Nanoviricides Inc

(NASDAQ: NNVC)

May 20, 2024

Healthcare	
52-WEEK HIGH	US$2.13
52-WEEK LOW	US$1.00
Price	US$2.07
MARKET CAP MLN	US$24.5
CASH (MLN)	US$3.2

Share Price

Major Shareholders	
Management & Board	2%
Vanguard	3.8%
Shares in issue (31 March 2024)	11,813,867
Avg three-month trading volume	1,125,194
Primary Index	NASDAQ
Next Key Announcement	Clinical data Autumn 2024

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Novel anti-viral could boost a US$3 bln market

New focus on viral respiratory infections especially highly transmissible RSV

Nanoviricides (NV), a US company, owns a novel, multi-target, oral anti-viral platform that has completed its first clinical study. The development pathway is now being focused on general viral respiratory disease in India and on Respiratory Syncytial Virus lung infection in the US. The successful completion of Phase 1 healthy participant dosing with no adverse events was a key milestone; we expect the technical data from late summer onwards. There remains a need across many viral diseases for effective therapies. If, as preclinical data indicates, the candidate, anti-viral NV-387, can be delivered orally at effective doses against multiple respiratory viruses, including potentially Influenza A, RSV and COVID-19, it could become a mass market product. It might be prescribed by primary care physicians adding a new, acute therapeutic category to the RSV vaccine and antibody market already worth about US$3 billion.

NV had US3.25mln of cash on March 31. Management has stated that this is not sufficient to fund NV till March 2025. However, the company has access to further cash, has solid assets, and is seeking further funds or secured loans.

The putative COVID-19 therapy, NV-CoV-2 Phase I, containing NV-387, completed dosing of the 36 healthy participants in both single-dose (Phase 1a) and multiple-dose arms (Phase 1b). Participants received either a syrup or a gummy containing the anti-viral agent NV-387. A next stage was planned in mild-moderate COVID-19 patients. However, patients are now hard to recruit so this stage has closed. Hence, we do not see further development of a COVID-19 indication in India.

As preclinical work shows that NV-387 is effective against influenza and RSV viruses, a general anti-viral first response oral therapy against "Severe Acute Respiratory Infection"-Viral (SARI-Viral) might be feasible. Currently, this is not a recognized class of anti-viral and an appropriate clinical development strategy needs to be agreed with Indian regulators. The market is an attractive option.

In the US, the focus is on RSV. RSV is a viral lower lung infection particularly dangerous to infants under six months and young children up to five years old. It can also be dangerous in older adults (over 60), though they can be vaccinated where children cannot (although maternal vaccination during pregnancy is available to protect new born and young infants).

To enter US development, NV needs a pre-IND meeting with the FDA, probably once the Indian Phase 1 technical data is available and analyzed. This could be late summer 2024, and could enable an IND to be filed in Q1 2025 and granted by spring the same year. A Phase 2 could then run over the 2025-26 winter RSV season; RSV infections are highly seasonal (see below).

We also note excellent preclinical data on Influenza A treatment with NV-387 compared to existing blockbuster therapies.

Financial – material cash uncertainty

Nanoviricides' 2023 accounts (10k) to June 30, 2023 showed cash (including prepayments) of US$8.46mln, down from $14.42mln in June 2022. In the accounts for the nine months to March 31, 2024, NV showed cash of $ 3.5mln (including prepayments). The cash burn, on average is US$1.6mln per quarter indicating about $2mln at the FY24 year end on June 30, 2024. There are some clinical trial payments and there will be Q3FY25 data processing and FDA regulatory costs. Given up to US$2mln Y/E cash and possible FY25 burn of at least $6-7mln, NV could need a at least US$4mln further in FY25 before any further trial costs.

A US RSV study has been roughly estimated to cost up to US5mln which would mostly be additional to the above but would, we understand, mostly be incurred in FY26 . Note that no US trial designs or costs can be clarified before the FDA pre-IND meeting so will not be clear till mid FY25 (late 2024). Any Indian SARI-Viral trial is still unclear but costs could be lower.

