EDISON

NetScientific

Operational update

On deck for multiple 2017 launches

Pharma & biotech

NetScientific's subsidiaries have made multiple advances on regulatory and commercial fronts. ProAxsis and Vortex will both be launching their first products in 2017, and to this end they have both received CE marks for sale in Europe, with Vortex receiving a Class 1 device designation for sale in the US. In addition, Wanda has signed two new contracts with care providers, bringing the total to four.

Year end	Revenue (£m)	PBT* (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/14	0.0	(6.2)	(15.3)	0.0	N/A	N/A
12/15	0.1	(11.3)	(24.4)	0.0	N/A	N/A
12/16e	1.1	(14.7)	(22.1)	0.0	N/A	N/A
12/17e	4.3	(13.2)	(20.2)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Vortex instruments ready for US launch

With the Class 1 designation, Vortex's VTX-1 is exempt from premarket notification and manufacturing control requirements in the US. The company expects the first US sales in 2017, and is targeting the research market. The product was recently featured in a peer-reviewed publication in the journal *Oncotarget*, which speaks to the utility of the product in the research setting.

PDS potentiates HPV vaccine

PDS Biotechnology has presented final clinical results from a dose escalation Phase I/IIa clinical trial. The trial examined safety and immune activation in 12 women following HPV vaccination and three dosing levels of the Versamune adjuvant. There were no serious adverse events or discontinuations, and there was a dose dependent increase in immune activation: up to 26x interferon ɣ and 21x granzyme B expression. The company will be progressing to Phase II.

Glucosense programme not going to the clinic

The company announced that the initial positive results seen with the Glucosense non-invasive glucose monitoring device have been difficult to replicate and that the programme will not be entering the clinic at this time. Although it is still on NetScientific's balance sheet, we do not expect the programme to advance in its current form and have removed it from our estimates and forecasts.

Valuation: 133p per share

We have reduced our valuation to £67.8m or 133p/share, from £71.7m or 140p, reflecting the discontinuation of the Glucosense programme, as well as a lower cash balance of £15.9m, offset by increasing the probability of success for PDS, as well as rolling over our NPVs and an updated exchange rate. NetScientific reported a cash outflow of £7.6m for H116 and has a net funding obligation of c £15m at the subsidiary level (down from £18m). While we expect these financing needs to be fully met via the Series A financings expected in 2016 or 2017, this could result in further ownership dilution for NetScientific.

9 December 2016

Price	**65.00p**
Market cap	**£33m**
	US$1.24/£
Net cash (£m) at 30 June 2016	15.9
Shares in issue	51.1m
Free float	85%
Code	NSCI
Primary exchange	LSE
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(0.8)	(11.6)	(29.0)
Rel (local)	(2.1)	(11.9)	(36.1)
52-week high/low		96.0p	63.0p

Business description

NetScientific is a transatlantic biomedical and healthcare technology group. Its portfolio of five core investments and one material investment is focused on three main sectors: digital heath (Wanda), diagnostics (Vortex, ProAxsis, Glycotest) and therapeutics (PDS Biotechnology).

Next events

Series A closures	2016-17
PDS Phase II initiation	Q416
Vortex product launch	H117
ProAxsis product launch	Mid-2017

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Edison profile page

Moving forward on multiple fronts

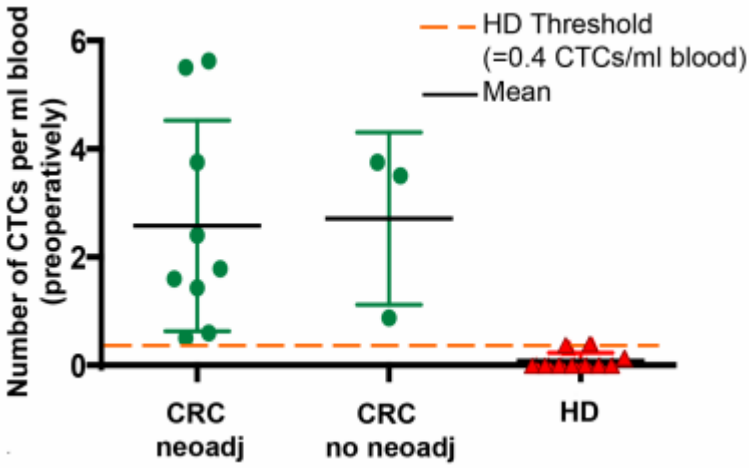
Since our last report, NetScientific has provided its half-year report and multiple other incremental updates on the operations of its subsidiaries as they advance their commercialisation and development programmes. Series A financings are still planned for all the majority-owned subsidiaries (Wanda, ProAxsis, Glycotest and Vortex).

