N4 Pharma plc

Nuvec®'s viability as a novel drug delivery system has taken a further step forward, with confirmation of its successful oral administration loaded with a DNA plasmid for ovalbumin. The oral route is significantly preferred by pharmaceutical groups and practitioners for both systemic and local drug delivery. Prospective advantages for those seeking to utilise the Group's unique silica nanoparticle technology for drug and therapeutic developments targeting multiple diseases, include safety, good patient compliance, ease of ingestion and pain avoidance, etc. Moreover, coming shortly after N4P's 7 December 2023 announcement that confirmed Nuvec®'s ability to be loaded with and concurrently deliver two (or more) different siRNA known to inhibit relevant oncology targets without changes to size or charge, which are two essential parameters for successful cellular uptake, forthcoming clinical validation presents potential for rapid elevation into lucrative third party licensing/partnering opportunities for both this and/or the Group's LipTide® platform (which was recently secured through the Nanogenics Limited acquisition). Now retaining a cash runway that extends into H2 2024 and with additional works exploring siRNA concentrations/dose loading/oral bioavailability underway which are likely to be followed by new *in vivo* studies, in tandem with possibility for further updates covering N4P's ongoing AAV viral vector testing, the coming months look to be particularly news heavy.

Preferred route for both systemic and local drug delivery

Oral drug delivery systems face the harsh physiological and physicochemical environment of the gastrointestinal tract ('GIT'), which limits both bioavailability and design of proposed carriers. Nuvec® nanoparticle administration using enteric coated capsules appears to be a highly innovative approach to such challenges when compared with competing research, which include biomimetic drug formulations and microfabricated devices that are being similarly explored for optimised targeting and systemic assimilation.

Most oral drug delivery systems presently focus on targeting local GIT diseases, such as gastric diseases, oral carcinoma, inflammatory bowel disease ('IBD'), colon cancer, etc. But new development of pharmaceutical technology, materials science, and physiological study of diseases has enabled N4P and its collaborative partner, the University of Queensland ('UoQ), to demonstrate potential for oral nanoparticle preparations to target drugs on focal sites outside the GIT.

The enteric formulation utilised by the UoQ was composed of a polymer coating which forms a barrier over the surface and permits transit to the small intestine, thereby restricting release of any drug until the point of reaching this organ. The first experiment conducted was a repeat of a study from earlier in 2023, in which an enterically-coated capsule containing Nuvec® loaded with a DNA plasmid for ovalbumin was administered. Protein expression was observed after 3 days which, following administration of a second capsule on the third day resulted in a much higher peak level of expression during days 4 to 7. Further tests are likely to investigate individual variability, including GIT evacuation times, pH and composition of

Stock Data

Share Price	0.85p
Market Capitalisation	£2.28m
Shares in issue:	268.78m
52 week high/low	2.70p/0.71p

Company Profile

Sector:	Pharmaceuticals
Ticker:	N4P
Exchange:	AIM

Activities

N4 Pharma plc ('N4 Pharma', 'N4P' or '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.

www.n4pharma.com/

5-year share price performance

Source: LSE

Past performance and forecasts are not a reliable indicator of future results.

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localised fluids that might also influence drug release in such an environment. Given the complexities involved in oral delivery, further progress in this area would potentially present significant opportunity and a further key point of difference for Nuvec® and its use as delivery system to target multiple diseases.

N4P's Board are now in the process of scoping out the next phase of work in order to accumulate sufficient data for it to focus on specific oral application and further news on this is expected to be announced in the new year. This could possibly make advancement of such delivery technology the key priority of Nuvec®'s 2024 development. In the meantime, the University of Queensland will also be continuing its work exploring the use of Nuvec® as an oral delivery system for vaccines as part of the Group's ARC funded grant with them.

N4P Finances - Runway sufficient to carry the Group to the start of H2 2024

TPI estimates that N4P's recent acquisition of Nanogenics Limited will have lifted the Group's cash burn from a little over £100k/month during H1 2023 to around £130k/month from Q4 2023 and going forward into the new financial year. With c.£1.29m cash/cash equivalents in the Group's balance sheet at end-June 2023, there appears to be runway sufficient to take it to the start of H2 2024 based on current programmes/schedules, although any decision to further ramp up of development of either of its delivery platforms or its new key preclinical candidate will likely bring this schedule closer.

Commercialisation Strategy - Focusing on strong commercial point of difference

Having already refined its near-term commercial strategy in order to highlight Nuvec®'s specific points of difference as a carrier of multiple siRNA compounds, the recent majority acquisition of Nanogenics has now also introduced a highly complementary but differentiated non-viral delivery technology along with a lead candidate that appears capable of securing a relatively quick route to clinic. Importantly, this opens opportunities to identify technical synergies through parallel development programmes involving both delivery platforms, while preclinical and clinical validation presents opportunity for third party partnering/licencing either individually or together.

Today's news is particularly exciting given that Nuvec® has already demonstrated ability to deliver multiple siRNA into the same cell, therein providing a unique solution for combination therapy treatments. Given that many drug development companies are presently undertaking early-phase preclinical/clinical testing/trials, they are generally more open to new, novel solutions than those at more advanced stages. Following its signing of two Material Transfer Agreements ('MTAs') back in 2021, one of which was with a major company in gene therapy and the second with a company developing its own DNA Covid vaccine, this work continues while the Group seeks further such partnership opportunities and, as such, the pace of progress here is largely determined by N4P's partner's own R&D work and drug launches.

Based on feedback from the patent examiner and further work the Group has already completed, it has been demonstrated that combining Nuvec® with adenoviral vectors (in addition to its earlier work on lentiviral vectors) can lead to an improvement in vector performance and a reduction in the amount of the viral vector required. Accordingly, it is presently pursuing patent applications in Europe (including UK); USA; Japan; India and Canada (and intends to file similar applications in Australia and China in due course) which, if granted, would be in addition to those already exclusively licensed from the UoQ in an effort to further strengthen the commercial protection of the delivery system. Having now demonstrated Nuvec®'s capability to orally transfect cells in the small intestine, the next step will be to repeat this success through *in vivo* studies, which management understands will be undertaken shortly, before moving onto clinical trials. During this period, marketing efforts and awareness raising exercises amongst interested parties will also be heightened.

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