Company Note

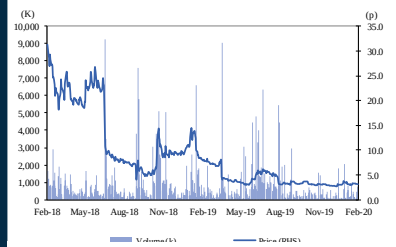
Prelims

25 February 2020

Corporate

Current price	**3.15p**
Sector	**Healthcare**
Code	**N4P**
AIM	**AIM**

Share Performance



	1m	3m	12m
N4P	-7.5%	-1.6%	-61.5%

Source: Thomson Reuters, Allenby Capital

Share Data		
Market Cap (£m)		**3.197**
Shares in issue (m)		**101.5**
52 weeks	High	Low
	3.75	**2.70**
Financial year end		**December**

Source: Company Data, Allenby Capital

Key Shareholders	
Nigel Theobald]	16.7%
David Farrier	12.0%
First Equity Ltd	3.5%

Source: Company Data, Allenby Capital

Emma Ulker

Phone: 0207-065-2690

emma@equitydevelopment.co.uk

www.allenbycapital.com

N4Pharma (N4P)

Focused on readying Nuvec® for the clinic

N4 Pharma is developing Nuvec®, an innovative silica nanoparticle for drug delivery with possible applications across cancer therapy and immunology. That includes enhancing the cellular uptake of novel and disruptive medicines like mRNA and DNA vaccines or therapies. The prospects for well-characterised and efficacious delivery nanoparticles remain very promising given the high amounts invested in the field, coupled with unmet need. In FY19 N4P achieved a range of milestones, managed cash tightly and is focused on achieving characterisation of Nuvec® to build a clinic-ready data package to support licensing discussions. Nuvec®'s transfection capability, versatility, safety and immune response-generation are all key positive factors that help de-risk the program.

- **Nuvec® meets key testing criteria:** including versatility in its ability to transfect cells with both pDNA and mRNA as well as capacity to promote an immune response, seen in vivo and in vitro testing. Nuvec's mechanism of action and toxicity profile are also favourable in testing to-date. Ongoing testing requirements include resolving in vivo loading consistency to fulfil the nonclinical protocols required of nanoparticles, including efficacy, safety and generating consistent and replicable results prior to clinical testing.

- **An extensive technical review to come:** N4P has appointed Nanomerics, a specialist in drug delivery nanotechnology affiliated with University College London (UCL), to complement ongoing testing, set over two seven month stages. Stage 1 will focus on testing in vitro DNA loading processes and the stability of Nuvec® loaded with both DNA and siRNA, targeting completion in Q220, in parallel with work conducted by N4P. Stage 2 will be conducted by Nanomerics alone and includes in vivo efficacy testing. Notably, it also provides the option to test Nuvec in a gene silencing model. This emerging and highly promising field of medicine has so far been held back by delivery challenges.

- **Financials and forecasts:** FY19 Opex of £0.9m was lower than our forecast of £1.1m and comprised £0.2m on R&D and £0.7m of G&A expenses, vs £0.8m and £0.6m respectively in FY18, related to the discontinued Generics division. Cash at end of December 2019 stood at £0.9m, following a £1m net placing. Making no material changes, our forecast cash runway is into Q121 to cover the technical review.

- **Conclusion:** Going forwards, conclusive and replicable in vivo testing outcomes could prove to be a catalyst for shares to rerate from the current valuation. The value of technologies such as Nuvec® is clearly shown by tie-ups such as the one struck by Alexion Pharma and nanotechnology company Arbutus in 2017. Terms included $7.5m upfront, up to $75m in milestones, in the context of Alexion's rare disease program.

Year End: 31 December					
(£'000)	**2018**	**2019**	**2020E**	**2021E**	**2022E**
GRANT REVENUE	73	0	0	0	0
EBITDA	(1,417)	(947)	(1,090)	(1,101)	(1,110)
OPERATING LOSS	(1,417)	(947)	(1,090)	(1,101)	(1,112)
NET RESULT	(1,185)	(876)	(872)	(880)	(888)
NET CASH (£m)	793	966	260	908	1,049

Allenby Capital acts as Nomad & Broker to N4Pharma (N4P).

Nuvec - a strong rationale in attractive markets

Nuvec® is being developed to address unmet need for effective and safer delivery technologies for drugs. Importantly, this includes the field of nucleic acids comprising RNA and DNA vaccines and therapies, which are being developed to activate the patient's own immune system to treat or prevent disease. The prospects for well characterised and efficacious delivery nanoparticles remain very promising, particularly since there have been no RNA or DNA therapies yet approved, and delivery is a key factor in holding back progress to date, owing to toxicity concerns as well as effective transfection.

