that we are participating in with pharmaceutical companies. For example, we are working with the NIH and multiple companies developing vaccines for Zika, dengue, malaria, HPV, cancer therapeutics, allergens, etc.

CEOFCO: *Are you working directly with the customers or would they get your devices through partners? What is the sales and distribution model?*

Mr. Lowy: We sell both directly and through distributors, and a full list of our distributors can be found on our website. We also have a fairly sophisticated educational program, where people can actually self-train using our online educational information and videos. Most people can train themselves within 20 minutes. In addition, the APHA has included our device in their training program, and every new pharmacist (about 14,000 per year) now gets trained on our needle-free device.

CEOFCO: *Are you seeing more and more shots being given at pharmacies as opposed to doctor’s offices?*

Mr. Lowy: Yes! Pharmacists have become care givers of vaccinations as well, although sometimes they are reluctant care givers, as many of them did not go to school to give injections. Our device is great for them because it is easy to use.

CEOCFO: Are you funded for the steps you would like to take? Are you seeking investment or partnerships?

Mr. Lowy: We are currently going through a fund raise. Up to this point, the company has been funded by high net-worth individuals, but we are now also looking at institutional funding, to support our commercial expansion and additional manufacturing capacity. Our logistics, warehousing and manufacturing are all outsourced, the latter being all US based (Wisconsin).

CEOCFO: Have similar products been tried in the past?

Mr. Lowy: Interesting enough, we do not really have any direct competitors and consider our primary competitor to be needle and syringe. We used to have one competitor who has since sold their IP, and disappeared from the market. Although there are other needle-free injectors out there, they are typically focused on only one application. For example, there are fair number that have gone after injectable insulin, but the problem from our perspective, is that insulin delivery is a very crowded market and requires variable dose which is expensive. Basically, we don't directly compete with any other company today that can address an entire portfolio of vaccines or drugs.

CEOCFO: Why PharmaJet?

Mr. Lowy: Besides having the ability to actually inject vaccines and drugs that exist today, coupled with clinical study support and FDA approval, we are partnering with companies on future injectable pharmaceutical opportunities, like nucleic acid vaccine development programs, that have the potential to work or work even better with needle-free delivery. There are some really solid scientific reasons why that may be, which is why companies in the field are interested in using our device to develop their pharmaceuticals.

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