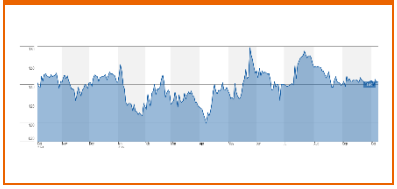
October 14, 2025

Healthcare	
52-WEEK HIGH	US$1.92
52-WEEK LOW	US$0.94
Price	US$1.37
MARKET CAP MLN	US$23.80
CASH (MLN)	US$1.56

Share Price



Major Shareholders	
Management & Board	2%
Vanguard	3.8%
Shares in issue (24 Sept 2025)	17,434,535
Avg three-month trading volume	181,412
Primary Index	NASDAQ
Next Key Announcement	Start African Phase 2

Company Information

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Dual track clinical development during 2026

NV-387 could compete as an acute therapy in the potential US$7.2 bln viral respiratory market

The Analyst's assessment

Nanoviricides (NV), a US company, targets the unmet medical need for an effective, broad-spectrum acute oral antiviral therapy with NV-387. NV's nano-polymer, micelle technology directly binds and destroys virus particles in the blood preventing them entering and infecting cells; in effect a highly selective, ruthless (but safe) nanomachine.

NV is now pursuing a dual track strategy for clinical development. The first trial will be against MPox virus, a relative of smallpox. The second is in respiratory viral diseases. NV's lead molecule NV-387 has already completed a Phase 1 study in 2023 showing safety and tolerability.

The immediate study, which could start by late CY25 or early in CY26, is for MPox. MPox is an endemic virus related to smallpox so has biodefense applications. Ethics approval for an NV-387 Phase 2 trial in Congo has already been gained; the next stage is a formal Phase 2 Clinical Trial Application (CTA). A successful African trial could lead to possible development funding from the US biodefense agency (BARDA).

The second planned study uses mostly the same CTA as the MPox study but will target respiratory viral diseases. An adaptive "basket-type" trial in India will gather data on NV-387 efficacy against flu, RSV and coronaviruses. This might start in winter 2026 but a later start is possible. This could lead to focused US trials, perhaps from 2027. Management notes independent estimates of a US$2.6 bln opportunity in RSV and US$4.6 bln in influenza.

NVs FY25 financial report showed Y/E US$1.6 mln in cash A further US$1.25 mln net was received through an "at the market" facility by 24 Sept 2025. We estimate a probable need for about $8 mln of FY26 funding at constant burn rates so NV may require a further US$6.75 mln as of October 2025. NV also has a US$3 mln loan facility from management. Non-dilutive funding for clinical development is being explored.

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; the results to date show that oral NV-387 is safe and well tolerated at high dose levels with no adverse events.

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. There are MPox cases in the US at a low level and of a milder strain (CDC MPox). Biosecurity contracts can be worth US$ 100+ mln.

RSV remains a serious medical issue in newborn children and infants (and also in older adults). It will progress through the proposed Indian "basket" study and then could move into a US program with an IND application then a US Phase 2.

Measles, a dangerous and highly contagious viral infection is resurging due to falling levels of childhood vaccination. It is still at a low level, but local epidemics can occur and there is no treatment. NV is looking at assisting with small investigator-led use.

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 – June 30 cash of US$1.6 mln with further funding needed

In FY25 (to 30 June 2025), NV had operating costs of US$9.6 mln; FY 24 costs were US$8.5mln. Higher FY25 costs were driven by a 31% rise in G&A expenditure (US$4.0 mln vs US$3.1 mln); R&D costs rose by 2.7% to US$5.6 mln.

On June 30, 2025, cash was US$1.6 mln after YTD equity funding of US$5.3 mln net through an At-The-Market (ATM) facility.

As of 24 Sept, 2025, there were 17.4 mln ordinary shares, up from 16.1 mln in June. In addition, there are 0.9mln Series A convertible shares but these only convert on a change of control.

