EDISON

ADR research

Bavarian Nordic

H114 results

US Imvamune contract confirmed

Pharma & biotech

24 September 2014

Option exercise for the second portion of the Imvamune smallpox vaccine delivery contract to the US government unlocks valuation upside and confirms the strength of the relationship. Other recent developments in the profitable infectious disease division include a first commercial Canadian Imvamune order and increased US government funding for early-stage foot and mouth disease and Ebola programs, with development of the latter being accelerated. Data from the Phase III PROSPECT prostate cancer trial of Prostvac – the main value driver of the cancer vaccines division – are not expected until H216; however, past and upcoming major conference updates on potential synergies with immune checkpoint inhibitors are contributing to a continuing active dialog with potential partners.

Year end	Revenue (US$m)	PBT* (US$m)	EPADR ($)	DPADR ($)	P/E (x)	Gross yield (%)
12/12	179.6	(8.6)	(0.2)	0.0	N/A	N/A
12/13	214.2	27.3	0.1	0.0	19.5	N/A
12/14e	217.9	9.3	0.0	0.0	N/A	N/A
12/15e	113.9	(19.3)	(0.1)	0.0	N/A	N/A

Note: Converted at DKK5.66/$. Gross yield excludes withholding tax. Investors should consult their tax advisor regarding the application of any domestic and foreign tax laws.

Infectious diseases: Progress with N. American govts

The US is the main Imvamune market; delivery of four million doses under the $118m BARDA option means FY14 guidance can be met and shows US government commitment in maintaining manufacturing/supply capabilities ahead of potential new orders of next-generation freeze-dried Imvamune from 2016.

Cancer vaccine pipeline: Broadening prospects

An ESMO 2014 Prostvac update should build on ASCO 2014 preclinical data on synergies with checkpoint inhibitors: a combination approach could maximize clinical and commercial potential. Start of two NCI-sponsored trials (Phase II CV-301 bladder cancer and Phase I MVA-BN Brachyury) has expanded the pipeline. CV-301 development plan finalization (based on FDA feedback) is expected H214.

Financials: Targeting EBIT break even for FY14

FY14 financial guidance remains revenue of DKK1.2bn, EBIT break even and cash preparedness of DKK600m (gross cash plus undrawn DKK120m credit line).

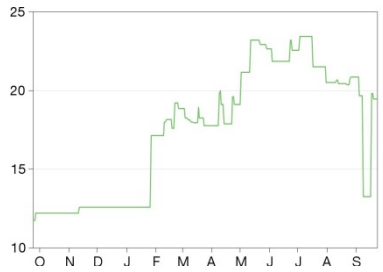
Valuation: $620m ($24/ADR) with upside potential

Our DCF-based valuation of $620m, $24/ADR (formerly $545m, $20.9/ADR), results from unwinding the risk adjustment on the US Imvamune order and inclusion of the Canadian Imvamune contract. Positive data from Prostvac's PROSPECT study (H216) and/or interim analyses (late-2014 onwards); partnerships for Prostvac and CV-301 in CRC; first confirmed European orders for Imvanex (2015); and Imvamune FDA filing (2016) would represent upside.

Bavarian Nordic is a research client of Edison Investment Research Limited

ADR price	**US$19.5**
Market cap	**US$509m**
ADR/Ord conversion ratio	1:1 DKK5.66/$1
Gross cash ($m) at end-June 2014	53.5
ADRs in issue (000s)	26,113
Free float	N/A
ADR code	BVNRY
ADR exchange	OTC Pink
Underlying	NASDAQ OMX
Depository	Deutsche Bank

ADR price performance



52-week high/low	US$23.4	US$11.7

Business description

Bavarian Nordic is a Danish biotech focused on developing and manufacturing novel cancer immunotherapies and vaccines for infectious diseases. Its lead products are Prostvac (prostate cancer) and Imvamune (smallpox).

