proactive research

February 28, 2025

Healthcare	
52-WEEK HIGH	US$3.59
52-WEEK LOW	US$1.02
Price	US$1.31
MARKET CAP MLN	US$20.2
CASH (MLN)	US$4.0

Share Price

Major Shareholders	
Management & Board	2%
Vanguard	3.8%
Shares in issue (14 February 2025)	15,641,000
Avg three-month trading volume	368,683
Primary Index	NASDAQ
Next Key Announcement	Start of African Phase 2

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Mpox – a possible US$100mln+ opportunity

African clinical study planned to support government funding application

The Analyst's assessment

Nanoviricides (NV), a US company, targets the unmet medical need for an effective, broad-spectrum acute antiviral therapy with NV-387. NV has now opted to pursue a clinical Phase 2 in Mpox, a virus infection related to smallpox. An African trial is being planned; management see this as the fastest and most cost-effective way to gain clinical proof of concept. Mpox cases have risen in Africa over 2024. Results are possible from mid-2025. If successful, this could lead to possible development funding from the US biodefense agency (BARDA), probably from CY2026 given government timescales. The potential RSV indication is on hold till resources are available to run the US Phase 2.

NV's nano-polymer, micelle technology is designed directly to bind and destroy virus particles in the blood preventing them entering and infecting cells. NV's focus is on acute treatment of diseases like Mpox, RSV, flu (including potentially "bird flu") and COVID19. NV's lead molecule NV-387 completed a volunteer first Phase 1 study in India in 2023 showing safety and tolerability.

NV needs its Mpox Phase 2 to provide data to gain BARDA development funding. A precedent is a 2025 US$375mln contract between BARDA and Shionogi to develop a COVID-19 product.

In the US, a smallpox vaccine, JYNNEOS, is stockpiled by BARDA plus some yearly private use. Vaccine sales were US$450mln in 2024. An acute anti-viral drug, Tecovirimat (Siga), has failed to show good efficacy against Mpox leaving an unmet need that might be filled by NV-387. Siga had 2023 Tecovirimat sales of US$131 mln, its only product. Siga has a market value of about US$400mln from ongoing BARDA stockpile contracts. This could indicate a future value benchmark for NV if NV-387 proves clinically efficacious.

Background

In 2023, NV-387 successfully completed a Phase 1 Indian study with various oral single and multiple doses using healthy participants. The full data is still being processed and the results to date show that oral NV-387 is safe and well tolerated with no adverse events.

NV has previously announced preclinical data on MPox using a mouse model. Mpox, is related to smallpox but with low mortality. Smallpox, although eradicated, is a major potential biosecurity risk hence the US government stockpiles drugs and vaccines. NV plans to file with regulators in March and start an African Mpox Phase 2 from April onwards. Results could be available from late summer CY2025. In the US, there are a few cases per week of Mpox. Outbreaks in the Western Hemisphere are triggered by the exotic pet trade and international travel (NIH); 31,000 US cases have been reported since 2022. In Africa, in 2024 to 1 Sept, about 5,732 cases were reported with 35 deaths (WHO).

We note the preclinical data on Influenza A with NV-387 compared to existing blockbuster therapies., Influenza can account for 1.5% of weekly deaths in January 2025 in the US: 200-300 per week according to CDC. Avian flu, present in US cattle, may become a hazard but the concern is transmission from infected birds (very rare) and mutation to allow human transmission, not seen.

RSV remains as an ongoing preclinical program. This will progress when funds allow with an IND application then a US Phase 2. There are vaccines and a good prophylactic antibody in infants.

The core NV-387 patents expire between 2026 and 2028. A 2020 application has limited designation. On an FDA approval, NV can rely on US exclusivity of five years plus six months for a pediatric indication or seven years if an orphan drug. Exclusivity is longer in Europe.

Financial – ATM providing cash; funding adequate for proposed MPox Phase 2

The operating cash burn over FY 24 (to 30 June 2024) was US$6.3mln. This was offset by US$3.1mln from the sale of common stock. The Q2FY25 10-Q report (14 February 2025) stated that cash resources are insufficient to fund a further 12 months. On December 31 2024, cash (including prepayments) was US$4.1mln. The ATM facility yielded US$4.0mln in H1FY25. We estimate that NV may require US$3.5mln more cash over the remainder of FY25. A US$3mln loan facility from the CEO is available; a previous US$1.5mln loan was converted to preferred stock in FY24.