Vortex's VTX-1 ready for sale; new testing tech out of Harvard

Vortex announced a series of regulatory advances that are important for the commercialisation of the circulating tumour cell (CTC) technology. The company received a CE mark from the EU for the VTX-1 cell isolation platform, preparing it for launch in Europe. The company also received a so-called Class 1 designation from the FDA. Medical devices (including diagnostic tests) marked as Class 1 pose the lowest threat to human health. Class 1 devices are exempt from 510(k) premarket notification requirements and GMP controls. Devices in this class cannot be used to diagnose a disease or provide medical guidance, although they can be used as part of a larger diagnostic procedure. This will allow the VTX-1 to be sold to researchers and interested clinical investigators in the US, and the company has announced that the first sales are expected in 2017.

The product was also recently featured in an article in the journal *Oncotarget*.[1] The authors, some of whom are from Vortex, used the VTX-1 chip to isolate CTCs from 15 colorectal cancer patients and screened these cells for mutations common to the disease (KRAS, BRAF, PIK3CA). On average 2.6 cells/mL of blood were isolated using the chip, and these levels were not affected by the use of neoadjuvant therapy (Exhibit 1). These cells were used to track individual patients through courses of treatment, monitoring the progress of their disease. The study also compared the rate of mutations detected in CTCs isolated from the chip with those found in circulating tumour DNA (ctDNA), an alternative liquid biopsy technology. The two types of test agreed between 74% and 91% of the time, depending on the mutation, although neither test identified all mutations, and therefore the authors concluded that the two technologies were complementary. The cells isolated with the VTX-1 showed mutations similar to biopsy 77.8% of the time. This study adds to the body of evidence for the utility of the technology both as a diagnostic and as a research tool.

Exhibit 1: Isolation of CTCs from colorectal cancer patients using the VTX-1



Source: Kidess-Sigal, et al.[1]

[1] Kidess-Sigal E, et al (2016) Enumeration and targeted analysis of KRAS, BRAF and PIK3CA mutations in CTCs captured by a label-free platform: Comparison to ctDNA and tissue in metastatic colorectal cancer. *Oncotarget*

In other news, Vortex has licensed electroporation technology from Harvard University. Electroporation is the process of using a pulse of electricity to temporarily form holes in the membranes of living cells. Many different molecules such as DNA, proteins or diagnostic chemicals can be introduced to the interior of a cell in this manner. In traditional electroporation procedures, cells are exposed to a range of electric field strengths and the damage to many cells is irreversible, leading to cell death. The new technology leverages the microfluidics in the VTX-1 chip to provide a more uniform electric field thereby decreasing cell death. Although the company has not provided specifics, this technology could potentially be used in future iterations of the device for a wide array of diagnostic procedures via probing of the intracellular function of CTCs.

PDS presents detailed immunology data

PDS Biotechnology recently presented the results from the open-label Phase I/IIa dose escalation study of PDS0101, its treatment in development for Human papillomavirus (HPV) related cancers. The results were presented at the Annual Meeting of the Society for Immunotherapy of Cancer. The trial enrolled 12 women with high-risk HPV infection and the primary outcome measure was safety and tolerability, although the patients were also examined to see if the vaccine induced an anti-HPV immune response. The enrolees each received 2.4mg of HPV vaccine (HPV-16 E6 and E7 peptides) and successive cohorts received successively larger doses of the Versamune adjuvant (1mg, 3mg and 10mg). This data release is the first time that the response of the patients with 10mg Versamune has been examined.