Next events

Prostvac update at ESMO	27 September
Q314 results	13 November
CV-301 development plan finalization	H214
Completion of enrolment in PROSPECT study	H214

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Update: US contract confirmed

Confirmation of option exercise of the second part of an existing BARDA contract[1] for Imvamune means that Bavarian Nordic will receive $118m for the delivery of four million doses of the smallpox vaccine in 2014 and therefore should deliver on FY14 financial guidance. There is minimal risk on delivery as 3.2 million doses of finished product are ready for shipping, with manufacture of the remainder imminent. Equally importantly, it highlights the strength of the longstanding Bavarian Nordic relationship with the US government, through the US Department of Health and Human Services (HHS), and increases confidence in future orders, likely to be of the improved freeze-dried formulation from 2016, to maintain the US strategic stockpile.

Bavarian Nordic's Q214 results highlighted various operational achievements. Developments in the profitable infectious disease division included the first confirmed commercial order from the Canadian government for Imvamune, as well as increased US government funding for early-stage Ebola and foot and mouth disease programs. More recently, Bavarian Nordic announced the acceleration of its collaboration with the National Institutes of Health (NIH) on the development of its Ebola vaccine programs, with the initiation of a Phase I trial of a combination vaccine regime[2] in 2015.

The new production unit at the dedicated commercial-scale poxvirus-based vaccine manufacturing facility in Kvistgaard, Denmark, has now been completed. This facility was formerly used solely for Imvamune production, but now, as a multi-product facility, it will be used for future commercial production of Prostvac and other pipeline products. Bavarian Nordic next steps are to validate the Prostvac manufacturing process and prepare launch material.

Enrolment for the Phase III PROSPECT prostate cancer trial of Prostvac is open at all 200 centers targeted and on track for completion by end-2014. Final PROSPECT data are not expected until H216, although three interim analyses will precede this (most likely in 2015). Nevertheless, an active dialogue is ongoing with potential partners, in part stimulated by conference presentations (ASCO 2014) on the potential synergies between MVA-BN and immune checkpoint inhibitors in both primary and metastatic preclinical tumor models. An additional Prostvac update is planned at ESMO 2014.

Upcoming news flow is presented in Exhibit 1, with the Bavarian Nordic pipeline shown in Exhibit 2.

Exhibit 1: Key anticipated news flow H214 and 2015

Programmed	Timing	Comment
Imvamune	H214	Complete Phase II trial of freeze-dried version to support pre-Emergency Use Authorization submission (for stockpiling).
	H214	Initiate Phase III open-label non-inferiority trial vs ACAM2000.
	H214	Deliver on second (final) portion ($118m) of contract with US government.
	2014+	Potential orders from European governments.
Prostvac	H214	Completion of enrolment into PROSPECT Phase III study
	2015	Interim analyses of PROSPECT study: no company guidance provided on timing. First analysis not expected until late 2014 at earliest, given recruitment completion by end-2014. First analysis a futility check; survival data possible at later analyses.
CV-301	H214	Finalization of development plan for prioritized indication(s) (colorectal cancer); potential to secure external funding.
MVA-BN RSV	2015	Submit IND application; followed by Phase I initiation.
MVA-BN Ebola	H214+	Ongoing discussions with US government regarding clinical development pathway.
	2015	Potential start of Phase I trials for monovalent and multivalent vaccine candidates
Financials	13 November 2014	Q314 results

Source: Edison Investment Research, Bavarian Nordic

[1]The first $110m of the contract (total value $228m) had been secured; it was comprised of four performance-based milestones of $20m (connected to production of the first four million Imvamune doses) and $29m associated with delivery. The second $118m of the contract is comprised of an $18m upfront payment with a further $100m that will be recognised pro rata with the delivery of four million Imvamune doses.

[2] This consists of a prime-boost regimen of two vaccines based on Bavarian Nordic's MVA-BN technology and Crucell's AdVac technology.

