THE WALL STREET TRANSCRIPT
Connecting Market Leaders with Investors

NanoViricides, Inc. (NYSEAMERICAN:NNVC)

DR. ANIL DIWAN, PH.D., is President and Executive Chairman of NanoViricides, Inc. He co-invented a bio-mimetic drug delivery platform, nanoviricides polymeric micelles, enabling site-specific targeting, multi-point attack, and encapsulation. Orally available, host-mimetic, direct-acting, nanoviricide drug NV-387 has successfully completed Phase I in healthy subjects and is being developed into Phase II. NV-387 has shown strong pre-clinical efficacy in RSV, influenza, COVID as well as Orthopoxvirus in lethal virus challenge animal models, attesting to its broad spectrum, reminiscent of antibiotics. Nanoviricides define a new paradigm "Re-Infection Inhibition," going beyond antibodies and small chemicals. The platform further enables cures of viral infections by encapsulating orthogonal APIs ex: Remdesivir, Ribavirin, Cidofovir, etc. Dr. Diwan was instrumental in designing and establishing the NanoViricides campus in Shelton that comprises R&D to Clinical Trial Drug Product Manufacturing facility of its nanomedicines. Dr. Diwan holds a Ph.D., (Bio)Chemical Engineering, Rice University and a BTech, Chemical Engineering, Indian Institute of Technology, Bombay (IITB).

SECTOR — PHARMACEUTICALS

(BFE601) TWST: It's been a while since you last spoke with *The Wall Street Transcript*. That was back in 2018, and a lot of significant progress has been achieved by your company on the clinical front since then. Can you give us an overview of your company today?

Dr. Diwan: As you may recall, in 2018 we were developing a therapeutic drug against shingles, a member of the herpes family of viruses, using our patented nanotechnology-based platform technology. We had completed all the non-clinical data sets and were actively looking for clinical trial sites when the pandemic broke in December 2019 limiting the sites' ability to find shingles patients with no comorbidities or pre-existing conditions.

The really great thing that happened is that we turned adversity into an opportunity. Due to the remarkably wide applicability of our broad-spectrum technology, we switched gears and quickly developed a new, novel drug against coronaviruses, the pressing global need at the time. We had a potential drug candidate against coronaviruses in hand as early as March 2020. By the first quarter of 2021, we had already gone into non-clinical GLP and safety toxicology studies for it, and got initial reports back from them.

At that time, we found that capacity in most clinical sites in the U.S. had been co-opted with the prospect of full utilization and large revenues by Big Pharma, so we diligently kept looking for credible and affordable clinical trial sites inside and outside the U.S. while refining the technology to make gummies, testing manufacturing scale up, exploring packaging options, etc.

We eventually did a collaboration in India, and our drug sponsor, our collaborator, was able to get approval from the Indian government to conduct the trial there, after a rigorous process of document submissions and reviews. A Phase I clinical trial of NV-387 started in June 2023 and the healthy subject portions were completed at the end of December of last year. We are now waiting for the final reports which go through all quality control processes, statistical analysis methodology, etc. It is taking longer than we anticipated but it's almost complete.

I want to give you some insight into our platform technology and how the drugs it generates are different from anything in the market today. We have seen in HIV, influenza and most other viruses, that viruses change very rapidly in the field . So, in our drug design, we went for a very broad-spectrum approach. The reason for that was to make sure that no matter what happens, we wanted to make sure that we are developing a drug that the virus doesn't escape from. We did that as a design principle.

The power of the patented NanoViricides platform we invented is that it is based on attacking the virus directly and using a host-mimetic approach, which means the virus is attacking human cells, host cells. The virus is using certain features and no matter how much it mutates, those features remain the same. That major realization was what we wanted to leverage when we founded NanoViricides in 2005.

So, then what happens? What do we have to do? We have to mimic exactly what the cell is offering to the virus particles. That's how we developed the polymeric micelle that we call NanoViricides. On small ligands, we copy from the features on the cells that the virus needs, no matter how much it mutates. We attach them coherently to a polymer backbone.

It's like a double-sided comb-like polymer in a structure that forms on itself, collapsing on the lipids inside. There is a lipid inside and a polymer on the surface with projections that the virus binds to. Once the virus binds, this is what we call nanomedicine, NanoViricide.

The glycoproteins that the virus is using for attaching to cells and fusing into cells are suspended in that lipid membrane so they fall apart. Because of that, the virus cannot replicate anymore and cannot infect anymore. It is just excreted by the body. And amazingly, there is no reliance on the body's immune system.