As of February 14, 2025, there were 15.64 mln shares, a rise of 2.5 mln since 30 June.

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.

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.

A US$100 mln+ opportunity in Mpox

Although smallpox, a major killer, has been eliminated, related but far less lethal related viruses are still circulating. One of these is "monkeypox", now referred to as Mpox (UK Health agency). There are two varieties (clades) circulating: I and II with subtypes.

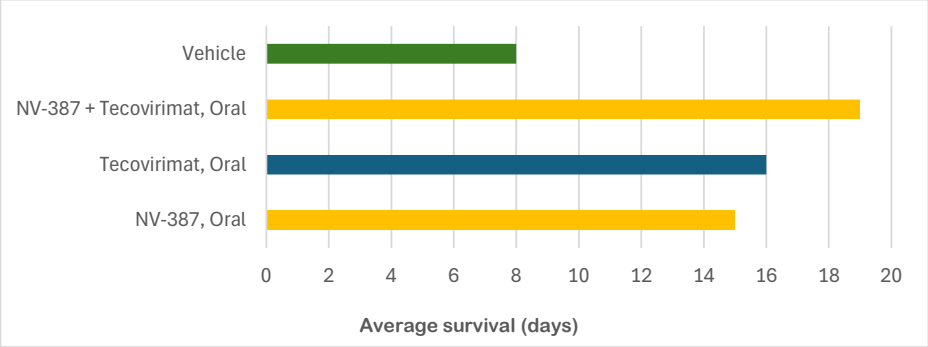
- Clade I/1b is virulent and endemic in central Africa and occasional cases are brought into the US by travelers. African cases rose in 2024.
- Clade II is milder. Clade IIa is in Africa; Clade IIb is present in the US at very low reported circulating levels, currently under 10 cases a week (CDC) after an outbreak in 2022.

Mpox transmission is through contact with infected individuals and Mpox transmits within households. However, most community transmission seems to be sexual, particularly male to male. After a symptom-free incubation of one to two weeks, a short fever ensures followed by pustules around the mouth and face. These spread, typically to the hands and feet, and gradually crust over. The infection resolves in 3-4 weeks. Mortality is low (about 1-4 %+) in adults in Africa infected by Clade I/Ib but it can be higher (about 11%) in younger children. The WHO reports a 2024 outbreak to 1 September in the Democratic Republic of Congo (5,147 cases) with 90 cases in other countries. Since 2022 in the US, there have been over 31,000 cases and 50 deaths due to Clade IIb. Up to 40% of cases required medical treatment, and 1-13% required hospital admission for treatment or isolation (Bavarian Nordic report).

There is an approved, effective vaccine, JYNNEOS (Bavarian Nordic); 2024 sales of US$450mln. The vaccine gives high antibody titers and in "real world" studies offered 66-89% Mpox protection. An acute therapy, tecovirimat is approved for smallpox (and by analogy Mpox) and is stockpiled for emergency use. Sales in 2024 (largely to the US stockpile) were US$130mln; tecovirimat has failed to show efficacy.

NV has mouse model data where lethal aerosolized doses of a murine pox virus (Ectromelia, so mimicking a possible bioterrorism incident) were given to mice. NV-387 either on its own or with Tecovirimat improved survival from 8 days (untreated) to between 15 and 19 days (Figure 1). Further work might be funded by **BARDA** (the US Biomedical Advanced Research and Development Authority).

Figure 1: preclinical Mpox data



Source: Analyst Hire based on Nanoviricides press release

Clinical development of NV-387 in Mpox

No trial plan is yet public for the African study. Results could be available from late summer CY2025.

