EDISON

Nanobiotix

Corporate update

Data, dollars and development updates

Pharma & biotech

During 2014 Nanobiotix continued to progress lead product NBTXR3, with positive data leading to a refined development strategy that could allow for first CE mark approval in STS in Europe by 2016. Capital increases and additional future commitments should allow Nanobiotix to continue with its recently expanded NBTXR3 development strategy and go-it-alone US commercial plans. During 2015 we expect more NBTXR3 clinical data from ongoing trials and the start of further trials under the current strategy.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/12	1.0	(5.2)	(0.65)	0.0	N/A	N/A
12/13	1.6	(8.1)	(0.75)	0.0	N/A	N/A
12/14e	1.9	(8.9)	(0.71)	0.0	N/A	N/A
12/15e	3.1	(12.2)	(0.86)	0.0	N/A	N/A

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

STS development plans refined during 2014

Following positive NBTXR3 data in the pilot soft tissue sarcoma (STS) trial, Nanobiotix recently started a pivotal study in c 180 patients as part of the strategy to bring NBTXR3 to market in Europe by the end of 2016 (via a CE mark process). Existing Asia-Pacific partner PharmaEngine has also elected to participate in the trial. Interim data could become available in H116 and could trigger the start of a potential bridging study in the US, depending on the data.

Expanded strategy broadens NBTXR3's potential

Aside from the ongoing clinical trials (STS pivotal study and head and neck pilot study), towards the end of 2014 Nanobiotix announced expanded development plans to include liver cancers (hepatocellular carcinoma HCC, and liver metastases) and high-risk prostate cancer, broadening NBTXR3's potential. Nanobiotix also intends to pursue NBTXR3 commercialisation alone in the US.

NBTXR3 data and strategy execution in 2015

During H115 interim data from the ongoing head and neck pilot study could become available, which could then be followed by a pivotal study. In addition, US/EU pilot studies in both liver cancers and high-risk prostate cancer could potentially start in H215. Further development of NBTXR3 will be funded by cash raised during 2014, which most recently includes €10.4m from a strategic US investor, with future potential commitments of €24.1m (€14.1m through warrants), which will also support the strategy to commercialise NBTXR3 alone the US.

Valuation: No changes to €464m rNPV

We make no changes to our €464m (€33/share) risk-adjusted NPV-based valuation, which includes NBTXR3 commercialised by Nanobiotix in both the US and Europe in the various planned indications included within the current strategy (STS, head and neck, liver cancers and high-risk prostate cancers).

9 January 2015

Price	**€17.49**
Market cap	**€247m**

Net cash (€m) at end June 2014	25.7
Shares in issue	14.1m
Free float	41%
Code	NANO
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	1.3	(8.7)	257.5
Rel (local)	3.7	(11.7)	253.9

52-week high/low	€24.44	€4.83

Business description

Nanobiotix is a French nanotechnology company developing radiotherapy enhancers for the treatment of cancer. Lead product NBTXR3 has completed pilot clinical STS development in Europe and is partnered with PharmaEngine in Asia-Pacific.

Next events

Interim head and neck data	H115
Start of pilot trials in prostate and liver cancers	H215
Expansion of STS trial to additional countries	2015
Interim STS data	H116

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Edison profile page

Valuation

We have made no changes to our recently updated Nanobiotix valuation of €464m, or €33/share. This includes NBTXR3 in the various indications being pursued under the current development plan (STS, head and neck cancer, liver cancers and high-risk prostate cancer), which we assume will be commercialised alone in the US and Europe. Our combined US/EU peak NBTXR3 sales are €1.4bn. Our valuation also includes a contribution for the partnership with PharmaEngine in Asia-Pacific in indications that we believe could be pursued in this region. The breakdown of our rNPV valuation, which uses a 12.5% discount rate, is shown in Exhibit 1.

Exhibit 1: Nanobiotix rNPV valuation

Product	Indication	Launch	Peak sales (€m)	NPV (€m)	Probability	rNPV (€m)	rNPV/share (€/share)
NBTXR3 – US/Europe	STS	2016	190	184.3	60%	108.4	7.7
	Head & neck	2019	350	301.3	40%	113.7	8.1
	Liver cancers including liver mets	2021	500	266.0	40%	99.9	7.1
	Prostate cancer	2021	400	213.4	40%	80.7	5.7
NBTXR3 – Asia	STS; rectal; oesophageal; liver cancer	2017	300	63.8	40%	25.5	1.8
Pro forma net cash				35.6	100%	35.6	2.5
Valuation				**1,064.3**		**463.7**	**33.0**

Source: Edison Investment Research

Commercialisation alone in the US and Europe

Nanobiotix always intended to commercialise NBTXR3 alone in Europe and at the end of 2014 following the private placement in the US, announced plans to also commercialise alone in the US (partnering could still be an option in the future, but would be dependent on the terms of any deal). Hence our forecasts and valuation were adjusted in our last note to reflect this updated strategy, reflecting the full development costs and a sales and marketing infrastructure, rather than a simple royalty. Although at the time of launch this will require a higher initial cash outlay to build a salesforce, this strategy will likely be far more profitable than a partnership in the longer term.