From July to 24 Sept, a further US$1.25 mln was raised. Our estimate is that NV will require at least US$8 mln in funding over FY26 so a further $6.7mln of funding is required as of October.

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.

MPox trial application progress and possible further opportunities

Alongside the existing focus on MPox with a planned Phase 2, new openings have arisen. The Mpox $100 mln+ opportunity was extensively discussed in our 28 February 2025 note.

Clinical development of NV-387 in Mpox – Congo trial to prove concept

NV has been granted approval to submit a Clinical Trial Authorization (CTA) for a Phase 2 in MPox by the National Ethics Committee for Health of the Democratic Republic of Congo (DRC). NV expects the CTA to be approved quickly once submitted; the application may be approved before the calendar year end. NV has identified a suitable clinical trial site and the trial will be run by a clinical trial organization.

If the trial results are positive, BARDA might fund development work. As a deal prototype, BARDA has agreed pay Shionogi US$375mln to help develop Ensitrelvir as a product for COVID-19 prophylaxis, an IND was filed in April on a rolling basis but the US trial does not appear to have commenced; Ensitrelvir is approved in Japan.

Viral respiratory diseases –Indian Phase 2 followed by focused US studies.

Because NV-387, and the nanoviricide concept generally, can target multiple virus strains and types, NV is planning to run a "basket-type" Phase 2 in India. This will need a revised CTA but most work is already in place. We envisage that this type of trial would aim to prescribe NV-387 or placebo direct to patients presenting with potential respiratory infection. Patient outcomes would be reported, and the virus type (if present) categorized later. This could give enough patients, depending on size, with common viral infections including Respiratory Syncytial Virus (RSV), influenza and coronavirus. As a follow on, a specific initial Phase 2 indication in the US could be pediatric RSV infection. There is a prophylactic RSV therapy but no acute treatment.

Measles: a treatment countering a worrying trend?

At current MMR vaccination levels, measles might become endemic again by the 2040s Two doses of MMR give 97% protection against measles, but vaccination rates vary a lot by state. A nanoviricide may offer an easy oral acute treatment. This might be initially developed with investigator-led studies.

An avian opportunity could take flight

NV-387 could have efficacy against bird flu; we have no specific data. It has been orally delivered in a Phase 1 so might be used as an emergency treatment in human bird flu cases..

Science background

MPox, manifested as pustules on the skin and spread by direct and sexual contact, comes in a more severe clade I strain (found in Congo) and a less severe, but still nasty, clade II strain which is endemic at low levels in the USA (CDC-MPox). MPox virus is related to smallpox so in theory, If NV-387 treats MPox, it could also be active if a smallpox outbreak occurred – this is a biosecurity risk as smallpox has been eliminated in the wild. There is an Mpox vaccine.

Respiratory Syncytial Virus (RSV) poses a serious health risk in newborn and young infants and in older adults. RSV is widespread in most winters. For young children up to eight months old, a protective monoclonal antibody, Beyfortus (Sanofi), is available and was widely used over 2024-25. A new product, Enflonsia (clesrovimab-cfor, Merck) was FDA approved in June 2025 and recommended for EU approval in September.

Flu, including bird flu, is genetically unstable and mutates quickly, hence the problem of trying to produce effective vaccines. NV-387, with its broad spectrum binding capability, could be effective against multiple flu strains. Bird flu can infect dairy cattle with very rare transmission to farm workers Human to human bird flu transmission has not occurred but remains a serious concern.

Measles is a contagious virus of the *Paramyxoviridae* family whereas flu is a member of the *Orthomyxoviridae*. Measles is genetically stable and targets a specific human receptor. We currently have no preclinical data on NV-387 against measles, but management has initiated an animal study.

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 1). At least five of these are then linked to form the polymer (Figure 2). Note the red, pendant, water-hating chains may may only be 50% present.