An analogous study in the DRC at two sites was run by the National Institute of Allergy and Infectious Diseases (NIAD) (NCT05559099); called PALM 007. This recruited nearly 600 patients and tested Tecovirimat. It took about two years to run (Shabil et al (2024)). Mortality was reduced from 3.6% to 1.7% but the study did not meet the primary endpoint of reduced time to lesion clearance. However, patients who received Tecovirimat early and had more severe disease had less severe symptoms. A US NIAD Mpox study, STOMP (NCT05534984) enrolled over 700 patients in Phase 3 over about two years. The trial stopped early in December 2024 on futility grounds as it failed to show efficacy in reducing the time to clear lesions (NIH STOMP). The failure of these two trials means that there is an unmet need for an effective acute Mpox therapy that NV-387 might fill. BARDA continues to buy Tecovirimat for the US stockpile as no alternatives are available. BARDA might fund development work from CY2026. BARDA recently agreed pay **Shionogi** US$375mln to help develop a preclinical (Phase 1 due in 2025) product for COVID-19 prophylaxis.

NV-387 – a novel, non-biological anti-viral opportunity

NV has been developing a range of anti-viral polymers for over 20 years. The latest iteration, with a world patent application filed in 2020, is NV-387. The molecule has three linked components:

- A virus binding component, these mimic the natural cell-surface molecules that the virus binds to so in the case of RSV this is a heparin-sulfate-like molecule;
- A water-soluble component (polyethylene glycol (PEG)) to enable the polymer to disperse in the blood and circulate systemically; and
- A water hating component to act as the core of the polymer and to "attack" and disrupt the shells of bound virus particles.

NV-387 is a polymer: it is assembled from multiple copies of the basic monomer (Figure 2). At least five of these are then linked to form the polymer (Figure 3). Note the red, pendant, water-hating chains may may only be 50% present.

Figure 2: Monomer structure

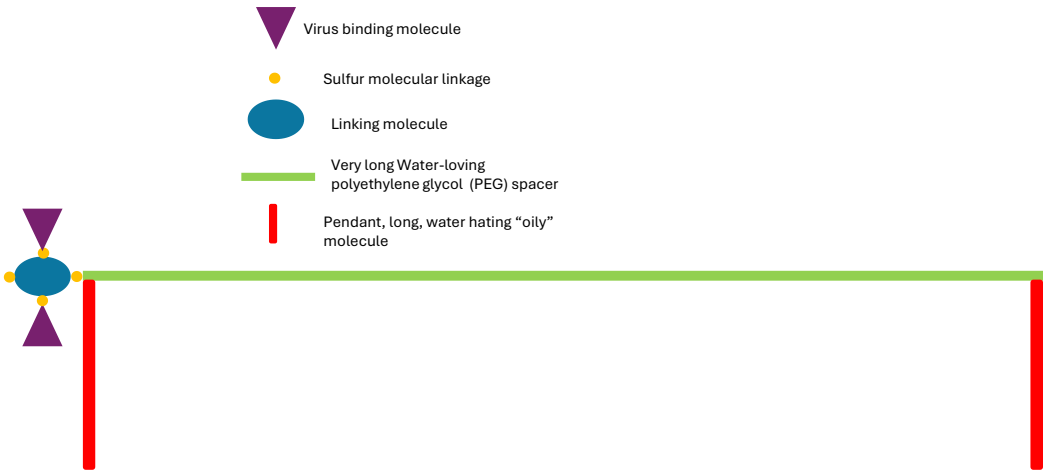
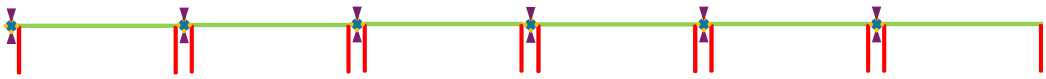
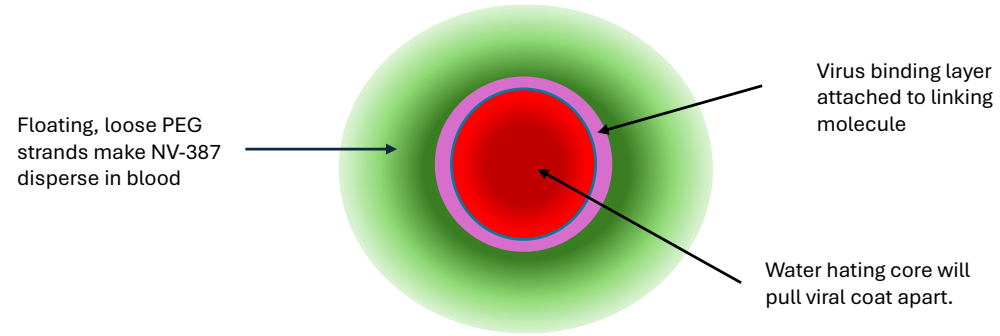


