

#### Stock Data

Share Price:	4.25p
Market Cap:	£6.5m
Shares in issue:	152.2m

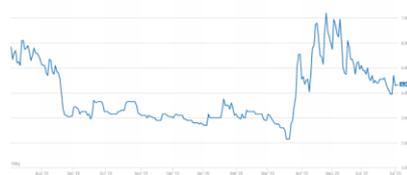
#### Company Profile

Sector:	Pharmaceuticals
Ticker:	N4P
Exchange:	AIM

#### Activities

N4 Pharma plc ('N4P, 'the Group') is a specialist pharmaceutical company developing a novel silica nanoparticle delivery system for vaccines and therapeutics for licensing to pharmaceutical and biotech partners. This nanoparticle has the potential to help commercialise cancer immunotherapy drugs and improve the effectiveness of viral vaccines. **Nuvec®**, the Company's lead development is a unique, non-viral adjuvant delivery system that has the potential to revolutionise vaccines and cancer treatments.

#### 1-year Share price performance



Source: [LSE](#)

Past performance is not an indication of future performance.

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TPI acts as joint broker to N4 Pharma plc

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## N4 Pharma plc

**N4P has provided an update on its Nuvec® optimisation programme and proof of concept work involving COVID-19. Interestingly, delays imposed by the Pandemic lockdown presented an opportunity for the Group to explore a new initiative regarding Nuvec®'s potential as an oral delivery system. Research on the Group's proprietary silica nanoparticles indicates that their unique spiky structure could provide a significant competitive advantage compared to existing, established routes of administration for vaccines (such as by injection) that are already in use. In order to now demonstrate and verify this potential, N4P has now commissioned additional work by its contract research organisation ('CRO'), Evotec Internation GmbH ('Evotec'), to undertake preliminary *in vitro* studies with a view to establishing that it can be optimised to transfect both murine intestinal cells and also human gastrointestinal mucosal/epithelial cells. Such an outcome is likely to rapidly attract new interest from various ongoing COVID-19 and other vaccine development programmes that could benefit from oral administration.**

### Potential Competitive Advantage

N4P's focus remains on the optimisation of the formulation and the continued generation of data for Nuvec®'s use as an injectable delivery system for vaccines and cancer treatments. Good progress made to date means that the Group is optimistic in terms to building on this and accelerating the work programme as the lockdown continues to ease.

More recent research indicates, however, that certain characteristics of Nuvec® could make it particularly well suited as a delivery system for oral vaccines. Success in this area potentially offers a competitive advantage over others that are less suited for oral delivery of vaccines. These include both the simplification and improved economics of being able to administer the drug outside a clinical setting, something that would be particularly valuable in less developed countries.

### Opportunity for COVID-19 trials collaboration

**While N4P's virtual model and contracted laboratories have ensured its testing schedules have not been significantly hindered by the lockdown, the COVID-19 Pandemic has nevertheless provided it with an ideal opportunity to demonstrate how Nuvec® might substantially enhance delivery of a potential coronavirus vaccine, as well as developments for other viruses that may well surface in the future. Having already demonstrated improved product consistency along with a significant data pack that is currently being generated from *in vitro* testing ahead of a still anticipated second half move to *in vivo* models, N4P appears ideally placed to commence licensing discussions with prospective partners later this year. The [new funds raised](#) from its 13 May 2020 equity placing, sufficiently bolstered the Group's existing c.£1m year-end cash position to ensure development work can move up a gear. With the lifting of lockdown restrictions, 2H 2020 operational burn should be expected to ramp-up from the c.£75k/month seen during 2019, as it progresses works including proof of concept ('POC') and the newly identified opportunity for oral delivery. Potentially this will be sufficient to attract participation in a COVID-19 vaccine development programme(s), thereby moving Nuvec® toward its first (partner-dependent) clinical trials collaboration along with demonstration of its GMP scalability.**