Exhibit 2: Bavarian Nordic R&D pipeline

Product	Indication	Stage	Notes
Cancer immunotherapies			
Prostvac	Castration Resistant Prostate Cancer (CRPC)	Phase III	Subcutaneous admin. 17 completed and five ongoing clinical trials in >2,000 pts. 1,200-pt Phase III randomized, double-blind, placebo-controlled PROSPECT trial underway of Prostvac ± GM-CSF in asymptomatic or minimally symptomatic metastatic CRPC (SPA granted; enrolment ongoing at 200 centers in 15 countries; expected to complete by end-2014; includes planned interim analysis for futility/efficacy; primary endpoint: OS; results: August 2016). Three NCI sponsored Phase II trials underway: 65-pt study of flutamide ± Prostvac in non-metastatic PC (results from 41-pts show an improvement in TTP for pts receiving Prostvac + flutamide [median TTP = 192 days] compared to flutamide alone [median TTP = 108 days]; final results: Decl 2014); 38-pt study of enzalutamide ± Prostvac in non-metastatic castration-sensitive PC (endpoint: PSA kinetics – tumor re-growth rate post-enzalutamide discontinuation; results: June 2016); and 76-pt study of enzalutamide ± Prostvac in mCRPC (primary endpoint: PFS; results: June 2016); and 50-pt study in patients with PSA progress after local therapy (surgery and/or radiation), 19-pts progressed to second part of the study combining Prostvac with Casodex (results: January 2023). In a 125-pt Phase II study Prostvac demonstrated an extension in median survival in advanced PC patients of 8.5 mths, a near 50% increase vs placebo, Hazard ratio of 0.56 (95% CI 0.37-0.85), p=0.0061). ASCO 2014 publications include new evidence for mechanism of action. In licensed from NIH; developed in collaboration with the NCI under a CRADA.
CV-301	Colorectal cancer (CRC)	Phase II	Prioritized indication: FDA feedback on CRC development plan expected H214. Randomized controlled trial in planning contingent on funding availability. NCI-sponsored (Duke University) 74-pt Phase II trial of CV-301 ± GM-CSF in resected metastatic CRC showed sig. longer OSl vs concurrent matched control patients (p<0.0001) but no difference in PFS. Well-tolerated: most common adverse effects were injection site reactions, fever, fatigue and muscle soreness (Morse et al, Annals of Surgery, 2013 May 7). NCI collaboration agreement signed 2011.
	Bladder cancer	Phase II	54-pt NCI-sponsored Phase II study ongoing of Bacillus Calmette-Guerin (BCG) ± CV-301 in high-grade non-muscle invasive bladder cancer who failed ≥ one induction course of BCG (results: 2017).
	Breast cancer	Phase II	NCI-lead 48-pt Phase II open-label trial of docetaxel ± CV-301 in metastatic breast cancer; prelim data presented at ESMO 2012 (PFS of 6.6mths in the CV-301 group vs 3.8mths in those on docetaxel alone, Hazard ratio 0.67 [95% CI 0.34-1.31], p=0.12 although study not powered for significance; 5-pts remained on study at time of analysis). Toxicity similar in both arms.
MVA-BN PRO	Prostate cancer (PC)	Phase I/II	Dual vaccine targeting Prostate-Specific Antigen (PSA) and Prostatic Acid Phosphatase (PAP) antigen. 18-pt US Phase I/II safety/tolerability study in non-metastatic hormone-insensitive PC complete. Prelim data showed vaccine induced T-cell responses to both antigens and also to other tumor antigens.
MVA-BN HER2	Breast cancer	Phase I/II	Vaccine targeting the HER2-Neu antigen. Two Phase I trials completed. Preclinical data shows induction of HER2-specific Th1 immunity and dampening of tumor-mediated immunosuppression by altering the balance of effector and regulatory T cells).
MVA-BN Brachyury	Advanced cancer	Phase I	Vaccine targeting brachyury protein, a novel tumor-associated antigen overexpressed in wide variety of cancers (incl. lung, breast and prostate). 28-pt NCI-sponsored Phase I ongoing (results: 2016).
Infectious disease vaccines			
Imvamune/Imvanex liquid-frozen	Smallpox vaccine	Approved (EU & Canada); Phase III (US)	Non-replicating vaccine (EU: approved Aug 2013 as Imvanex based on data in >3,400-pts; Canada: approved Nov 2013; US: Phase III). Supplied for emergency use to the US Strategic National Stockpile under a US gov. contract (20m+ doses delivered to-date). US licensing strategy based on two Phase III trials: 4,000-healthy individual lot consistency study (fully enrolled; results: 2015) and a randomized open-label non-inferiority study of Imvamune vs current US licensed smallpox vaccine (ACAM2000, Sanofi Pasteur) in 440-military personnel (to initiate in H214; results: 2015).
Imvamune freeze-dried	Smallpox vaccine	Phase II	Freeze-drying offers storage and transportation advantages, plus increased shelf-life vs liquid-frozen version. 650-pt Phase II to support emergency use initiated May 2013 (fully recruited, results being finalized with expected FDA submission in 2015). April 2014 US government exercised a $21.9m option to fund technology transfer for higher capacity commercial manufacture.
MVA-BN Anthrax	Combined smallpox and anthrax vaccine	Preclinical	Evaluation of a combined smallpox and anthrax vaccine. Aiming for improved safety and suitability for high-risk groups, requiring fewer vaccinations compared with the currently available anthrax vaccine, and a freeze-dried formulation conferring storage and transportation benefits.
MVA-BN Filo	Filoviruses (Marburg and Ebola)	Preclinical	Advanced development contract (up to US$17.9m over five years) awarded by the National Institute of Allergy and Infectious Diseases (NIAID) in November 2012. Several candidate vaccines evaluated during a two-year base period (valued at US$4.4m); potentially to be followed by GMP production and Phase I testing of the lead candidate under 'several contract options' exercisable into 2017. Ongoing discussions with US Government regarding a clinical development pathway for MVA-BN Ebola vaccine candidates: (1) NIH plans to initiate a Phase I study of a combination vaccine prime-boost regimen using MVA-BN technology and Crucell's AdVac technology in 2015; and (2) a multivalent vaccine candidate for the two major Ebola strains may progress into an NIAID-run Phase I within 12 months.
MVA-BN FMDV	Foot and mouth disease virus	Preclinical	US$1m development contract awarded by US Department of Homeland Security Science and Technology Directorate in November 2012; base contract expanded by additional $400k in July 2014.
MVA-BN RSV	Respiratory syncytial virus	Preclinical	Lead candidate in NIH-sponsored toxicity study to support IND submission in H214; initiation of Phase I trial in 75 adult volunteers expected in 2015.
MVA-BN Burkolderia	Burkholderia	Preclinical	US$ 0.5m contract from the Defense Threat Reduction Agency (DTRA), part of the US Department of Defense awarded Feb 2014 to fund the design, development and testing of vaccines against two bacterial pathogens, *Burkholderia pseudomallei* and *Burkholderia mallei*.