Figure 1: Monomer structure

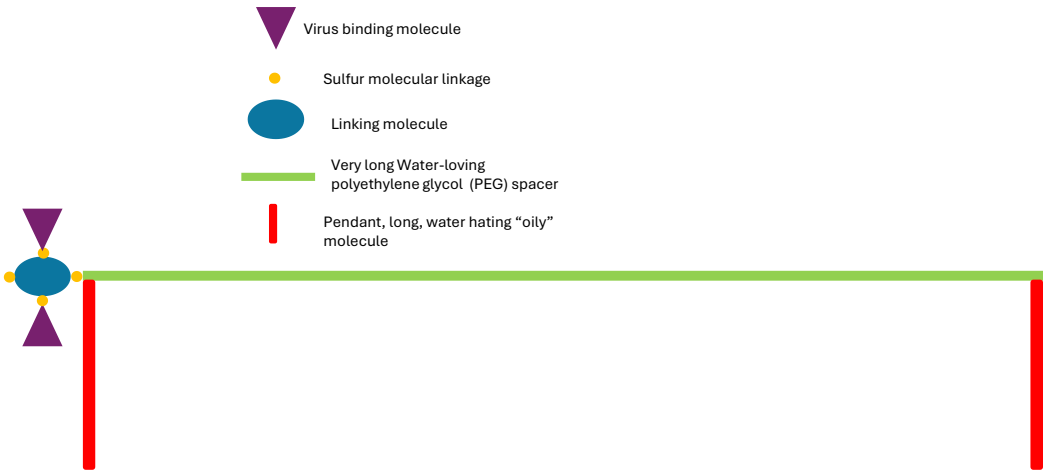
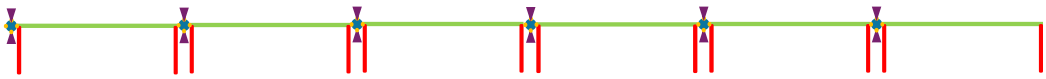
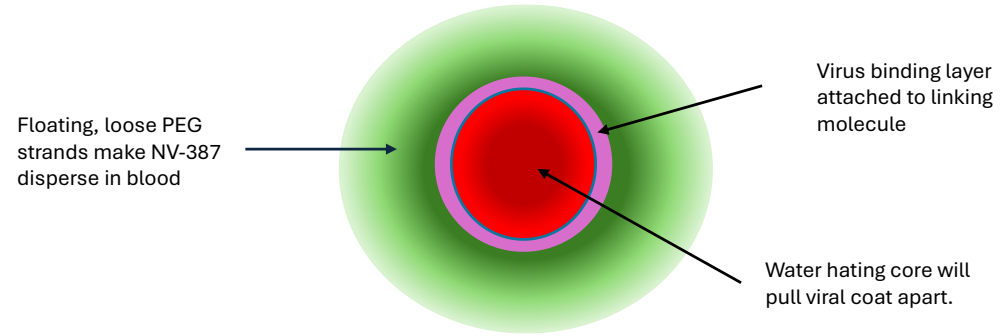


Figure 2: polymer structure shown as a linear molecule



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 3.

Figure 3: schematic of NV-387 micelle



Sources: Analyst Hire based on patent applications and discussion with management

MPox status and opportunity

Mpox manifests as pustules on the skin and is spread by direct and sexual contact. It comes in a more severe clade I strain (found in Congo) and a less severe, but still nasty, clade II strain which is endemic at low levels in the USA (CDC-Mpox). Mpox virus is related to smallpox so in theory, If NV-387 treats Mpox, it could also be active if a smallpox outbreak occurred – this is a biosecurity risk as smallpox has been eliminated in the wild.

NV had previously announced an African Mpox study was being planned. An announcement on 8 May disclosed that the National Ethics Committee for Health of the Ministry of Public Health of the Democratic Republic of Congo (DRC) has approved the trial ethics. This allows a trial design to be submitted for a Clinical Trial Authorization from the DRC pharmaceutical regulator: Autorité Congolaise de Réglementation Pharmaceutique (ACOREP). This could be completed by late 2025. If so, the trial could be relatively quick to run and produce during 2026.