Our valuation is split in the US and Europe by each indication that is being developed or is in the development plan. These include STS, where we assign a 60% probability of success, commensurate with a Phase III asset. NBTXR3 is regulated as a medical device in Europe, rather than as a drug and hence the pivotal study in Europe should be the final stage of development before approval. For all other indications (head and neck cancer, liver cancers and high-risk prostate cancer), we assign a 40% probability of success. The development status of each indication is as follows:

- **Soft tissue sarcoma (STS):** a pivotal STS study in 180 patients recently began following approval in France, with expansion across Europe (funded by Nanobiotix) to additional countries as further approvals are granted. Partner PharmaEngine is funding recruitment in Asia-Pacific. Interim data from this trial are expected in H116 followed by full data and CE mark approval as a medical device in Europe potentially by end 2016. This could lead to initial self-pay sales in STS, with full reimbursement likely sought once survival data become available in other indications, potentially 12-18 months later. A bridging study could start in the US once interim data become available.
- **Head and neck cancer:** a pilot trial in head and neck cancer is ongoing and interim data could become available during H115. This could provide NBTXR3 proof-of-concept in another indication. If positive, a pivotal study could potentially start from 2016.

- **Liver cancers (HCC and liver metastases):** a pilot study in this indication could start in H215, which if positive could lead to pivotal development in 2017 and potential launch in 2021. Liver metastases (tumours arising in the liver from the spread of other primary cancers such as colorectal cancer, breast cancer, lung cancer etc) could be a significant opportunity for NBTXR3, as for example in colorectal cancer alone there are nearly 150k new cases in the US each year, with around 50% who develop hepatic metastases. We more conservatively assume around 100k liver metastases patients in the US and Europe who could be eligible for NBTXR3.
- **High-risk prostate cancer:** similar to liver cancers, a pilot study in this indication could also start in H215, with potential launch in 2021.

Our forecasts in Asia continue to assume partner PharmaEngine will develop NBTXR3 in a number of indications, which include STS and could include rectal, oesophageal and liver cancer (the precise indications to be developed have not yet been disclosed).

Financials

We have made no changes to our last published financial forecasts, which include R&D spend for each of indications included in our valuation. These include: (1) the recently started pivotal STS trial in Europe; a bridging study could start in the US in H216, which is incorporated in our forecasts; (2) the pilot head and neck trial that is ongoing in Europe and could be followed by a pivotal US/European trial in 2016, which is factored in our forecasts; and (3) €2-3m spend for pilot trials in each of liver and prostate cancers, which we assume will start in H215.

We also include the build-out of a commercial infrastructure in Europe in 2016 in readiness for launch at end 2016/early 2017, although this is likely to be quite limited in the early part of launch.

Our unchanged forecasts continue to suggest current net cash of around €35.6m (based on reported net cash at end June of €25.7m together with the estimated net proceeds of €9.9m from the recent private placement) should be sufficient to fund operations to H216, assuming development continues in all planned indications. This could potentially be met by the €10m commitment from Capital Ventures International (CVI) as part of the recent private placement, the terms of which are summarised below (we do not include this future commitment or the exercise of the warrants in our financial forecasts):

- **€10.4m private placement:** Nanobiotix secured €10.4m cash through a private placement to CVI in December through the issuance of 650k shares at €15.99/share (we assume net proceeds of c €9.9m).
- **650k warrants could raise €14.1m:** a warrant is attached to each new share, with an exercise price of €21.63, which could raise a further €14.1m. These warrants expire on 30 June 2016 and can be exercised by CVI at any point before expiry. Nanobiotix can require CVI to exercise the warrants if Nanobiotix's share price is >€32.45 for 20 days in a 30-trading day period.
- **A further €10m could be raised in the future:** CVI has committed to purchase up to a further €10m of new shares (up to 650k shares) between 25 November 2015 and 31 March 2016. By this point additional data from STS and from head and neck could be available, both of which will help to inform decisions on the future clinical development.