Source: Edison Investment Research; Bavarian Nordic; clinicaltrials.gov. Notes: NCI = National Cancer Institute; CRADA = cooperative research and development agreement; OS = overall survival; TTP = time to progression; PFS = progression free survival;

Infectious diseases: Continuing US progress

The confirmation of option exercise for the delivery of the second four million Imvamune doses under the April 2013 RFP-3 contract to maintain the Strategic National Stockpile (SNS) is significant on a number of fronts. The receipt of $118m in upfront and delivery payments will ensure that the company will meet FY14 financial guidance (which was contingent on exercise); 3.2 million doses of finished product are ready for shipping, with the remaining 800k doses expected to complete manufacturing by end-September. It also further demonstrates US government commitment to the maintenance of Bavarian Nordic's manufacturing capabilities and ability to supply Imvamune and maintain the SNS in the longer term. The latter is particularly important as 2015 will be a year of transition with respect to Imvamune.

Imvamune has been, and is currently being, supplied to the US government as a liquid-frozen formulation. The next-generation freeze-dried formulation, which will have longer shelf life, is in development under a separate contract with BARDA, but is not expected to become available until 2016 at the earliest. The fully US government-funded Phase II study required to show comparable safety and efficacy to the existing liquid-frozen version of Imvamune is now fully recruited, and FDA submission to support emergency use is expected in 2015. However, a new contract would need to be secured for the procurement of freeze-dried Imvamune; management expects to initiate a dialogue with the US government regarding this in H214.

We assume that a new procurement contract will be secured; on the basis of the longstanding Bavarian Nordic/US government relationship and significant government investment already made coupled with the limited three-year shelf life of the existing Imvamune stockpile. This is further supported by the BARDA option exercise to transfer the validated freeze-dried manufacturing process to a larger capacity commercial-scale facility, supporting future product supply. We have revised our valuation to reflect this increased confidence (higher success probability), although uncertainty remains about the size and timing of any future awards.