Figure 3: polymer structure shown as a linear molecule



In practice, because they have a water loving part (the PEG) and a water hating part, the polymers form micelles with the water hating part inside and the PEG strands outside, Figure 4.

Figure 4: schematic of NV-387 micelle



Sources (Figures 2-4): Analyst Hire based on patent applications and discussion with management

Influenza and bird flu indications

Flu is a respiratory viral infection. The two proteins on any flu virus surface are hemagglutinin (H) and Neuraminidase (N). There are various types of these identified by numbers. Simplistically, H1N1 is human flu and H5N1 is bird flu. Apart from vaccination and some largely ineffective anti-viral products, that need to be taken verry soon after infection, there are no treatments. If NV-387 or a derivative can bind and neutralize flu virus in the blood, it could limit symptoms and speed recovery.

Hemagglutinin binds to sialic acid sugars on the surface of cells in the respiratory tract. However, sialic acids link together to form chains in different ways in human and birds. So H1 binds α2-6 links and H5 binds α2-3. These give very different molecular shapes so normally H5N1 cannot infect mammals.

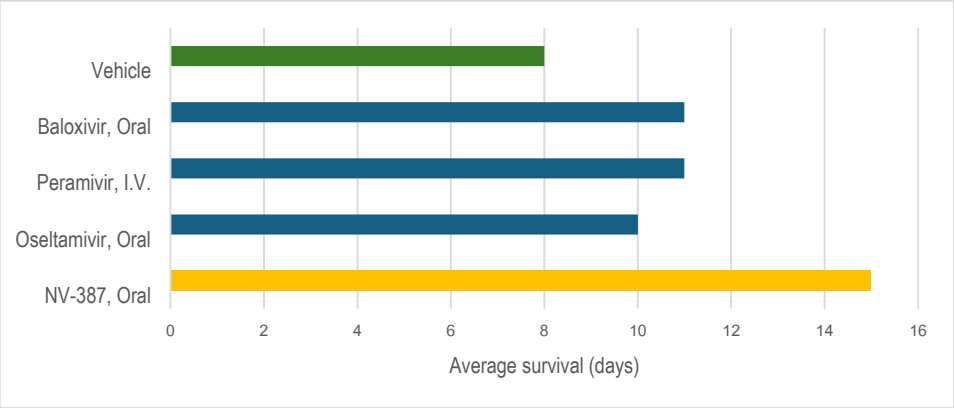
Nonetheless, viruses evolve and diversify rapidly and the a bird flu strain has infected cattle and can be acquired by humans working with cattle - although it currently does not transmit between human hosts and is a mild strain. H5N1 in cattle is found mainly in the mammary gland (whose cells produce α2-3 sialic links) and is probably spread by milking equipment (Mostafa *et al* (2024)).

So far, there has been only rare direct infection from wild birds and infected poultry (Kolzov 2025). To date, there have been 24 cases and two deaths. Currently (January 15 2025) CDC assess the risk as low but this is being monitored. The concern is that this virulent strain mutates to enable human to human transmission.

Figure 6 shows an NV influenza challenge animal model, data from May 2024. Animals were given a very high, lethal, dose of virus and died in about a week unless treated. Current antivirals gave some protection, but NV-387 showed a longer survival time.

Flu challenge clinical trials are routine. These are when volunteers are infected with flu under controlled, residential, condition and responses to therapies assessed. Hence, If NV-387 gains an IND, it should be feasible to run a challenge study relatively quickly to give a clinical profile.

Figure 6: preclinical mouse data on NV-387 against influenza.