That's the background of the platform technology. We came up with NV-387 using this patented platform technology. As I said, we have completed the Phase I clinical trials and are awaiting the data sets and final reports.

We are already working on developing Phase II clinical trial protocols. Phase II is a critical milestone in terms of efficacy, and that will open up revenue sources for us like collaborations, licensing, etc.

In terms of de-risking NV-387, we developed our own internal manufacturing for multiple reasons. That has sped up our programs because we don't have to wait on six- or nine-month timelines. As soon as we need something, we commission the production and in less than two to three months, we can have the product in hand, full scale. We have therefore "designed for manufacturability" and this substantially increases the probability of success in Phase II.

You asked about the three viruses: COVID, RSV, and influenza. In lethal viral challenge studies we found NV-387 works against all three of them individually in lethal infections.

RSV is a killer disease. It's a very serious problem. That market has been estimated at about $8 billion a year. There are two vaccines and two antibodies, but none of them are available after infection takes place. They are all for prevention, even the antibodies. That's a big problem.

Why would you want to give your newborn something that is completely foreign to their system so that you can protect that infant against something that may or may not happen? That is still a $2 billion market, just the antibodies. I think one of them is crossing into multiple billions now, way beyond that. That alone is taking us into that billion-dollar stratospheric space.

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TWST: We now have the spread of mpox and RSV, and of course, COVID-19 is still very much with us. It sounds like NV-387 could really help contain the spread of these viruses. Is that accurate?

Dr. Diwan: Yes. Even for diseases that have a vaccine, a drug treatment is needed to contain the spread of the virus. In the percentage of cases where the vaccine has been ineffective, the person who is infected is producing viruses in trillions of particles. All you need for the virus to spread is anywhere from one virus particle in the case of rabies to a thousand particles in the case of the flu to infect a person. In the case of rabies, it's a single virus particle that is a death sentence.

So, viruses are different — you have to combat the virus to prevent its spread. You have to get infected persons/animals to stop making copies of the virus, stop producing the virus and stop disseminating them. Vaccines don't do that. Antibodies don't do that because the virus immediately mutates.

What typically happens is that the virus mutates against the small chemical drug. Case in point, an influenza drug recently produced called XOFLUZA. In a clinical trial of XOFLUZA, they found that 10% of the patients had influenza viruses that were resistant to the XOFLUZA drug — in their own clinical trial. It still was approved.

But this is the problem with small chemical drugs. A single point mutation in the virus, something that is very common, can lead the drug to become ineffective. That's why we developed this broad-spectrum approach. Not only is NV-387 broad spectrum, it is something that the viruses cannot resist and they will not escape from it even by simple changes like mutations and recombinations. The need for such drugs is huge.

In the case of RSV, there is no current drug treatment, but ribavirin is used as a positive control. Ribavirin is a very toxic drug and is given as a last resort if the case is hopeless. And we treated animals infected with RSV, lethally infected with ribavirin and with our drug. And our drug NV-387 cured the virus. There were no lung plaques, nothing. The animals survived.

We are looking at doing Phase II clinical trials in RSV if we can generate enough funding for that, and we have developed clinical protocols for what we call SARI — Severe Acute Respiratory Infections — caused by viruses. We will be doing one composite clinical trial in which we will be evaluating the NV-387 drug against many different viruses.

In COVID, we compared against Remdesivir, and our drug was substantially superior. We were getting 18 days of survival in lethal animal studies, 14 days even given orally. With Remdesivir, survival was only about nine days. The untreated animals were dying at between six and eight days.

We have a drug that really works well. NV-387 has already shown to be working on the tripledemic viruses. We believe, because of the mechanism and design, that it probably works against all respiratory viruses. We have to prove that. So, we are turning the pharma industry's philosophy of developing "many drugs against one bug" — used for HIV and Hepatitis C — on its head and developing "one drug against many bugs."

This philosophy was used to develop penicillin and antibiotics as standard treatment against bacterial infections, and we are bringing this approach to developing drugs to treat viral infections for the first time.

Developing the platform, proving the technology, and de-risking manufacturing scale-up, that's all complete. Now we are just going to have to wait for NV-387 to go into commercial practice.

Lastly, you were talking about mpox. In 2022, when another strain of mpox, clade II, spread into European countries and the United States, there was a major threat that it could become pandemic just like COVID. We had a suspicion at that time, again because of the mechanisms, that NV-387 might work against it.