Nevertheless, revenue uncertainty remains for 2015 onwards as contracts for this period have not been secured and a gap in US government Imvamune orders is anticipated ahead of availability of the freeze-dried formulation in 2016. Management is in discussions about ways in which to alleviate the financial impact, and the additional $1m in government funding allocated to support ongoing studies into long-term storage of frozen bulk drug substance could form part of this strategy. These studies are evaluating and validating ways in which to improve the shelf life of the bulk drug by improvements in the storage technology. There is potential for BARDA funding to be secured for 2015 to procure equivalent doses of bulk (rather than finished product) to maintain the SNS, which can later be used in the manufacture of freeze-dried Imvamune, and/or implement process improvements that further generate improved yield. We note that the trend for improving margins on US Imvamune deliveries reflects Bavarian Nordic's investment in production, and this will be an important contributor to future profitability given that the US government contracts are for fixed values.

Bavarian Nordic has also secured its first commercial contract with the Canadian government Public Health Agency following Imvamune's approval in 2013. This contract, coupled with a separate contract with the Canadian Department of Defence, totals 65.7k doses, with options for delivery of a further 454.3k doses over the next two years. While the US is the main market for Imvamune, contracts such as this, and also potentially from European governments (Imvamune is approved as Imvanex in Europe) represent upside.

Cancer vaccines: Combination potential

Bavarian Nordic's cancer immunotherapy programs have potential utility as both monotherapy and in combination. Recent preclinical data at ASCO 2014[3] highlighting synergistic potential with checkpoint inhibitors – showing that immunotherapy stimulates, and checkpoint inhibitors amplify, the immune system response to tumor cells – has reinvigorated ongoing partnering discussions for Prostvac and will also have implications for other pipeline programs.

Prostvac (for prostate cancer) is currently the main value driver of the cancer vaccine business division. It is the company's preference to partner this asset before the Phase III PROSPECT[4] monotherapy trial reads out in H216, so that there are no delays to launch. A Prostvac update at ESMO is scheduled for 27 September and is likely to build on the ASCO 2014 presentations on its mechanism of action and the synergistic potential of the prime-boost technology platform. In tandem, a number of NCI-sponsored Phase II combination trials with anti-androgen therapies are ongoing: final read out of the first, a combination with flutamide, is anticipated within the next six to 12 months, while results from the two trials in combination with Tandy (enzalutamide) are likely from 2016. A combination approach is increasingly common in oncology, and could maximize Prostvac's clinical and commercial potential. Data from these and from planned, combination trials will provide further insights into the settings (early- vs late-stage prostate cancer; monotherapy vs combination) in which Prostvac could potentially be used. In addition to combinations with checkpoint inhibitors or anti-androgen therapies, there is similar rationale for combining Prostvac with local radiation therapy. Exhibit 3 provides an outline of the benefits of combining Prostvac (or other Bavarian Nordic pipeline cancer vaccine candidates) with various anti-cancer approaches.

Exhibit 3: Combination rationale for poxvirus immunotherapy

	Other anti-cancer therapy	Benefits
BN Platform Immunotherapies	Anti-androgen or ADT therapy	■ Improve immunogenicity of tumor ■ Significant augmentation of therapeutic benefit from synergy ■ Improved time to develop anti-cancer immune response ■ Persistent anti-cancer response after therapy is complete ■ Minimal to no added side effects from immunotherapy ■ Potential for dose reduction of partner therapy
	Immune checkpoint inhibitors	
	Local radiation therapy	

Source: Bavarian Nordic

Bavarian Nordic is also looking to progress the development of its next most advanced cancer vaccine CV-301. CV-301 could ultimately become a more valuable programmed than Prostvac as it has potential across wider cancer indications (conferred through its incorporation of the CEA and MUC-1 tumor-associated antigens, which are more widely expressed than prostate specific antigen). At present, Bavarian Nordic does not have the resources to initiate a pivotal trial in the prioritized indication of metastatic colorectal cancer (mCRC), and thus will be seeking a development partner and/or collaborative funding. Finalization of the development plan for mCRC, following discussions with the FDA, is expected in H214, and may provide impetus to licensing discussions. The recently initiated NCI-sponsored Phase II bladder cancer trial provides an example of the collaborative funding that may be available, although this is most likely for earlier stage trials in promising indications outside of mCRC.