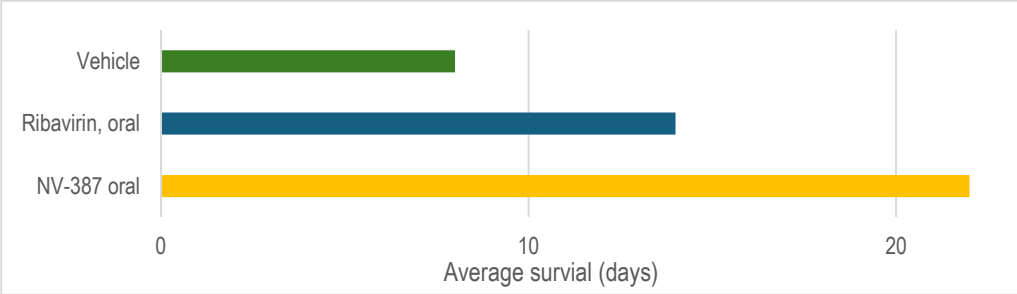
Source: Analyst Hire based in NV data

In the early 2000's, several governments started to stockpile anti-viral drugs, like Tamiflu (Oseltamivir, Roche) in case of an epidemic. The ASPR keeps a strategic stockpile of therapeutics like Tamiflu. The US also has the Influenza & Emerging Infectious Diseases (EID) medical countermeasures program focused on vaccines.

RSV preclinical data and commercial opportunity

NV announced preclinical data NV-387 against RSV on 14 May 2024. The reported experiment compared oral ribavirin (see below) 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 and so potential cure with oral NV-387 (Figure 5).

Figure 5 – Preclinical efficacy of NV-387 against RSV



Source: Analyst Hire based on Nanoviricides reports

Ribavirin 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. It is used off label in adults.

RSV market

Respiratory Syncytial Virus (RSV) poses a serious health risk in newborn and young infants and in older adults. RSV is widespread in most winter seasons although the level varies markedly. Most people and infants have mild flu-like symptoms which resolve in a few days. RSV can be lethal in young children with historically 65,000 hospitalizations a year. As acquired immunity wanes, older adults (60+) start to be at risk with historically up to 193,000 hospitalizations.

The clinical need was recognized early but RSV vaccines in the 60's had complications and were abandoned. New, biotech, vaccines were developed, and two adult vaccines were approved in 2023: from GSK, Arexvy; and from Pfizer, Abrysvo. Moderna developed an RNA vaccine: mResvia: This was approved in summer 2024 for adults; an infant indication was abandoned.

After combined 2023 global sales of about US$2.5bln, a potential, but very rare, side effect: Guillain-Barré syndrome, (GBS, an autoimmune condition targeting peripheral nerves) was quantified as a risk for Arexvy and Abrysvo. This led to US medical advice limiting vaccination to the highest risk groups: over 75-year-olds and at risk over 65s. Only one lifetime vaccination is now given. This led to a dramatic 50% fall in US sales of Arexvy and Abrysvo from a combined US$2.2bln in 2023 to US$1.2bln in 2024; Modena's mResvia FY24 sales were US$25mln but without GBS risk.

For young children up to eight months old, a protective monoclonal antibody, Beyfortus (Sanofi), was approved in 2023; over winter 2024-25 stocks will enable all newborns to be protected, US 2024 sales were US$1.1bln, up 130% from 2023. The adult vaccine Abrysvo can be given to pregnant women and antibodies are passed to the fetus protecting the child after birth.

Nanoviricides opportunity for NV-387

Before the vaccines were available, 54,000 individuals over 75 would be hospitalized each winter with RSV in the US. Vaccination should now cut this significantly but vaccination protection wanes over the subsequent two years and so an effective acute treatment may still have a key medical role. Other adults do not now get vaccination unless high risk and have no current direct therapy.

In young infants, Beyfortus is given with normal childhood vaccines after birth in the RSV season. It is funded by US government programs and by private insurance. However, Beyfortus is not routinely given to children over eight months and there are an estimated 19,000 infants aged 12-23 months in the US hospitalized with RSV each winter. Also, Beyfortus reduces RSV by 80% but this still leaves some younger children who may still need hospitalization and possible additional therapy.

