

PharmaJet's Needle-free Delivery is improving the effectiveness of nucleic acid drugs and biologics



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CEOCFO: Mr. Cappello, what is PharmaJet?

Mr. Cappello: PharmaJet is a biotech company that has developed a safer way of administering drugs and biologics, by developing a needle-free injection platform, that in many cases, makes pharmaceuticals work better.

CEOCFO: Would you tell us about the technology?

Mr. Cappello: Jet injection technology has been around for over fifty years. The military used to use it, but for a long time, the technology was very archaic. PharmaJet was established to really revolutionize jet injection technology by making it safer. We did that by developing a reusable hand piece, a reusable injector, and a disposable needle-free syringe. Therefore, you simply fill the drug or biologic into our proprietary needle-free syringe, you load that into the reusable injector, and simply give an injection. The injectors can be used over 20,000 times, and they do not require any external power source.

CEOCFO: How does the drug get into the body? What is at the end of the syringe that gets it from the syringe to the person?

Mr. Cappello: When many people hear "needle-free" they still think there is a needle, or a needle retracts, or little micro needles. We are one of the only solutions that is truly needle-free. We push the drug or biologic into a fine, precise fluid stream, and that fluid stream is what actually penetrates the tissue and gets deposited into the body. Therefore, there are no foreign objects that enter the body besides the fluid.

CEOCFO: How does the fluid get into the body?

Mr. Cappello: The injector pushes it through the skin through a small orifice in our needle-free syringe creating a very fine stream of vaccine or drug. It is that fine stream of the vaccine or drug that basically acts as a liquid needle and pierces the skin.

CEOCFO: Then is it a legitimate question to ask why we have needles at all? Why will we in the future?

Mr. Cappello: I agree! Needles have been out there for many, many years, but as we are finding out, as some of our more forward-thinking drug and biologic partners are learning, there is a better way to deliver their medicines. We think similar to how Nucleic Acid vaccines are starting to take over, that needle-free delivery will follow suit.

We are hopeful that the PharmaJet Systems will become a standard in care, and while we have not identified a single injectable that does not work with our Systems, there are many older vaccine technologies that have used things like aluminum adjuvants and other types of technologies, to get them to work in the muscle more effectively. These are not great to be deposited into the skin, so until the vaccine technologies catch up, there will likely still always be needle and syringe delivery.

CEO CFO: *Aside from the wonderful idea of not feeling something when it is going into your body, and as I see on your site "Outstanding patient and caregiver experience", what are the other advantages?*

Mr. Cappello: The top advantage of the technology is really around improving effectiveness of drugs and biologics. We are finding, and our partners are reporting, an increase in effectiveness of their pharmaceutical products when they are delivered with the PharmaJet devices. That is really the biggest benefit of the technology, where our mission is to improve people's lives, and we believe that improvement of these drugs and biologics does that in the greatest way.

Another key benefit is that our intradermal injection system has been proven to lower the total cost of an immunization. We can use less vaccine, make it more effective, and consistently deliver it into the skin, which collectively lowers the total cost of a vaccination. Therefore, we can vaccinate many, many more children or adults. This has been proven with partners like Zydus Cadila, as well as with our partnership with the World Health Organization, the Gates Foundation, and PATH, around the Global Polio Eradication Initiative. Together, we have proven that with the needle-free intradermal delivery of polio vaccine, you can use one fifth the dose that is typically administered into the muscle. You can deliver it into the skin layer and get as good or better effectiveness, at a much lower total cost.

"I would say it is most important because we can enable the next generation of drugs and biologics to come to market, and those will have a profound impact on patients' lives. Vaccines have shown, and preventative care has been shown, to be the most cost-effective way of reducing healthcare cost in the world. We can enable more of those, especially Nucleic Acid-based drugs and biologics, to come to market." Chris Cappello

CEO CFO: *Do you manufacture this yourself?*

Mr. Cappello: We own all the IP. We have done all the design inhouse, and we own all the manufacturing equipment, or tooling. We partner with world class contract manufacturers, both in the US and outside the US, to make the physical product. However, we are the legal manufacturers, so we are the ones that register with the regulatory bodies, like the FDA and others across the globe.