[3] Two posters presented at ASCO 2014: (1) Anti-tumour efficacy of poxvirus-based active immunotherapy alone and in combination with sub-therapeutic dosing with immune checkpoint inhibitors, and (2) Magnitude and quality of tumour-infiltrating T cell response upon poxvirus-based active immunotherapy alone and in combination with CTLA-4 immune checkpoint inhibition.

[4] A pivotal Phase III trial in asymptomatic/minimally symptomatic metastatic CRPC (mCRPC). It is a randomized, double-blind, placebo-controlled three-arm trial (Prostvac + GM-CSF; Prostvac alone; placebo control) with an overall survival (OS) primary endpoint. The trial has a Special Protocol Assessment (SPA) specifying a required hazard ratio of ≤0.82 (18% reduction in risk of death). The final analysis requires 534 deaths, although there is the possibility of earlier data as the trial design includes three event-driven pre-specified futility/efficacy interim analyses (criteria undisclosed). The earliest an interim analysis could occur is late-2014 (futility only); one or more analyses in 2015 (futility/efficacy) are more likely. Timing of these is largely defined by survival in the placebo arm, but a positive efficacy finding in favor of Prostvac could result in early filing.

Sensitivities

Bavarian Nordic is subject to the usual biotech risks (clinical, regulatory, partnering, financing, commercialization), with key stock-specific sensitivities relating to main value drivers Prostvac and Imvamune. An important near-term catalyst is the outcome of the Phase III PROSPECT trial (including the potential of an early stop for efficacy following planned interim analysis); this may provide clarity on the timing and structure of a Prostvac partnership. Potential combination data – with other novel approaches such as enzalutamide and checkpoint inhibitors – will also assist in assessing Prostvac's overall commercial potential (penetration and pricing) in a dynamic prostate cancer market. Current revenues are generated from US government contracts for Imvamune, hence there is reliance on government spending (allocations to biodefence, availability of future funding). Continued supply is assumed, but timing is unknown. European orders are unlikely to be forthcoming until preparedness programs (stockpiling) are outlined and finalized.

Valuation

Our updated sum-of-the parts valuation of Bavarian Nordic is $620m or $24/ADR (previously $545m, $20.9/ADR). The change reflects the fact that we have increased our success probability for future Imvamune US contracts (from 50% to 70% due to increased confidence that new contracts for the freeze-dried formulation will be secured), and included the Canadian Imvamune contract as well as rolling forward our forecasts to reflect the passage of time and updating the FX rate to DKK5.66/US$ (DKK5.44/US$ previously). The components of our valuation are shown in Exhibit 4.

Exhibit 4: Valuation of Bavarian Nordic

Value driver	Value ($m)	Value per ADR ($m)	Notes
Prostvac (CRPC)	683	26.2	For CRPC. Launch date: 2018. Peak sales: $1.3bn (global, assuming a price of $50,000 pa). Risk adjustment: 60% (reflecting Phase II data and benign safety profile). Effective royalty: 40%.
CV-301 (mCRC)	62	2.4	For mCRC. Launch date: 2020. Peak sales: $865m (global, assuming a price of $50,000 pa). Risk adjustment: 25%. Royalty: 20%.
Imvamune US	216	8.3	Assumes deliveries under 2013 contract are completed by late 2014/early 2015, and subsequent replacement contract(s) of the freeze-dried formulation up to 20m doses are delivered 2016-21. Risk adjustment for new contracts: 70%. Price per dose: $28.5 (average under 2013 contract).
Imvanex	44	1.7	Assumes European government contracts of 12m doses secured for delivery in 2015-20. Risk adjustment: 25%. Average price per dose: $25 (discount to US pricing).
Imvamune Canada	5	0.2	Assumes delivery of 500k doses (total delivery potential if future options exercised under August 2014 Canadian government contracts August 2014). Average price per dose: $25 (discount to US pricing).
R&D	(128)	(4.9)	
Admin	(110)	(4.2)	
Tax	(193)	(7.4)	
Capex	(12)	(.5)	
Gross cash	53	2.0	As at end June 2014: includes cash, investments and financial liabilities.
Total	**620**	**23.8**	

Source: Edison Investment Research, Bavarian Nordic. Note: DCF out to 2025; WACC of 12.5%; US$/DKK of 1/5.66.