Development of NV-387 for RSV in the US will require an IND. A Phase 2 will then indicate efficacy. We have no current timeline as a US clinical development would be expensive.

Patents and protection

The original patents on the polymer format were filed in the early 2000's by Dr Divan and co-workers and assigned to AllExcel Inc. AllExcel is funded by Theracour; both appear to be controlled by Dr Divan. Theracour then licenses the IP to Nanoviricides. The core patent was filed in 2007 and will expire in 2027. The US application of this patent was abandoned.

The latest patent application by AllExcel covering NV-387 and its use in drug delivery (as a possible COVID-19 product) was filed in 2020, WO2022272181A1; the designated territories do not cover the US or Europe. The means that US regulatory exclusivity for NV-387 if approved will be five years. If classed as an orphan drug, this rises to seven years. A further six months is added for a pediatric approval.

In Europe, data exclusivity will be granted for six years (currently eight) plus market protection for a further two years. An orphan indication gives 10-year exclusivity. Pediatric use adds another six months.

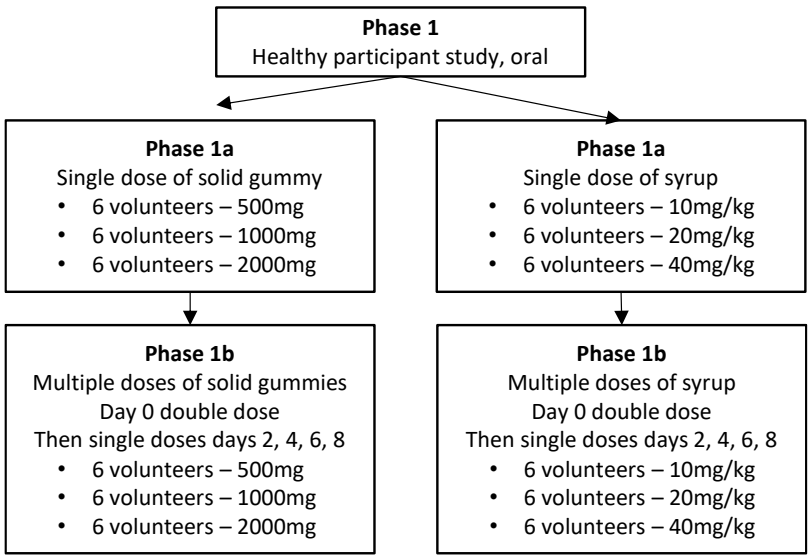
Given some of the indications have low patient numbers, orphan designation appears possible but needs to be sought by NV

Clinical data to date

NV-387 competed a volunteer Phase 1a (single dose) and Phase1b (multiple dose) study in India in December 2023. There were 18 participants in each arm and 3 dose levels of 500mg to 2000mg, Figure 7. At the time of writing, the only report from the study is that NV-387 was well tolerated with no serious adverse events noted. Data analysis is reported to be ongoing by the CRO.

The key aspect to note from the final report, expected in 2025, will be the pharmacokinetics, that is how much NV-387 enters the blood and over what time course. As an oral product, the bioavailability and clearance rate are crucial. There is no detailed report of the preclinical animal data and in any case, it is difficult to relate animal study dosing to human studies where doing is usually much lower.

Figure 7 – Phase 1 trial structure



Source: Analyst Hire based on Nanoviricides reports.

Financial statements

NV has published its Annual report to June 30 2024 and the H1 statement to 31 Dec 2024. The H1FY25 cash burn was US$4.8 mln before equity funding, using the At the Market (ATM) facility, of US$4.0mln. We therefore assume a cash use over all of FY25 of about US$10mln. There are costs to complete the data from the Phase 1 and undertake the African trial. Overall, we therefore assume a cash need in FY25 of US$7.5mln of which US$4mln was gained in H1FY 25.