The field of gene silencing using small interfering RNA (siRNA) for example is only just opening up, following the first FDA approval in the class of Onpattro (patisiran/Alnylam) in 2018, that treats the rare nerve disorder hATTR amyloidosis. The silencing, or prevention of production, of selected proteins via mRNA targeting, has a broad potential to target any disease-causing gene, thus offering scope for a massive end market. Onpattro generated Q419 and FY19 global net product revenues of $55.8m and $166.4m respectively and is pegged by analysts to achieve >$1.bn in peak sales.

Nuvec® is a silica nanoparticle with a spiky morphology offering a large surface area to trap drug payloads. N4P is developing Nuvec in nonclinical studies to confirm its potential as a drug delivery particle for a range of therapeutic payloads. This would provide scope for licensing it non-exclusively to biopharma partners, and to be developed in tandem with a drug once nonclinical characterisation is completed successfully. Deals' precedent suggests that drug delivery platforms can drive lucrative partnerships. For example, US giant Moderna (MRNA, market capitalisation of $6bn) has licensed the Lipid Nanoparticle (LNP) technology used in Onpattro to help advance its own pipeline of mRNA therapies.

The tendency of lipid nanoparticles to track to the liver can cause unwanted toxicity, plus the limited suitability of these particles for payloads such as nucleic acids are other disadvantages that Nuvec® could address.

Key criteria are confirmed

In FY19 N4P achieved a range of milestones, meeting key criteria, and is working to complete the remaining steps in building complete characterisation of Nuvec essential for building the technology transfer package. The notable features of Nuvec® established in nonclinical testing to-date include:

- Suitability for loading a range of DNA and mRNA antigens and successful transfection of cells in vitro – establishing Nuvec®'s fundamental efficacy in early testing;
- Nuvec®'s mechanism of action to transfect cells is via endocytosis into the cell and the release of payload into the cytoplasm – essential for nucleic acids to act on protein levels;
- Nuvec® has a good safety profile: it degrades naturally in the body and does not track to the liver – this implies liver toxicity, a key limitation in lipid nanoparticles, can be avoided;
- Nuvec® works for pDNA and mRNA having shown an in vivo antibody response for both - offering scope as a versatile delivery particle.

Nuvec®'s in vivo loading consistency is a factor that requires further investigation since Nuvec® currently delivers a good response from 2-3 injections but has shown inconsistent or negative responses when just 1 injection is used during in vivo testing.

The Company has set out a refined 2-stage plan incorporating its research collaboration with Nanomerics in order to complete full physical, chemical, in vitro and in vivo biological characterisation of Nuvec®. The approximate 14-month timeline set out is within industry standard guidelines[1] and allows for an enhancement compared to the original testing and technical review set out at the interim results in September.

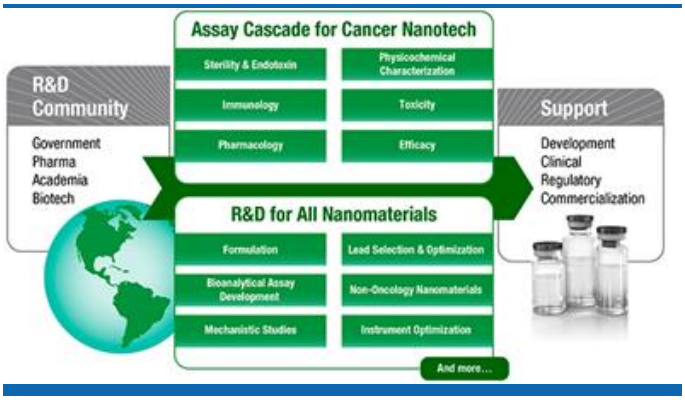
- Q1 2020 – refining the improved Nuvec® DNA loading process;
- Q2 2020 - in vitro testing of improvements;
- Q2-Q3 2020 - in vivo testing of improved transfection and immune response;
- Q3-Q4 2020 - conduct in vivo cancer model.

Phase 1 of this work will run alongside the existing planned in vitro and in vivo dispersion formulation testing, as previously announced. Phase 2 will replace the previously planned efficacy work, enabling N4P to undertake two efficacy studies.

During Phase 1 the 30-day stability of four different Nuvec® formulations will be tested using both a well characterised plasmid DNA, enabling outcomes to be compared to standard tests, as well as a novel siRNA. In Phase 2 the efficacy of the plasmid DNA will be tested in an in vivo antibody generation model, with an option to test the siRNA antigen in a gene silencing tumour model. The EU's termination of the EU NCL Horizon 2020 project in which Nuvec® had been enrolled, is not expected to setback the timeline.

To help place the work plan in context, let us examine the guidelines for testing nanomaterials put in place by US and European consortia. For example, the US-based Nanotechnology Characterisation Laboratory (NCL) carries out characterisation of a nanoparticles' physical attributes, in vitro biological properties, and in vivo compatibility via an Assay Cascade. The time required to characterise a nanomaterial from receipt through the in vivo phase is anticipated to be 1 year.

