

Medigen – Developing Vaccines for Emerging Viruses using Molecular iDNA Technologies



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CEOCFO: Mr. Pushko, the first thing I see on the Medigen, Inc site is vaccines for life. What is the vision behind the company?

Mr. Pushko: The company develops vaccines for emerging diseases, primarily caused by viruses. We all know that viruses can cause outbreaks, epidemics, and pandemics, as we recently learned from the Covid-19. Medigen develops vaccines for viruses that may appear in the US in the future. We would like to have the vaccine before the virus is actually causing the problem. When an outbreak happens, we will be ready, and we will meet the disease with an effective vaccine. Medigen also helps other vaccine developers to manufacture their vaccines, serving as contract development and manufacturing organization (CDMO) for them.

Vaccines for life means that we develop vaccines to protect life, and this also means vaccines that provide life-long immunity. Our vision is – a single shot with the vaccine, and the person protected from target pathogen for life.

CEOCFO: About how many viruses that might attract your attention are floating around at any given point in time?

Mr. Pushko: Many of the viruses are known, with many identified as a threat to public health. We mostly focus on such viruses that are causing outbreaks and epidemics abroad. However, with travel, commerce and changing climate patterns, these viruses can be introduced to the US and cause a health crisis here in the US. The examples of such diseases caused by viruses are bird flu, Lassa fever, yellow fever, chikungunya, and other exotic viruses.

There are also viruses that are undiscovered. Viruses continue to evolve, and some of them can become a threat in the future. Medigen currently develops vaccines for known threats that have already been identified by the CDC, or WHO; however, our vaccine platform can be easily adapted to new threat viruses.

CEOCFO: You use molecular biology, protein engineering, and molecular virology. Would you tell us about those three methods, and what your proprietary techniques are as well?

Mr. Pushko: Medigen uses unique methods and know-how to develop our patented vaccines. The vision of the company is to create “domesticated” viruses as vaccines to protect against pathogenic viruses. These vaccines do not cause harm to people, while they make people immune to pathogenic viruses. Medigen does have a proprietary vaccine platform. We

call it iDNA, an immunization DNA. We have encoded our vaccines in the DNA and prepared several experimental vaccines using this platform.

CEO CFO: *Does the medical community understand your approach? Are they onboard with it, or is it something that people in medicine still don't fully understand?*

Mr. Pushko: Most scientists are onboard with the idea. About half of all vaccines currently approved for human use are live vaccines. Many of our customers also develop live vaccines. Immunity from live vaccines resembles natural immunity in people, and it is effective and long-lasting.

Because our vaccines are still experimental, we do not plan to test these vaccines in some categories of people with underlying medical conditions, such as immunity disorders. Once safety of the vaccines is established in healthy populations, vaccination can be extended to additional categories of people to evaluate safety and efficacy.

CEO CFO: *Would you tell us about some of the other services? Are you choosing the vaccines to work on, or are companies coming to partner with you on it? How does the business side of your Medigen work?*

Mr. Pushko: This is a very good question, thank you. One part of Medigen business is to develop our own proprietary vaccines that will protect people against emerging viruses. Another part of our business is to provide contract services. Medigen provides vaccine CDMO services, to other companies who develop innovative vaccines.

Other companies come to us if they need to manufacture a novel vaccine, and Medigen develops the manufacturing process and manufactures their products for further testing according to strict FDA rules. Recent examples of contract manufacturing that Medigen successfully completed for other companies included an innovative Covid-19 vaccine and an experimental Herpes virus vaccine.

"When an outbreak happens, we will meet the disease with an effective vaccine." Peter Pushko

CEO CFO: *You recently expanded your physical space. Why now?*

Mr. Pushko: Medigen needs additional space to expand our manufacturing capability to manufacture our own vaccines, as well as expand CDMO services. We would also like to be able to manufacture more than one product at a time. Therefore, the time was right to expand the facility, and to acquire additional capabilities.

CEO CFO: *Is there newer equipment, newer technologies that you are able to take advantage of?*

Mr. Pushko: We are acquiring additional equipment to expand our capabilities. For example, we acquiring air filtration units, air particle counter, ultra-low freezer, centrifuge, and other equipment, to expand our vaccine production and storage capabilities, as well as vaccine testing. We also acquired and hired additional competent staff to work on our projects and CDMO projects. Therefore, our expansion of the facility goes hand in hand with expanding our equipment capabilities, and also hiring talented staff.

CEO CFO: *Is it as difficult to find staff in your industry as it is in many others?*

Mr. Pushko: Hiring staff has been challenging at this particular time, because there is a lot of competition in the vaccine space. As you know, Covid-19 vaccine manufacturers have been active during these pandemic years, working on manufacturing multi-million doses of Covid-19 vaccines. Therefore, we are competing with the large manufactures for the best research and manufacturing staff. However, we have been successful in attracting talented personnel, and they really help to move all vaccine projects and CDMO projects forward.

CEO CFO: *When you develop a vaccine, what do you do with it? Do you manufacture it? Do you partner? Do you sell it?*

Mr. Pushko: Most of Medigen vaccines are in preclinical trials. We are testing these vaccines in animals, to make sure they are fully safe and efficacious before we test in humans. After all preclinical testing is completed, we pass the vaccine to medical doctors for Phase 1 clinical trial in humans. We are fortunate to collaborate with talented doctors from the universities and the US government. After Phase 1 clinical trial, testing is continued in humans until vaccine is approved by the FDA, before commercial sales can begin.

For our CDMO customers, once Medigen manufactures the vaccines, we store or ship them in a controlled way to the clients or client-designated party for further testing including human clinical trials.

CEOCFO: *It seems like you have a lot on your plate. How do you juggle what is going on, or is it easier than I would think?*

Mr. Pushko: We are proud to have a good pipeline of vaccines for emerging viruses. We use our platform technology to develop all these vaccines. We use our platform technology to make vaccine against one virus, then another virus, and with each new vaccine, we acquire additional methods and additional skills, so each next vaccine is easier to manufacture than the previous one. We already have data to support that our vaccine manufacturing can be successful.

CEOCFO: *Are you seeking funding, partnerships, or investment as you move forward?*

Mr. Pushko: We are open to partnerships and investments. Hopefully CEOCFO publication would be a good step to partnerships and investments with the business and financial community.

CEOCFO: *There are so many companies to look at in your industry and your arena. Why does Medigen, Inc stand apart from so many others?*

Mr. Pushko: We have a unique niche in vaccines for emerging viruses. Many other companies are focusing on vaccines against viruses that already circulate in the US, for example, seasonal flu and Covid-19 viruses. Vaccination against these require large scale up that sometimes is challenging and can encounter supply chain issues due to multi-million dose manufacture. Established vaccine manufacturers had to deal with the supply chain issues during pandemic years, which most manufacturers have successfully resolved.

Our company is focused on a very unique and particular niche in the vaccine business, vaccines for emerging viruses, and we have our platform technology that allows us to develop vaccines using molecular iDNA technologies faster than traditional vaccines. Therefore, we think that our patented technologies will bring bright future to our vaccines for life.