Accordingly, management has stated in the Q3FY24 report that current cash is not sufficient to fund the company for a further 12 months. NV has a line of credit from the CEO for up to US$2mln and is seeking to mortgage its headquarters, laboratory and GMP facility. An ATM facility for US$5.7mln was entered in August 2023 and became active in April 2024 which could yield cash if the market allows.

In our tentative financial forecasts, we have assumed careful cost control and added some extra US trial costs with an assumption of a further US5mln of funding plus the US$2mln CEO loan. The current market capitalization of about US$24mln would allow further funding.

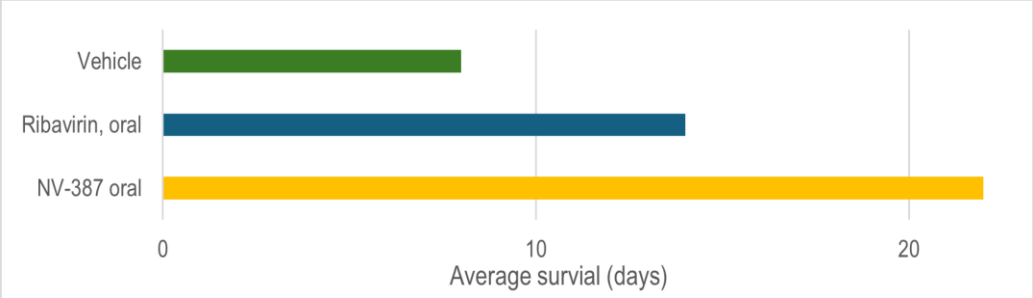
Dr Anil Diwan has been president and chairman since the company's founding in 2005. He invented novel polymeric micelle based nanomedicine technologies and founded TheraCour Pharma and AllExcel to develop the concept. TheraCour provides paid services to Nanoviricides. He also founded Karveer Meditech in India. He has a doctorate from Rice University, Texas, and followed a career in the pharmaceutical industry. He is married to NanoViricides' CFO Ms Vyas.

Preclinical tests show significant anti-RSV activity

NV announced more preclinical data on RSV on 14 May. The reported experiment compared oral ribavirin (as noted an off-label route in RSV) against oral NV-387. Mice infected with high RSV doses lived eight days if untreated, on average 14 with oral ribavirin and over 22 days on average (the end date of the experiment), hence indicating survival, with oral NV-387 (exhibit 2). Clearly, at the doses used (undisclosed) this is a major efficacy gain. It argues for a clinical trial.

Ribavirin is used orally to treat hepatitis C. It was approved in 1985 by the FDA as an inhaled formulation to treat severe RSV infection in children. It would normally be combined with other therapies. Oral doing is also used off label in adults. Adults undergoing chemotherapy or who have had stem cells transplants are particularly at risk of RSV.

Exhibit 1: RSV: mouse challenge model.



Meeta Vyas, CFO, has both board and senior executive experience in a broad range of entities including publicly listed corporations, not-for profit and medium to large companies. Meeta has experience in performance and process improvement in finance and operations, strategy and management. She holds an MBA in finance from Columbia University and a BS in chemical engineering from MIT.