The main catalysts that could trigger a re-rating of the shares are:

- partnership deals for Prostvac and CV-301 in CRC.
- readout of PROSPECT (2016) and results of potential interim analyses (2015).
- Imvamune/Imvanex: First confirmed European orders; Phase III read out and FDA filing; further US orders (for freeze-dried formulation); and
- progress of other pipeline assets (in particular, cancer immunotherapy and infectious disease assets or indications, which are currently not included in our valuation). For example, the MVA-BN programs for RSV, anthrax and Ebola/Marburg, and other indications for CV-301.

Financials

At Q214 results, Bavarian Nordic management reiterated FY14 financial guidance; company guidance and Edison estimates for FY14 are shown in Exhibit 5. H114 revenue of DKK450m (19% lower vs DKK556m in H113) was solely generated by the infectious disease division (delivery of 2.6 million doses of Imvamune to the US National Stockpile plus development and contract work under US government contracts). Imvamune margins have recovered from the production challenges of Q114 (due to one-off yield issues) and the full-year contribution margin expectation is in line with FY13. Ongoing process and yield improvements should contribute to enhanced margins in the medium term.

R&D spending (on the ongoing PROSPECT trial and Phase III Imvamune lot consistency study) declined to DKK191.6m (H113: DKK282.3m). This R&D figure excludes capitalized Imvamune development costs of DKK27.6m (H113: DKK38m) and contract expenses of DKK31m included within COGS (vs DKK50m in H113), but includes DKK17.6m (DKK118m) of amortization/expensing of the Imvamune development project in progress. Pre-tax loss for the period was DKK63.8mm (H113: loss of DKK42.7m).

Bavarian Nordic ended H114 with cash preparedness of DKK423m, of which DKK303m was gross cash and equivalents, with the remainder attributed to the undrawn DKK120m credit line.

Exhibit 5: Financial guidance and Edison estimates for 2014

Measure	Guidance (DDKm)	Guidance ($m)	Edison estimates (DDKm)	Edison estimates ($m)	Notes
Revenue	1,200	212	1,233	217.9	Deliver and recognize 6.5m Imvamune doses to US National Stockpile (2013 contract).
EBIT	Break even	Break even	1.5	0.27	The infectious diseases division is expected to deliver EBIT of DKK400m, which will be offset by a DKK400m EBIT loss from the cancer immunotherapy division.
Cash preparedness	600	106	597	105	Includes cash and equivalents and undrawn DKK120m credit line.
R&D spend	600	106	585	103	NB: This figure includes the following item (stripped out in our model).
– Contract expenses	110	19.4	107	18.9	Research services under US government Imvamune contracts. Included in COGS.
Expensing of Imvamune development project in progress	50	8.8	50.1	8.8	Amortization of Imvamune intangible (expensed through the P&L) as doses are delivered under the US government contracts.

Source: Edison Investment Research, Bavarian Nordic. Note: estimate changes are largely driven by the updated $5.66 DKK FX rate.

The cash flow from the exercise of the $118m US Imvamune option will ensure that Bavarian Nordic meets its guidance for 2014. However, 2015 will be a transition year for the company, given an anticipated gap in US government Imvamune orders before the freeze-dried formulation becomes available in 2016. Management is in discussions about ways in which to alleviate the financial impact, and we await confirmation regarding this. Nevertheless, revenue uncertainty remains for 2015 onwards; our forecasts are significantly lower than 2014 as Imvamune/Imvanex contracts for this period have not yet been secured. We expect potential European contracts or further US orders for the freeze-dried formulation (both of which are risk-weighted in our valuation); if these are not secured or there is a significant delay, there is likely to be a future funding requirement pre-Prostvac launch, which could be addressed by a Prostvac partnership.