The company did not provide a complete safety profile but it did note that no dose limiting toxicities, serious adverse events, or discontinuations due to adverse events were observed. The main adverse event that was observed was injection site reactions that were more severe at higher Versamune doses. No other treatment emergent adverse events were correlated with increases in dose.

The HPV specific immune response was measured in the patients by measuring the increase in interferon ɣ (IFN-ɣ) and granzyme B following inoculation with HPV antigen. An increase in IFN-ɣ is indicative of antigen specific immune response, and granzyme B increases in response to cytotoxic T-cell activation. Nine of the 12 participants in the study had positive IFN-ɣ responses and six of the twelve had positive granzyme B responses (Exhibit 2). The study was complicated by the presence of two outliers (one in the 1mg cohort and one in the 3mg cohort) with unusually high baseline IFN-ɣ. Neither of these outliers responded to either assay. Additionally, the granzyme B assay could not be performed due to low sample volume in the 1mg cohort. The addition of the 10mg cohort in this data release increases our confidence in the reproducibility of the induction effect, given the limitations of the 1mg and 3mg cohorts. However, the increased dose does not appear to improve T-cell activation any further. The company is progressing to Phase II clinical trials.

Exhibit 2: Dose dependent Versamune sensitisation

Cohort	n	IFN-ɣ			Granzyme B		
		# responders	%	Fold increase	# responders	%	Fold increase
1mg	3	2	67%	14	1	50%*	3
3mg	3	2	67%	24	2	67%	21
10mg	6	5	83%	26	3	50%	18

Source: PDS Biotechnology. Note: *One patient not tested due to low sample volume.

ProAxsis on track for 2017 launch

Similar to Vortex, ProAxsis received a CE mark for its NEATstik neutrophil elastase test. This will enable the test to be sold on the European market, where the company is targeting a mid-2017 commercial launch. Neutrophil elastase is a marker of inflammation and respiratory disease and the company intends to market its test for the management of cystic fibrosis and chronic obstructive pulmonary disease.

Wanda signs two new contracts

Wanda has announced two more sales agreements with A to Z Home Health Care and 24Hr HomeCare, bringing the total number of provider contracts to four. Both companies are domestic healthcare service providers based in California. This rate of signing new contracts is consistent with our estimates, and we expect acceleration in the future with increasing proof of positive outcomes for patients and reduced costs for caregivers.

Glucosense not progressing to the clinic

Glucosense is a prototype-stage company founded to develop a non-invasive method of monitoring blood glucose. NetScientific has announced that the company had difficulty with the reproducibility of its technology and therefore the device will not proceed to clinical testing. Glucosense remains on NetScientific's balance sheet, but the future of this programme is in question and we have removed it from our valuation. NetScientific invested £0.7m in the company.

Valuation

We have reduced our valuation to £67.8m or 133p per share from £71.7m or 140p. This change reflects the removal of Glucosense from our valuation and a lower cash balance, partially offset by rolling over our NPVs to the most recent reporting period and an updated exchange rate (from $1.32/£ to $1.24/£). We have also increased the valuation of PDS to reflect an increased probability of success (10% from 7.5%) following the recently presented detailed clinical trial results. We expect to update our valuation following the closure of the Series A financings, which are expected in the near term, as well as with initial sales reports from Vortex and ProAxsis, which are expected when these companies launch their commercial products in 2017.

Exhibit 3: NetScientific valuation

Development Program	Prob. of success (%)	Profitability	Peak sales (£m)	Margin (%)	rNPV (£m)	Ownership (%)	Share value (£m)
Vortex	15.0%	2020	150	44%	13.1	95.0%	12.4
Wanda	7.5%	2019	374	53%	26.2	71.3%	18.7
Proaxis	10.0%	2020	50	51%	7.2	56.5%	4.0
Glycotest	10.0%	2019	123	51%	13.8	87.5%	12.1
PDS	10.0%	2021	302	57%	31.0	14.9%	4.6
Total							51.8
Net cash and equivalents (H116) (£m)							15.9
Total firm value (£m)							67.8
Total shares (m)							51.1
Value per share (p)							133