Current therapies and previous studies

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 US use. Sales in 2024 (largely to the US stockpile) were US$130mln; tecovirimat has failed to show efficacy but might be better than nothing in an outbreak.

An analogous study to that probably proposed by NV was run in two sites in the DRC was run by the National Institute of Allergy and Infectious Diseases (NIAID) (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 Tecovirimat failed to show efficacy in reducing the time to clear lesions (NIH STOMP).

Flu and bird flu indications and human risk

Flu is a respiratory viral infection. Apart from vaccination and some largely ineffective anti-viral products, that need to be taken very 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. The two proteins on any flu virus surface are hemagglutinin (H) and Neuraminidase (N). Human flu over the 2024-25 season was usually H1N1 or H3N2 (CDC-flu). Flu also mutates quickly so NV-387 needs to prove efficacy against multiple strains.

Bird flu is H5N1, but a recent strain is H7N9. Hemagglutinin binds to sialic acid sugars on the surface of cells in the respiratory tract. However, the sialic acid forms are different in humans and birds. NV-387 appears to bind both human and bird flu strains - though we have not seen data. H5N1 in cattle is found mainly in the mammary gland (which has bird-like sialic acid forms) and is probably spread by milking equipment (Mostafa *et al* (2024)).

As of Feb 26 2025, CDC assessed the risk as low with 70 cases of bird flu in humans; 67 of these worked with poultry or cattle. The concern is that this virulent strain mutates to human-to-human transmission. So far in 2025, this has not been reported.

In the early 2000's, several governments started to stockpile anti-viral drugs 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. NV-387 might be included in such programs after appropriate development

RSV preclinical data and commercial opportunity

Respiratory Syncytial Virus (RSV) poses a serious health risk in newborn and young infants and in older adults. RSV is widespread in most winters and can be lethal in young children with historically 65,000 hospitalizations a year - through this varies widely. As acquired immunity wanes, older adults (60+) start to be at risk with historically up to 193,000 hospitalizations. 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. The adult vaccine Abrysvo can be given to pregnant women to protect the child after birth.

After combined 2023 global sales of about US$2.5bln, rare side effect was noted for Arexvy and Abrysvo. This led to US medical advice limiting vaccination. This led to a 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.

For young children up to eight months old, a protective monoclonal antibody, Beyfortus (Sanofi), is available and was widely used over 2024-25. US 2024 sales were US$1.1bln, up 130% from 2023; worldwide, sales were about US$1.8 bln. Sanofi was reported in June 2025 as increasing capacity ahead of the 2025-6 season.

A new antibody for prophylaxis, Merck's Enflonsia, was approved by the FDA in June 2025 and recommended for EU approval in September. It should gain sales in the US in autumn 2025 but its main sales impact will be in 2026. Other products are in development.

Nanoviricides opportunity for NV-387

Before the vaccines were available, 54,000 individuals over 75 were hospitalized each winter with RSV in the US. Vaccination should now cut this significantly, but an acute treatment may still have a key medical role. Other adults do not now get vaccination (unless high risk).

In young infants, Beyfortus is given after birth in the RSV season. 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. Enflonsia will be similar.

According to the CDC, Beyfortus reduces severe RSV by 79% and hospitalizations by 81%. Merck's Enflonsia reduced RSV infections by 60% and hospitalizations by 91%. This still leaves some younger children who may still need additional therapy; and not all will receive antibodies.

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 pediatric clinical development would be expensive. However, development from 2027 might be feasible.

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

Corporate structure

Nanoviricides operates as the top, public company for two separate private companies that hold the IP. 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

Financial statements

NV reported its FY25 financial data on 30 September 2025.