CEO CFO: *What do the traditional needle makers feel about this? Often, when something has been entrenched in the market, and something new comes, current manufacturers are not happy.*

Mr. Cappello: I agree. I think they probably feel like there is room in the market for both technologies. Where we really have an advantage over needle and syringe, is delivering Nucleic Acid pharmaceuticals. You may have heard a lot about mRNA or DNA vaccines. Our device has been proven, in multiple clinical studies, to be more effective than needle and syringe, when delivering Nucleic Acids. Therefore, I think they are starting to take a closer look at us, based on this type of data.

CEO CFO: *How do you reach out to potential customers or partners?*

Mr. Cappello: Right now, most of our customers or partners learn about us from our other partners, who, as they progress through clinical stages of development, usually publish articles, or go to conferences where they share data. They have been sharing some very remarkable data on the effectiveness of the technology, as I said, largely in delivering Nucleic Acids. Therefore, a combination of referrals from current partners, as well as the sharing of this data at industry conferences, is driving most of our partnerships.

CEO CFO: *How do we know it is more effective? What kind of material did you need to accumulate to assess the long-term viability?*

Mr. Cappello: What is unique about PharmaJet is that any claims or data that we make, or share, are not using data generated by PharmaJet. We leverage all our world class drug and biologic partners to generate that data, independent of PharmaJet. Therefore, it is actually our partners who are making the claims of more effective and sharing that data. We

feel very confident in being able to share that, as it is, many times, peer reviewed, published data in scientific journals, and it is usually generated under regulatory controlled studies, such as FDA IND studies.

CEOCFO: *How do you go from here to being the standard of care? What do you need to do? Are you funded to move ahead? Give us the road map.*

Mr. Cappello: It all comes down to growing our novel pharmaceutical pipeline. Right now, we have over 50 pharmaceutical partners that we are working with. What we have found with COVID is that those typically take anywhere between 7 and 10 years to come to market, and many of them will not make it to market. However, COVID has really shaken the development cycle of drugs and vaccines.

We are seeing that cycle being accelerated, not from a diminishment of quality or rigor, but in taking out the bureaucracy and throwing more resources at clinical development. Therefore, the way we become a standard of care is to fill our pipeline with more partners, continue to demonstrate improved effectiveness, as well as continue to look for ways to shorten and expedite the clinical development cycle, to get these lifesaving drugs and biologics to market.

CEOCFO: *What changed at PharmaJet when you took over as president and CEO? It has been almost a year and a half. What has changed for PharmaJet?*

Mr. Cappello: I was fortunate enough to be working here for the past 11 years under a board and part of a management team that we have been building over the last 5 years. In that sense I have not had to change a lot, because we had built such a strong team. However, in the last year, what has changed most significantly is that some of the strategies that I had helped put in place have now started to come to fruition. Therefore, helping really execute on where we knew the business could go, with our partner, we just scaled our manufacturing from 10 million syringes, to over 300 million syringes in the last year.

To support our partner Zydus Cadila, in the launch of their COVID vaccine, in the last year, as a company, we have put in place a ground floor to an executive management reporting system for all the priorities of the business, that makes it very transparent and clear on what the priorities are and what people should be focusing on, on a day-to-day basis.

CEOCFO: *Are you able to scale up if needed? Are there challenges in doing so?*

Mr. Cappello: There are huge challenges, just like in all companies. You name it, we have faced it in the last year. The freeze in Texas at the Dow Chemical Plant held up a lot of high-grade specialty polymers that impacted our manufacturing. We have had to validate additional raw materials that go into our system, deal with backed up or late shipping routes, and scale up overseas when travel was not allowed. All those challenges that most of the globe has been facing, we have been, too. I would say, it is a little bit exacerbated at PharmaJet, as we are in the middle of scaling 25-fold. However, we have fantastic partners and a really good operations team here, that has made that possible.

CEOCFO: *Why is PharmaJet important?*

Mr. Cappello: I would say it is most important because we can enable the next generation of drugs and biologics to come to market, and those will have a profound impact on patients' lives. Vaccines have shown, and preventative care has been shown, to be the most cost-effective way of reducing healthcare cost in the world. We can enable more of those, especially Nucleic Acid-based drugs and biologics, to come to market.

Secondly, we can improve vaccination rates. There is needle fear, there is needle aversion, and we have seen a strong preference for the technology driving upwards of 18% increase in vaccination rates in campaigns that use our products, increasing the total amount of people that need or want to be vaccinated.

Lastly, our partners can grow their clinical pipelines, as well as potentially lower their overall costs in partnering with us, and so enabling those partners to bring their novel drugs and biologics to market quicker and at less cost.

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