Exhibit 2: Financial summary

€000s	2009	2010	2011	2012	2013	2014e	2015e	2016e
Year end December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS								
Revenue	2,768	1,135	1,360	971	1,595	1,928	3,103	7,130
Cost of Sales	(95)	0	0	0	0	0	0	(143)
Gross Profit	2,673	1,135	1,360	971	1,595	1,928	3,103	6,987
Research and development	(3,443)	(4,186)	(5,213)	(4,312)	(6,026)	(7,500)	(12,000)	(26,000)
Selling, general and administration	(729)	(1,045)	(1,375)	(1,811)	(3,749)	(3,600)	(3,708)	(11,375)
EBITDA	(1,295)	(3,935)	(5,030)	(5,006)	(7,945)	(9,020)	(12,432)	(30,192)
Operating Profit (before amort. and except.)	(1,490)	(4,092)	(5,213)	(5,146)	(8,171)	(9,163)	(12,594)	(30,376)
Intangible Amortisation	(9)	(4)	(14)	(7)	(8)	(9)	(11)	(12)
Exceptionals	0	0	0	0	0	0	0	0
Other	(1)	(0)	(0)	(22)	0	0	0	0
Operating Profit	(1,499)	(4,096)	(5,227)	(5,175)	(8,179)	(9,172)	(12,605)	(30,389)
Net Interest	(10)	11	(19)	(77)	34	285	434	58
Profit Before Tax (norm)	(1,500)	(4,081)	(5,233)	(5,223)	(8,137)	(8,877)	(12,160)	(30,318)
Profit Before Tax (FRS 3)	(1,510)	(4,086)	(5,247)	(5,252)	(8,145)	(8,887)	(12,170)	(30,331)
Tax	0	0	0	(79)	18	0	0	0
Profit After Tax (norm)	(1,501)	(4,081)	(5,233)	(5,324)	(8,118)	(8,877)	(12,160)	(30,318)
Profit After Tax (FRS 3)	(1,510)	(4,086)	(5,247)	(5,331)	(8,126)	(8,887)	(12,170)	(30,331)
Average Number of Shares Outstanding (m)	4.5	6.8	7.7	8.2	10.8	12.4	14.1	14.1
EPS - normalised (€)	(0.3)	(0.6)	(0.68)	(0.65)	(0.75)	(0.71)	(0.86)	(2.15)
EPS - normalised and fully diluted (€)	(0.3)	(0.6)	(0.68)	(0.65)	(0.75)	(0.71)	(0.86)	(2.15)
EPS - (IFRS) (€)	(0.3)	(0.6)	(0.68)	(0.65)	(0.76)	(0.72)	(0.86)	(2.15)
Dividend per share (€)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	96.6	100.0	100.0	100.0	100.0	100.0	100.0	98.0
EBITDA Margin (%)	-46.8	-346.7	-369.7	-515.8	-498.0	-467.9	-400.6	-423.4
Operating Margin (before GW and except.) (%)	-53.8	-360.6	-383.3	-530.2	-512.2	-475.3	-405.8	-426.0
BALANCE SHEET								
Fixed Assets	569	682	580	485	545	641	625	766
Intangible Assets	6	2	7	0	9	17	23	28
Tangible Assets	540	638	511	416	468	556	534	670
Investments	23	42	63	69	68	68	68	68
Current Assets	3,096	7,253	2,333	13,539	6,894	36,240	26,780	4,895
Stocks	0	0	0	0	0	0	0	0
Debtors	0	0	0	1	1	1	2	4
Cash	1,084	649	899	12,361	5,002	34,348	24,887	3,000
Other	2,012	6,604	1,434	1,177	1,891	1,891	1,891	1,891
Current Liabilities	(1,214)	(1,539)	(1,415)	(2,160)	(3,282)	(4,093)	(4,933)	(2,933)
Creditors	(1,027)	(1,349)	(1,119)	(1,800)	(3,051)	(3,843)	(4,683)	(2,683)
Short term borrowings	(187)	(190)	(295)	(360)	(231)	(250)	(250)	(250)
Long Term Liabilities	(522)	(505)	(573)	(1,167)	(975)	(1,725)	(3,280)	(13,566)
Long term borrowings	(500)	(474)	(527)	(1,072)	(875)	(1,625)	(3,175)	(13,466)
Other long term liabilities	(22)	(31)	(46)	(95)	(100)	(100)	(104)	(100)
Net Assets	1,928	5,891	926	10,697	3,182	31,063	19,193	(10,838)
CASH FLOW								
Operating Cash Flow	(1,667)	(4,157)	(4,862)	(3,786)	(6,837)	(7,932)	(11,288)	(31,898)
Net Interest	(89)	13	(7)	(119)	(18)	285	434	58
Tax	0	0	0	0	0	5	0	0
Capex	(97)	(245)	(60)	(45)	(196)	(231)	(140)	(321)
Acquisitions/disposals	0	0	0	1	4	(17)	(17)	(17)
Financing	2,722	8,011	15	14,807	14	36,468	0	0
Dividends	0	0	0	0	0	0	0	0
Net Cash Flow	869	3,621	(4,914)	10,858	(7,034)	28,577	(11,011)	(32,178)
Opening net debt/(cash)	(540)	(396)	15	(76)	(10,929)	(3,895)	(32,473)	(21,462)
HP finance leases initiated	0	0	0	0	0	0	0	0
Other	(1,013)	(4,033)	5,006	(5)	0	0	0	0
Closing net debt/(cash)	(396)	15	(76)	(10,929)	(3,895)	(32,473)	(21,462)	10,716

Source: Nanobiotix accounts, Edison Investment Research. Note: Long-term liabilities include our future fund-raising estimate of €10m in 2016, assuming all clinical trials progress as planned. This could potentially be met by commitments from the strategic US investor, Capital Ventures International (CVI).

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