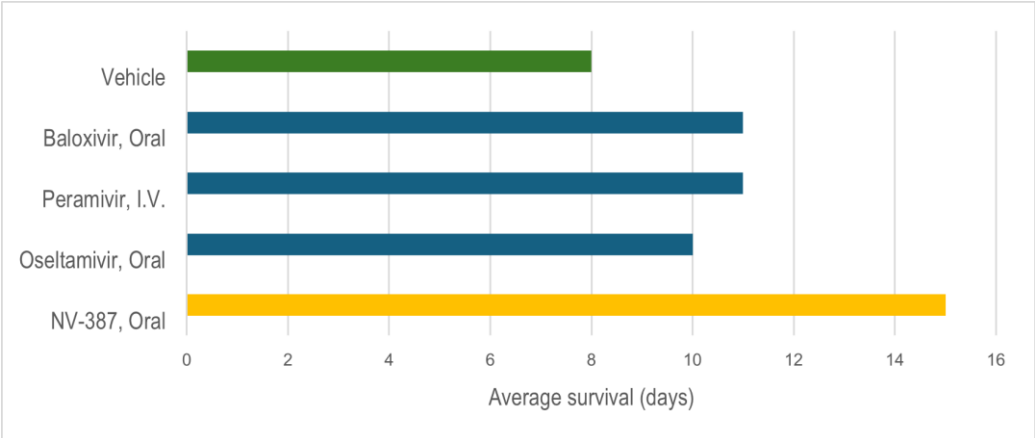
New preclinical data indicates wide spectrum NV-387 activity

NV has been developing the preclinical science of its micelle-based nanomedicine. The lead product is a sophisticated polymer (NV-387) to trap and disrupt viruses in the blood. The therapy aims to reduce the viral load to prevent infection of healthy cells and to enable the immune system to clear viruses rapidly. NV-387 has previously been observed to have preclinical "strong effectiveness" against RSV.

In new data (May 2024), NV has shown that NV-387 can be effective in a mouse model against Influenza A (H3N2). This model used a lethal dose of virus to get a clear effect in a short time. The data indicates a strong protective effect from NV-387. Fortunately, deaths from influenza are rare as a percentage of cases so mortality is not a good measure of a future clinical trial. Importantly, this used oral dosing (level undisclosed) which in this mass market is essential.

There are various existing therapies (Exhibit 2) but these need to be given early to have any effect. They typically reduce the duration of the symptoms by about 24 hours if taken within 48 hours of the infection starting. NV-387 increased survival by 88% compared to the control (called vehicle), Exhibit 2. Note that these preclinical experiments are very interesting but need translation into a human clinical context. Influenza trials tend to be large.

Exhibit 2: Influenza A: mouse challenge model.



NV has further shown in preclinical studies (first reported during 2023) that NV-387 destroys a mousepox virus (Ectromelia) related to the MPox virus. MPox (formerly called monkeypox and a relative of smallpox), a zoonotic (animal) virus, can be transmitted amongst humans by contact, usually sexual by the skin. MPox was a minor healthcare scare over summer 2023 as there were some transmitted cases in Western countries from a mild imported strain.

Some MPox strains can be dangerous but it has low transmissibility. There is a vaccine and a therapy, tecovirimat which is not formally approved. Tecovirimat as an acute MPox therapy has its human use based on animal data and by analogy with other orthopoxviruses. A possible emergency use indication of NV-387 as a combination with tecovirimat is possible (given there is soon to be at least technical Phase 1 data) as it appears synergistic in NV's preclinical work.

The new data is from an animal model where lethal aerosolized doses of Ectromelia (mimicking a possible bioterrorism incident - presumably involving smallpox) were given into the lungs of mice. In this case, NV-387 either on its own or with Tecovirimat improved survival from 8 days (untreated) to between 15 and 19 days.

Further work could be funded by BARDA (the US Biomedical Advanced Research and Development Authority). Smallpox vaccination is very effective if a threat is identified early.

RSV as a core lead in the US

In the US, the focus is on RSV. RSV is a viral lower lung infection particularly dangerous to infants under six months and young children up to five years old. It can also be dangerous in older adults (over 60) but adults can be vaccinated; young children cannot be (although maternal vaccination during pregnancy is available). It has been noted (**Li et al 2022**) that "More than 95% of RSV-… infection episodes and more than 97% of RSV-attributable deaths . were in low-income and middle-income countries" so an effective oral product could save lives. In high-income countries (Europe, Japan and North America), there are about 1.6 million hospitalized cases a year in under 5-year-old children - although data is not robust. Most countries report only severe hospitalized cases. Hence, there are many more unconfirmed community cases and an oral therapy could have a much wider market.