Now, smallpox, mpox, pox viruses are very different. I myself call them bricks. They are very difficult to pull apart, to attack. We were kind of on back footing on that.

When the 2022 outbreak occurred, we started studying and even did a press release saying that we were working on it. But our approach was to see what we already had in our portfolio and if something works, and develop from that. Fortunately, NV-387 worked very well.

It worked as well as Tecovirimat, an antiviral prescription drug. And Tecovirimat again is a small chemical drug. It works against a single protein in the exit of the virus from cells. It was excellent in animal studies also, so we use that as positive control.

NV-387 actually matched what Tecovirimat did in two kinds of animal studies: One was for a skin infection model. The other one was a lung infection model. The virus is given as an aerosol.

In both of those studies, NV-387 was very good and it matched Tecovirimat. Here is a drug that actually works in the same animal models that Tecovirimat was developed with, and it is a completely different mechanism. It is a broad-spectrum mechanism. It is giving you a rationale to believe that the virus cannot escape it, and that it will be useful against multiple clades of the virus, which Tecovirimat failed.

We are developing a systemic drug based on the same one. Because these viruses erupt on the skin, but they are living inside the cell in usually neural ganglia or some inter-inner spaces. Systemic infection is also important to finally control the virus and hopefully cure it out of the body.

We had developed NV-HIV-1 antiviral against HIV, which had tremendously good results in animal studies. However, that is an extremely expensive study for us to undertake. When we can get a collaboration for it, we are going to go after it. Right now, there are very good drugs that are developed against HIV, most of them as preventives, but there is a lot of development.

The competition and the risk has increased. The potential is still there because there is no cure yet. The number of virus cases has not decreased substantially in the last few years at least, so we do have to develop a drug against that. We are going to do that in collaborations only because we cannot handle the cost of the drug development there.

In influenza, we were developing a drug, and it seems like NV-387 itself is sufficiently responsive to that. We could go with that itself. Later on, what happens is NV-387 attacks the virus life cycle on one side only, outside the cell before it has infected. All the existing approaches except antibodies have been trying to do the other thing, which is the replication cycle, inhibiting how the virus is producing itself. Most of the drugs are doing that.

Some of the drugs like Tamiflu and TPOXX, they are trying to block the virus from exiting the cell after it has formed. That is the intracellular part of the life cycle. We have the extracellular part of the life cycle.

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In the clade I, they did a clinical trial, the one that is going on in Congo right now. They completed that clinical trial around August 19. NIAID — the National Institute of Allergies and Infectious Diseases — came out with the final report and published that it was found to be safe but not effective.

So, it did not improve the recovery any better than placebo or standard of care. Basically, there is no point in giving the drug, because you are only going to add side effects.

That is the situation right now in mpox. There is a vaccine against smallpox that they are going to deploy, but there is no treatment right now. So, we believe that using NV-387 in that theater is a very good opportunity, not just from our company's perspective, but for the world.

TWST: Are there any other lead drug candidates? If so, where are they in the pipeline?

Dr. Diwan: We started in 2005. We worked against influenza, HIV, Dengue, herpes viruses. We essentially have attacked 40 different indications, and have had some positive results against each of them.

Out of them, NV-HHV-1, the drug against shingles developed as a skin cream for applying to the rash, that has completed non-clinical studies. It's ready for going into Phase I. That's the most advanced drug. That drug also works against HSV1 and HSV2, cold sores, and genital ulcers. We will expand it to that as a rash treatment.

If we have a drug that combines both of these, then that is a complete cure against most of the viruses. Any virus that does not produce latency in cells — which means herpes viruses and HIV are out, almost every other virus is in — in that scenario, you can produce a real cure.

We have programs and animal study results on that. We just are in the optimization stage for that part. My original strategy was that because everybody is working on that kind of drug, we will get a collaboration. Once we have shown that our drug works on the outside, we'll get a collaboration.

Then we go with that drug and encapsulate and use it. That's why we developed the NV-387-R, Remdesivir encapsulated into NV-387. That didn't go too far.

Now we have developed our own, too. We are very optimistic on our own developments compared to those developments because the objectives were different. Our drugs are less toxic, hopefully. They are still in the early stages of development.

That is another potential opportunity for NanoViricides' platform technology, that we can encapsulate other drugs. We can decorate the polymeric micelle with multiple ligands. We can be more specific. We can go with broad ligands. We can be less specific and attack many general viruses. We have already shown all of those things in cell culture studies, in animal studies.