Income statement

Year to 30 June	$(000s	2022A	2023A	2024A	H1FY25	2025E
Revenue						
Cost of sales						
Gross profit						
R&D		(5,785)	(6,392)	(5,437)	(3,089)	(6,179)
SG&A		(2,329)	(2,551)	(3,079)	(2,137)	(4,275)
Operating profit/(loss)		**(8,114)**	**(8,943)**	**(8,516)**	**(5,227)**	**(10,454)**
Financial		7	355	222	73	140
Tax						
Net profit/(loss)		**(8,107)**	**(8,589)**	**(8,294)**	**(5,154)**	**(10,314)**
Other						
Comprehensive loss		**(8,107)**	**(8,589)**	**(8,294)**	**(5,154)**	**(10,314)**
Av shares (Mln)		11.53	11.63	11.87	14.13	18.00
EPS		-0.70	-0.74	-0.70	-0.36	-0.57

Cash flow

Year to 30 June	$(000s	2022A	2023A	2024E	H1FY25	2025E
Net profit		(8,107)	(8,589)	(8,294)	(5,154)	(10,314)
Operational cash flow		(5,891)	(5,670)	(6,316)	(4,786)	(9,442)
Investments		(324)	(152)	(157)	(47)	(150)
Financing		(235)	(95)	3,120	3,993	7,500
Net change in cash		**(6,450)**	**(5,917)**	**(3,352)**	**(840)**	**(2,092)**
Beginning balance		20,517	14,066	8,150	4,798	4,798
Ending balance		**14,066**	**8,150**	**4,798**	**3,958**	**2,706**

Balance Sheet

Year to 30 June	$(000s	2022A	2023A	2024E	H1FY25	2025E
Intangibles		384	348	340	327	327
PPE		8,694	8,107	7,512	7,172	6,888
Non-current		9,078	8,455	7,852	7,499	7,215
Pre-paid exp		350	295	173	114	114
Cash		14,066	8,150	4,798	3,958	2,706
Total assets		**23,495**	**16,900**	**12,823**	**11,571**	**10,035**
Trade payables		58	157	376	252	252
Related party payables		214	233	720	867	867
Related party milestone		-	1,500	-	-	-
Other current liabilities		140	144	262	65	266
Total liabilities		**413**	**2,034**	**1,359**	**1,184**	**1,385**
Share capital		145,574	145,946	150,839	154,916	158,339
Retained earnings		(122,492)	(131,081)	(139,375)	(144,529)	(149,689)
Total equity		**23,082**	**14,866**	**11,464**	**10,387**	**8,650**
Total liabilities & equity		**23,495**	**16,900**	**12,823**	**11,571**	**10,035**

Source: Nanoviricides reports (SEC database), Analyst Hire estimates

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 2024 10k filing, controls TheraCour. TheraCour carries out research work paid by and licensed to NV. A third owned company, AllExcel holds the patents on NV-387.

The Indian NV-CoV-2 trial was run by Karveer Meditech; a small Indian pharmaceutical company owned by the Diwan family. Karveer is reimbursed for the trial costs by NV.

Investment conclusion -African Mpox trial may enable BARDA funding

Nanoviricides has a novel therapeutic product with much needed acute anti-viral capability. A Phase 1 showed safety and tolerability. The African Phase 2 in Mpox will give valuable data from late summer 2025 on the potential efficacy against Mpox infection. This could open the way to non-dilutive research and development funding by US protection agencies from 2026.

Since Tecovirimat has just failed in two large clinical studies, we presume that BARDA could be interested in seeking a more effective product to replace it and hence be potentially willing to fund NV-387 development. Nanoviricides will require further funding to achieve these goals as US grant funding before CY2026 seems unlikely due to US government timescales.

The analogy with Siga, the producer of Tecovirimat, shows that NV-387 as an emergency use, US stockpiled product, could have sales of around US$100+mln a year and a future value of about US$400mln; US$300mln before cash. This compares to NV's US$19.5mln (25 January); US$15.5mln before cash. Other indications, like RSV, would boost that future value.

However, NV does not have an IND for NV-387 and is reliant on adequate data from the proposed African study and the completed Indian Phase 1a to convince BARDA to fund further development. The possibility of NV winning a BARDA award should be tempered by the uncertainty around the Trump administration's policies and the changes in US public sector funding due to the current, Musk-led, DOGE initiative.

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