Hall *et al* (2009) reported that: "In the United States, RSV is associated with 18% of all respiratory illnesses in children <5 years, 20% of all hospitalizations, 18% of all emergency department visits, and 15% of all pediatric office visits."

However, there is an existing prophylactic antibody injection in the US, Beyfortus (Nirsevimab, Sanofi /Astra Zeneca), and funded by US government programs. Given as a single injection to children under 8 months old, this is FDA approved and CDC recommended. It reduces the risk of severe RSV disease by about 80%. It can be used in older infants. The other 20%, and untreated infants, could be the market for NV-387. Sales of Beyfortus in 2023 were €547mln (US$592). A second, older, product (Palivizumab, Sobi) needs monthly injection and can be given up to two-year-olds. Sales were reported at just SEK879mln (US$82 mln).

Older adults can be vaccinated, but not over 60-year-olds all are vaccinated in the US. The two FDA approved vaccines are:

Arexvy (GSK) which is 83% effective at preventing severe infection in year one and 58% effective in year two. A booster is then needed. Arexvy had 2023 sales of over £1.2bln (US$1.4 bln).

Abrysvo (Pfizer) is a newer product but behind in the market. It gave 89% protection in Year One; Year Two data is not yet available. Sales in 2023 were US$890mln. Pfizer has commented that it is seeking to broaden the indication to "adults aged 18 and older adults with underlying medical conditions." Abrysvo is also indicated as a Maternal vaccine. Given at 32-36 of pregnancy, it confers RSV immunity on the child when born.

Hence, there remains an acute market for rapid treatment of severe RSV as many are not vaccinated, protection is not total for those that are and there is a large adult population with morbidities that put them at risk. Development as a pediatric indication would be complex as dosage and safety will need to be established; we would see an adult version likely being first to market.

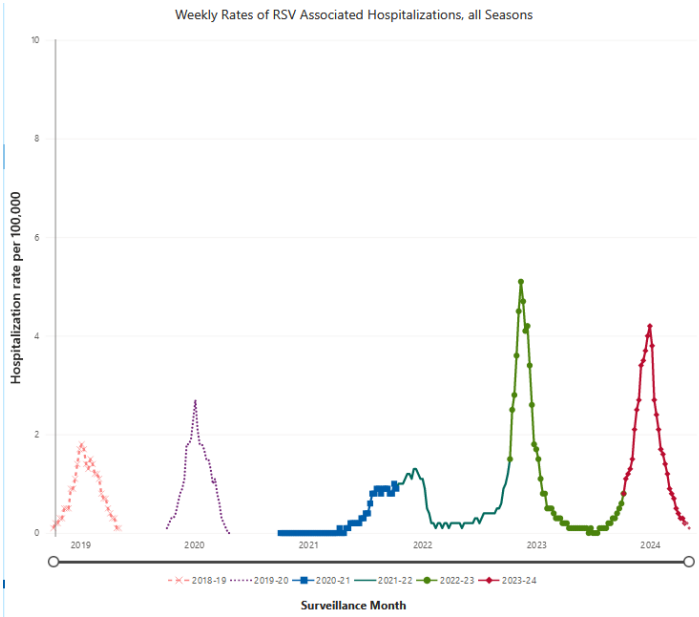
To enter US development, NV needs a pre-IND meeting with the FDA, probably once the Indian technical data is available and analyzed; this could be late summer 2024, about September. With planning and follow-up work, an IND could be filed in Q1 2025. This could lead to a granted IND by the end of Q1 so a trial can be ready for the 2025-26 RSV winter season. It is possible that a preliminary US study may be required.

RSV is highly seasonal (Exhibit 3) with a peak between mid-November and early January. In 2023-4, there were about 27,000 cases at the weekly peak with 181,000 infections overall, but this is very variable and was probably a bounce back after COVID-19 restrictions due to lower herd immunity. In 2019, the peak week was under 6,000 cases. If the season is missed, then data may not be adequate till mid-2026.