Exhibit 1: Assay Cascade Nanotechnology low ahead of election



Source: Nanotechnology Characterisation laboratory (NCL)

[1] Nanotechnology Characterisation Laboratory (NCL)

Financials

We have made no material changes to our previous forecasts, which are based on flat expenses, and now include FY22. End of December 2019 cash of £0.9m provides a runway through FY20 on this basis. We illustrate potential equity funding of £1.5m being raised in FY21, and another £1m in FY22, although in practice quantum and timing will depend on the outcome of partnering discussions and of the ongoing technical review.

INCOME STATEMENT - Year End December - £'000	2018	2019	2020E	2021E	2022E
Grant income	**72.8**	**-**	**-**	**-**	**-**
Gross Profit	72.8	-	-	-	-
Administrative expenses	(643.7)	(730.4)	(840.0)	(848.4)	(856.8)
R&D expenses	(846.2)	(216.9)	(250.0)	(252.5)	(255.0)
Operating loss before exceptionals	**(1,417.1)**	**(947.3)**	**(1,090.0)**	**(1,100.9)**	**(1,111.9)**
Interest income	(1.0)	(1.4)	-	0.5	1.8
Loss Before Taxes	(1,390.4)	(948.7)	(1,090.0)	(1,100.3)	(1,110.0)
Current tax income	205.5	72.4	218.0	220.1	222.0
Net result	**(1,184.8)**	**(876.4)**	**(872.0)**	**(880.3)**	**(888.0)**
EPS (p)	(1.3)	(0.9)	(0.9)	(0.7)	(0.5)
Average no. of shares	89.4	100.2	101.5	125.3	165.0

Source: Company data, Equity Development

BALANCE SHEET - Year End December - £'000	2018	2019	2020E	2021E	2022E
Current assets	**1,070**	**1,065**	**260**	**908**	**1,049**
Cash and cash equivalents	793	966	260	908	1,049
Accounts receivable	277	99	-	-	-
Current liabilities	**(190)**	**(78)**	**(141)**	**(166)**	**(190)**
Accounts payable	(160)	(52)	(115)	(139)	(164)
Other current liabilities	(30)	(26)	(26)	(26)	(26)
Equity	**880**	**987**	**119**	**743**	**859**
Share capital	17,964	19,004	19,004	20,504	21,504
Other	(17,084)	(18,017)	(18,885)	(19,761)	(20,645)

Source: Company data, Equity Development

CASH FLOW STATEMENT – Year End December - £'000	2018	2019	2020E	2021E	2022E
Operating cash flow	**(1,344)**	**(806)**	**(705)**	**(852)**	**(859)**
Loss before tax	(1,390)	(949)	(1,090)	(1,100)	(1,110)
Non-cash adjustments	(26)	5	4	4	2
Change in working capital	2	(83)	163	24	25
Tax paid	71	221	218	220	222
Investing cash flow	**28**	**-**	**-**	**-**	**-**
Other investing cash flows	28	-	-	-	-
Financing cash flow	**783**	**979**	**-**	**1,500**	**1,000**
Proceeds from equity	784	980	-	1,500	1,000
Other financing cash flow	(1)	(1)	-	-	-
Net increase in cash	**(533)**	**173**	**(705)**	**648**	**141**
Cash at start of year	1,326	793	966	260	908
Cash at end of year	**793**	**966**	**260**	**908**	**1,049**
Net cash at end of year	**793**	**966**	**260**	**908**	**1,049**

Source: Company data, Equity Development

Conclusions

We are encouraged by the milestones already met and the fact that remaining work is based around altering testing parameters, rather than fundamental alteration of the nanoparticle. This also offers scope for extended characterisation and efficacy testing.

Furthermore, N4P has made Board changes to optimise technical development as well as maximising commercial opportunities. Dr John Chiplin has moved into the Chairman's role – with Dr David Templeton taking on the role of Technical Director – and with Dr Chris Britten moving across into Business Development. The three of them bring considerable biopharma experience to bear.

The planned outsourcing of Chemistry Manufacturing and Controls (CMC) operations, also appears to allow greater flexibility and potentially greater cost efficacy going forwards.

Clearly hitting key milestones going forward will mean achieving positive testing outcomes, with the pathway now further refined and extended, but with the timeline broadly unchanged. We also look forward to news on partnering, as well as potential acquisition targets that might be complementary to Nuvec®, plus news on the Company's patent application for Nuvec®. Our forecasts provide a cash runway sufficient to cover key inflection points.

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Research Disclosure

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Allenby Capital, 5 St Helen's Place London EC3A 6AB, +44 (0)20 3328 5656, www.allenbycapital.com