Now, we are progressing into clinicals. It's a big program. The market opportunity is huge. If you look at RSV alone — pediatric RSV is a very serious problem.

TWST: As CEO, what is your vision for the company?

Dr. Diwan: We want to do the proof of concept first: Phase II. We have already started working on trying to get collaborations. The pharmaceutical industry depends upon relationships, upon people having confidence in you. It takes a long time, but we are getting there. We believe that we will be successful in getting pharmaceutical collaborations and that will advance it much further.

My perspective on the business strategy is that we go both ways. So far, because it was a completely novel technology, we had said and we continued with the perspective that we don't expect collaborations to come in until proof of concept is there, but we will continue to march on our own. We are going to be able to do Phase II for NV-387.

We have three approaches depending upon the finances and the strategy. We will choose one of them in 2025, and once we have done one proof of concept, things open up. That's our strategy right now.

And then once NV-387 is taken forward, NV-HHV-1 is waiting. Other drugs are just waiting for the scale-up and the usual things that we have to do for regulations. We are not novices in regulatory. We already know what we need to do.

TWST: What should our readers and investors understand about your revenue model and the part it plays in your overall business strategy?

Dr. Diwan: Licensing revenues are an important part of our business strategy. Collaborations will generate milestone payments, provide co-development financing, and lead to licensing revenues. That has been the typical model for the pharma industry, and we believe that will open up for us when we get to Phase II.

That will be the first part of how revenue is generated. The next part is after commercial sales, after relevant regulatory approvals in regions around the world.

An mpox drug treatment is an immediate need. We may be able to go into Phase II for mpox. It depends upon the political climate and whether the epidemic continues. Phase II itself may give us at least, just like what happened with the COVID pandemic, permission to sell and generate initial revenues. That will also give us opportunities to generate grant revenues.

We are also working on our own commercial strategy, which is taking Phase II into multiple viral indications.

We have a 10-kilogram facility now, 10 kilograms of active ingredient, which can treat between anywhere from one thousand to a few thousand patients, depending upon the severity of the disease.

If you look at the $3,000 model, that's still $3 million in one batch. It's not big, but it's not small either. It is something that a company like us that spends around $0.5 million in a quarter — that kind of revenue is big for us. That gives us the market introduction opportunity.

Any of these developments, all of these drugs are of interest to BARDA — the Biomedical Advanced Research and Development Authority — mpox especially, to NIAID and governments across the world. Eventually, that will also generate the opportunity to collaborate with governments and bring in non-dilutive financing.

Those are all the different ways of getting financing and revenues together. It doesn't happen right away, but you just have to keep plugging away on each. And as your program moves forward and as success builds, that is what generates momentum.

TWST: What effects, if any, are you feeling from macroeconomic or geopolitical factors right now?

Dr. Diwan: I am the last person to comment on that. We are a small cap, small business. We require very small amounts of funds, so we are protected from that kind of environment in that sense. That said, the big biotech crash of the last two years, like for everybody else, that, of course, wiped out our market cap substantially. That made raising money difficult.

That has happened to almost all the companies. Macroeconomics and geopolitical factors affect the entire sector. We are not immune to those, but our requirements are small. We keep them small on purpose. That insulates us from those problems.

TWST: Are things easing in the biotech industry? Are some of those challenges easing, or is it more of the same?

Dr. Diwan: Compared to the last two years, 2024 has been better. We have seen upward movements in many different market caps, including our own. The mpox pandemic caused some specific companies to go up, particularly in vaccine space, not so much in antiviral space, but it will also come into antivirals. Once people understand what antivirals can do, the market cap changes.

Overall, what happens is that when pharma companies get a lot of revenue, they start buying companies or technologies, licensing technologies. That actually started building up in 2024 and faded to some extent. I think that it will come back again in force.

What I have heard in most biotech meetings, and from economic experts and pundits in the biotech space, interest rates need to come down. When the interest rates come down, the market space in small cap especially improves.

TWST: Is there anything else you would like to share?

Dr. Diwan: We started with a dream: We want to revolutionize how viral infections are treated. We are attacking a whole viral market, but even the early fruits that we are trying to catch are taking us into the $20 billion market space. The opportunities are endless and we believe that we are completely revolutionizing this field of antiviral treatments.

TWST: Thank you. (NS)

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