Source: NetScientific reports, Edison Investment Research

Financials

NetScientific released financial results for H116 showing an operating loss of £6.3m, with £3.7m in R&D spending. We expect spending to increase (£15.5m for 2016 and £16.1m for 2017), reflecting the clinical advancement of the subsidiary development programmes, offset by increased revenue (£1.1m for 2016 and £4.3m for 2017). Our spending estimates have been reduced (by approximately £5m for 2016 and 2017) to reflect the removal of the Glucosense programme from our estimates. The company ended the period with £15.9m in cash. It should be noted that all these estimates reflect current ownership stakes of the various subsidiaries and we expect these values to change to reflect the potential dilution from upcoming financing rounds. We expect these financings to offset future funding requirements for these companies. Based on the current ownership structure, the company will require £21m in additional financing (recorded as illustrative debt in 2017) before profitability in 2019, offset by £6m in cash spending attributable to minority interests, for a net obligation of £15m, a reduction from the previous estimate of £18m.

Exhibit 4: Financial summary

£000s	2014	2015	2016e	2017e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	24	122	1,074	4,323
Cost of Sales	0	(6)	(236)	(968)
Gross Profit	24	116	838	3,355
Research and development	(3,098)	(7,256)	(9,677)	(9,677)
Selling, general & administrative	(3,212)	(4,260)	(5,844)	(6,391)
EBITDA	(6,352)	(11,530)	(14,958)	(12,850)
Operating Profit (before GW and except.)	(6,286)	(11,400)	(14,820)	(12,713)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	(948)	(1,518)	(258)	0
Operating Profit	(7,234)	(12,918)	(15,079)	(12,713)
Net Interest	77	78	102	(525)
Other (change in fair value of warrants)	0	0	0	0
Profit Before Tax (norm)	(6,209)	(11,322)	(14,718)	(13,238)
Profit Before Tax (IFRS)	(7,157)	(12,840)	(14,976)	(13,238)
Tax	30	94	76	66
Deferred tax	0	0	0	0
Profit After Tax (norm)	(6,179)	(11,229)	(14,642)	(13,172)
Profit After Tax (IFRS)	(7,127)	(12,746)	(14,900)	(13,172)
Average Number of Shares Outstanding (m)	35.9	38.2	51.1	51.1
EPS - normalised (p)	(15.3)	(24.4)	(22.1)	(20.2)
EPS - IFRS (p)	(17.9)	(28.4)	(22.6)	(20.2)
Dividend per share (p)	0	0	0	0
BALANCE SHEET				
Fixed Assets	3,040	2,946	3,457	4,469
Intangible Assets	10	1	0	0
Tangible Assets	348	285	472	334
Other	2,681	2,660	2,985	4,135
Current Assets	17,720	23,799	10,101	16,729
Stocks	0	0	358	1,441
Debtors	853	560	71	432
Cash	16,867	23,239	9,571	14,755
Other	0	0	100	100
Current Liabilities	(1,324)	(2,206)	(3,516)	(3,009)
Creditors	(1,281)	(2,156)	(3,516)	(3,009)
Short term borrowings	(43)	(50)	0	0
Long Term Liabilities	(740)	0	0	(21,000)
Long term borrowings	(687)	0	0	(21,000)
Other long term liabilities	(53)	0	0	0
Net Assets	18,696	24,538	10,042	(2,811)
Minority Interest	(1,098)	(1,805)	(5,071)	(7,939)
Shareholder Equity	17,598	22,733	4,971	(10,750)
CASH FLOW				
Operating Cash Flow	(6,698)	(10,752)	(13,450)	(14,207)
Net Interest	67	38	43	(525)
Tax	19	83	0	66
Capex	(336)	(299)	(290)	0
Acquisitions/disposals	(2,181)	(144)	(346)	(1,150)
Financing	0	18,208	0	0
Dividends	0	0	0	0
Other	119	0	0	0
Net Cash Flow	(9,010)	7,133	(14,043)	(15,816)
Opening net debt/(cash)	(25,069)	(16,136)	(23,189)	(9,571)
HP finance leases initiated	0	0	0	0
Exchange rate movements	(140)	(212)	(293)	0
Other	218	131	718	0
Closing net debt/(cash)	(16,136)	(23,189)	(9,571)	6,245

Source: NetScientific accounts, Edison Investment Research

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