Most young children get RSV, mostly as a mild infection in winter - but it does result in many hospitalizations. There is also a market for the over 60s who did not receive vaccination. Note the above figures are just severe, laboratory confirmed cases. RSV is a highly contagious respiratory infection, and many more people will be infected over the seasonal peak. If NV-387 proves cost-effective and can be made widely available, it could help alleviate mild but debilitating symptoms in many people.

The overall strategy still seems to us to be sound since RSV is a known problem and at least a US$3bln market (for vaccines and antibodies). Some market estimates (not seen in detail) have estimated market growth to about US$8 bln.

Exhibit 3: RSV infection in the US is seasonal



Source: Center for Disease Control RSV Dashboard. Laboratory confirmed cases.

Corporate Structure

Nanoviricides operates as the top, public company for two separate private companies that hold the IP. NV has seven employees. The President and CEO, Dr Diwan, according to the 2023 10k filing, controls TheraCour. TheraCour carries out research work paid by and licensed to NV.

The Indian NV-CoV-2 trial is run by Karveer Meditech, a small Indian Pharmaceutical company owned by the Diwan family. Karveer is reimbursed for the trial costs by NV. We assume any SARI-Viral product trials will also be run via Karveer.

Financial forecasts

Year to 30 June	$(000s)	2022A	2023A	Q324A	2024E	2025E
Revenue						
Cost of sales						
Gross profit						
SG&A		(2,329)	(2,551)	(1,870)	(2,492)	(2,750)
R&D		(5,785)	(6,392)	(4,255)	(4,958)	(5,500)
Operating profit/(loss)		**(8,114)**	**(8,943)**	**(6,125)**	**(7,451)**	**(8,250)**
Financial		7	355	187	249	149
Tax						
Net profit/(loss)		**(8,107)**	**(8,589)**	**(5,938)**	**(7,202)**	**(8,101)**
Other						
Comprehensive loss		**(8,107)**	**(8,589)**	**(5,938)**	**(7,202)**	**(8,101)**
Av shares (Mln)		11.53	11.63	11.75	11.70	11.70
EPS		-0.70	-0.74	-0.51	-0.62	-0.69

Balance sheet

Year to 30 June	$(000s)	2022A	2023A	Q324A	2024E	2025E
Intangibles		384	348	327	340	331
PPE		8,694	8,107	7,603	7,507	6,907
Non-current		9,078	8,455	7,930	7,846	7,238
Pre-paid exp		350	295	277	295	295
Cash		14,066	8,150	3,257	1,645	1,152
Total assets		**23,495**	**16,900**	**11,465**	**9,786**	**8,685**
Trade payables		58	157	341	157	157
Related party payables		214	233	213	250	250
Related party milestone		-	1,500		-	-
Other current liabilities		140	144	259	144	2,144
Total liabilities		**413**	**2,034**	**813**	**551**	**2,551**
Share capital		145,574	145,946	147,670	146,018	151,018
Retained earnings		(122,492)	(131,081)	(137,019)	(136,782)	(144,884)
Total equity		**23,082**	**14,866**	**10,652**	**9,236**	**6,134**
Total liabilities & equity		**23,495**	**16,900**	**11,465**	**9,786**	**8,685**

Cash flow statement

Year to 30 June	$(000s)	2022A	2023A	Q324A	2024E	2025E
Net profit		(8,107)	(8,589)	(5,938)	(7,202)	(8,101)
Operational cash flow		(5,891)	(5,670)	(4,834)	(6,355)	(7,343)
Investments		(324)	(152)	(58)	(150)	(150)
Financing		(235)	(95)		-	7,000
Net change in cash		**(6,450)**	**(5,917)**	**(4,892)**	**(6,505)**	**(493)**
Beginning balance		20,516,677	14,066	8,150	8,150	1,645
Ending balance		**14,066**	**8,150**	**3,257**	**1,645**	**1,152**

Source: Nanoviricide reports(SEC database), Proactive estimates

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