## Nuvec® - A novel nucleic acid delivery system

Nuvec® demonstrates significant promise as a non-viral delivery vehicle for DNA/RNA, with key advantages compared to lipid, other silica and viral systems, including high capacity loading and protection of nucleic acid. *In vitro* analysis suggests this functionalised silica nanoparticle is capable of localised *in vivo* transfection efficiency, through both subcutaneous and intratumoural routes, while remaining well tolerated at high doses with no induction of high levels of inflammatory cytokines. Offering an excellent safety profile, N4P is now focused on achieving Nuvec®'s formulation optimisation/stability and scalability along with COVID-19 proof of concept for delivery.

## Development work now expected to pick up

Prior to suspension of activities due to the lockdown, work with [Nanomeric](#)s, the drug research company, at [UCL School of Pharmacy](#) had demonstrated that [Polyethylenimine](#) ('PEI') loaded Nuvec could be dispersed and resuspended in an aqueous solution ready for the loading of DNA. Not surprisingly, progress has been hindered due to the rota system employed by the main laboratories contracted and has seen optimisation of the DNA loading take longer than expected so this work currently remains ongoing. Assessment of such characteristics are expected to be the starting point when work gradually recommences at Nanomeric's laboratories from 13 July 2020.

With respect to studies involving COVID-19, however, Evotec remains on track with its *in vitro* testing of Nuvec® loaded with the coronavirus plasmid and, in conjunction with the Group, continues to look at ways in which it can accelerate the commencement of Stage 3 of this work while performing the *in vivo* protein expression studies in parallel. Significantly, assays to detect the spike protein antigen arising from the plasmid transfection and also the antibodies produced *in vivo* have already been established by Evotec.

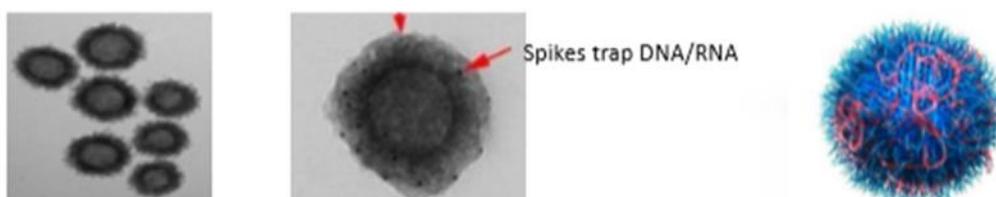
## Potential delivery system for oral vaccines.

To date, the majority of work with Nuvec® has been around its administration by injection in keeping with the vast majority of vaccines (both existing and in development) which use a parenteral administration of the dosage through injection be it intravenous, subcutaneous or intramuscular. More recent research on Nuvec®, however, indicates that its unique spiky structure could give it a competitive advantage as a potential delivery system for oral vaccines.

There are, nonetheless, a number of issues that need to be overcome for an orally delivered vaccine and established delivery systems used in the parenteral space are not well placed for this. In each case, data N4P has accumulated on Nuvec®, suggests that it could be a viable solution to address these issues. In particular, the fact that protection from the stomach acid and pepsin proteolysis can be achieved readily by delivering the product in acid resistant tablets or capsules. This is a well-established principle in pharmaceutical development and would be readily applicable to Nuvec® which has been shown to be suitable for lyophilisation. The monodisperse nanoparticulate product would be suitable for inclusion in an acid resistant capsule.

In general, therefore, a preformed, silica nanoparticle such as Nuvec® should be more resistant to the digestive actions of the intestinal milieu. Previous studies have also demonstrated that it reduced the digestive effect of nuclease enzymes on DNA/RNA when added to the incubation medium. Moreover, its mucoadhesive properties that result from the engineered design of long silica spikes coated with a cationic charge by PEI will encourage binding to the mucosa cells.

### Microscopic Images together with Graphic Model of Nuvec®



Source: [N4 Pharma](#). AGM Presentation, April 2020

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