Exhibit 6: Financial summary

$m	2012	2013	2014e	2015e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	179.6	214.2	217.9	113.9
Cost of Sales	(90.7)	(85.6)	(94.2)	(47.3)
Gross Profit	88.9	128.6	123.7	66.6
EBITDA	(5.6)	32.1	14.1	(8.9)
Operating Profit (before GW and except.)	(5.6)	32.1	9.1	(18.5)
Intangible Amortization	0.0	(26.2)	(8.8)	(5.4)
Other	0.0	0.0	0.0	0.0
Exceptional	0.0	0.0	0.0	0.0
Operating Profit	(5.6)	5.9	0.3	(23.9)
Net Interest	(3.0)	(4.8)	0.2	(0.8)
Other	0.0	0.0	0.0	0.0
Profit Before Tax (norm)	(8.6)	27.3	9.3	(19.3)
Profit Before Tax (FRS 3)	(8.6)	1.1	0.4	(24.7)
Tax	(33.8)	(9.4)	0.4	(1.2)
Deferred tax	0.0	0.0	0.0	0.0
Profit After Tax (norm)	(42.4)	17.9	9.7	(20.5)
Profit After Tax (FRS 3)	(42.4)	(8.3)	0.8	(25.9)
Average Number of Shares Outstanding (m)	26.1	26.1	26.1	26.1
EPS - normalized (DKK)	(0.9)	0.4	0.2	(0.4)
EPS - FRS 3 (DKK)	(0.9)	(0.2)	0.0	(0.6)
Earnings per ADS - normalized ($)	(0.2)	0.1	0.0	(0.1)
Earnings per ADS ($)	(0.2)	(0.0)	0.0	(0.1)
Dividend per share (DKK)	0.0	0.0	0.0	0.0
Gross Margin (%)	49.5	60.0	56.8	58.5
EBITDA Margin (%)	(3.1)	15.0	6.5	(7.8)
Operating Margin (before GW and except.) (%)	(3.1)	15.0	4.2	(16.2)
BALANCE SHEET				
Fixed Assets	113.8	97.5	96.7	83.9
Intangible Assets	26.2	18.5	18.0	14.0
Tangible Assets	56.6	57.0	56.1	48.6
Other	31.0	22.0	22.6	21.3
Current Assets	158.1	159.1	137.4	109.8
Stocks	40.5	41.3	23.2	19.4
Debtors	97.2	94.0	84.3	71.6
Cash	20.2	23.8	29.8	18.7
Other	0.3	0.0	0.0	0.0
Current Liabilities	(85.7)	(68.8)	(45.7)	(31.3)
Creditors	(76.5)	(67.3)	(44.2)	(29.8)
Short term borrowings	(9.3)	(1.5)	(1.5)	(1.5)
Long Term Liabilities	(9.6)	(15.3)	(14.6)	(14.6)
Long term borrowings	(6.5)	(12.7)	(12.0)	(12.0)
Other long term liabilities	(3.0)	(2.6)	(2.6)	(2.6)
Net Assets	176.6	172.5	173.7	147.8
CASH FLOW				
Operating Cash Flow	5.5	28.3	8.3	(6.7)
Net Interest	(1.5)	(2.0)	(0.5)	(0.8)
Tax	(0.5)	(0.3)	(0.7)	(1.8)
Capex	(8.0)	(27.5)	(16.5)	(3.4)
Acquisitions/disposals	0.0	0.3	0.0	0.0
Financing	0.0	0.0	0.4	0.0
Dividends	0.0	0.0	0.0	0.0
Other	(0.1)	0.0	0.0	0.0
Net Cash Flow	(4.5)	(1.1)	(9.0)	(12.7)
Opening net debt/(cash)	(85.7)	(81.4)	(79.8)	(70.8)
HP finance leases initiated	0.0	0.0	0.0	0.0
Exchange rate movements	0.0	0.0	0.0	0.0
Other	0.2	(0.5)	0.0	0.0
Closing net debt/(cash)	(81.4)	(79.8)	(70.8)	(58.1)

Source: Edison Investment Research, Bavarian Nordic accounts. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of US$1 to DKK5.66. Bavarian Nordic reports statutory accounts in Danish kroner. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

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