NV had FY25 operating costs of US$9.8 mln. Over FY24 costs were US$8.5 mln. The higher FY25 YTD costs were driven by 31% increased G&A expenditure to US$4.0 mln due to increased investor outreach activity. R&D costs rose by 2.1%. On June 30 2025, cash (excluding prepayments) was US$1.6 mln after net equity funding of US$5.3 mln.

We estimate that NV will need a further US$8 mln in cash over FY26. A further $1.25 mln net has already been raised from the At-The-Market facility between July and 24 Sept 2025; this leaves a gap of about US$6.75 mln. The CEO has extended a $3 mln loan facility if required. Management is also seeking non-dilutive funding such as a partnering deal.

Income statement

Year to 30 June	$(000s	2024	2025	2026E
Revenue				
Cost of sales				
Gross profit				
R&D		(5,437)	(5,549)	(5,660)
SG&A		(3,079)	(4,043)	(4,123)
Operating profit/(loss)		**(8,516)**	**(9,592)**	**(9,783)**
Financial		222	125	50
Tax				
Net profit/(loss)		**(8,294)**	**(9,467)**	**(9,733)**
Other				
Comprehensive loss		**(8,294)**	**(9,467)**	**(9,733)**
Av shares (Mln)		11.87	15.12	18.50
EPS		-0.70	-0.63	-0.53

Cash flow

Year to 30 June	$(000s	2024	2025	2026E
Net profit		(8,294)	(9,467)	(9,733)
Operational cash flow		(6,316)	(8,479)	(8,780)
Investments		(157)	(57)	(50)
Financing		3,120	5,296	8,000
Net change in cash		**(3,352)**	**(3,239)**	**(830)**
Opening balance		8,150	4,798	1,559
Ending balance		**4,798**	**1,559**	**729**

Balance Sheet

Year to 30 June	$(000s	2024	2025	2026E
Intangibles		340	319	311
PPE		7,512	6,834	6,159
Non-current		7,852	7,153	6,470
Pre-paid exp		173	112	112
Cash		4,798	1,559	729
Total assets		**12,823**	**8,824**	**7,311**
Trade payables		376	459	459
Related party payables		720	821	821
Related party milestone		-	-	-
Other current liabilities		262	26	26
Total liabilities		**1,359**	**1,307**	**1,307**
Share capital		150,839	156,359	164,580
Retained earnings		(139,375)	(148,842)	(158,575)
Total equity		**11,464**	**7,518**	**6,005**
Total liabilities & equity		**12,823**	**8,824**	**7,311**

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

Investment conclusion – dual track development promising

Nanoviricides has a novel therapeutic product with much needed acute anti-viral capability. A Phase 1 showed safety and tolerability. The African Phase 2 will give valuable data on the potential efficacy against MPox infection and by analogy on smallpox. We presume that BARDA could be interested in funding NV-387 development to replace Tecovirimat, depending on data. 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$300mln before cash.

The concept of an Indian "basket" Phase 2 respiratory study is a clever one that could produce results in 2026. Finding which respiratory viruses show the best response to NV-387 will aid future development. The FDA typically has a focused approach - but this is slow and expensive when gaining initial data.

With an appropriate data set, US INDs can be sought against specific viral infections. RSV, probably as a pediatric indication. Is a likely first US trial. Immune therapies have created a sizable, and now competitive, market (over US$1 bln) but there remains a need for an effective therapeutic. This is an obvious commercial market opportunity.

Measles, due to reducing MMR vaccination rates, is a threat and a major outbreak is possible. A nanoviricide product could offer an acute treatment route but there is a significant amount of development work needed and the market is currently tiny - unless seen as a biodefense issue. NV is considering investigator led use to provide a human evidence base in specific cases

Finally, transmission of bird flu to humans, although rare, has the latent potential to become a major risk if human to human transmission develops. This could be a biosecurity indication.

Overall, the evolving dual development track over 2026 looks extremely promising. The availability of a large clinical data set will assist with the move into US development possibly from 2027. It accordingly seems as if 2026 could be a pivotal year for clinical validation and potential value inflection.

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