



*Small but heading for the big time*

## ***Nanobiotix Half Year Results for the six months ended 30 June 2014***

### ***Significant operational and clinical progress made***

**Paris, France, August 28, 2014 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205)**, a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, has published today its half year results for the six months ended 30 June 2014.

#### **Financial highlights:**

- Total revenue of circa €1m (H1 2013: €0.7m) comprises the pro-rata share of the original upfront payment from PharmaEngine (€92k), research tax credits (€666k) and subsidies (€240k)
- The increase in R&D costs at €3.3m (H1 2013 €2.7m) are in line with our development plans while General costs remain stable due to our ongoing internalization process
- Underlying loss after tax for the period was €4.2m (H1 2013: loss €4.3m) in line with our expectations
- Successful capital increase with preferential subscription rights of €28.1m in March 2014.
- Cash balance as at 30 June 2014 was €27m (H1 2013: €8.1m)

#### **Main operational highlights:**

- Positive phase I results for NBTXR3 presented at ASCO annual conference and Best of ASCO
- Development timetable for NBTXR3 accelerating; CE mark registration and approval could be obtained in 2016
- Strengthening of the Supervisory Board and management team to support development plans
- Pivotal study preparation, final step leading to registration of the product

#### **Laurent Levy, Chief Executive Officer at Nanobiotix, said:**

*“At the beginning of this financial year, we flagged 2014 as pivotal to the company. Events in H1 have already demonstrated this, with a significant capital raising, and the publication and presentation of successful clinical results for our lead product at the annual ASCO conference. We have also accelerated our clinical development plans for launch of NBTXR3, aiming to obtain CE marking in 2016. We have the necessary funds and shareholder support following the oversubscribed €28.1m capital raising in Q1.*

*In the second half of the year, we will continue to focus on the progress of NBTXR3 and its international development. We will also be developing market access and reimbursement strategies of our product in preparation for launch.”*

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## CEO's Operational Report

2014 is proving to be a pivotal year and has seen an eventful first six months both financially and operationally, notably in the clinical development of NBTXR3. The key highlights of the period have been summarised below.

### Overview

Nanobiotix is a pioneer in nanomedicine, developing a first-in-class proprietary technology called NanoXray. The strategy of the company is to establish a pipeline of products as cancer nanomedicine reference points in the oncology markets.

The company is developing three different products that can be administered either by direct injection into the tumor (NBTXR3), intravenous injection (NBTX-IV) or topical application to fill tumor cavities just after tumor surgery (NBTX-TOPO). Currently, NBTXR3 is regarded as a medical device in Europe and a drug in the United States (US).

### Financial developments

#### €28.1m capital raise

Nanobiotix achieved a successful €28.1m capital raise based on a share price of €10.60, broadening the shareholder base in Europe. There was a significant demand for the shares so the company issued an additional 15% of new equity over the initial offering size. The aim of the capital raise was to provide the company with additional resources to finance its development strategy for NanoXray.

In April 2014, following the completion of the capital increase, the original institutional shareholders remaining invested in the company represented 30.2% of its capital. There was also a significant increase in retail shareholders (43.6% of the capital against 13.1% previously). Importantly for the company, the international mix of institutional investors has grown substantially, with 79 non-French shareholders representing 10.7% of the capital compared to 2% previously, from the UK, Belgium, the Netherlands, Luxemburg, Italy, etc.

#### Capital market Index

In June 2014, the company was added to the CAC® PME Index which tracks the performance of between 20 and 40 French PEA PME eligible companies. The company is already included in the Next Biotech Index in Europe. Nanobiotix's inclusion on the PME index is helpful to raise the company's profile and the stock's visibility to new potential investors.

### Product development – NBTXR3

NBTXR3 is the first product of the NanoXray portfolio to reach clinical development. The product comprises nanoparticles which can be injected directly into cancer cells. With the application of radiotherapy, these nanoparticles absorb X-rays which significantly enhances the radiation dose within the cancer cells without increasing the dose to the surrounding healthy tissues. Potential indications for this product include soft tissue sarcoma, head and neck cancer, liver cancer, glioblastoma (a specific form of brain cancer), rectal and prostate cancer.

#### Soft tissue sarcoma (STS)

STS cancers arise from different types of tissues such as fat cells, muscles, joint structures and small vessels. Patients with high grade STS have poor prognoses, with many undergoing radiotherapy prior to surgery to remove the tumor.

Nanobiotix achieved a successful phase I proof-of-concept clinical study for NBTXR3 for STS in 2013 and completed the study in H1 2014. The final very positive results were presented at ASCO on 2 June 2014. The Phase I clinical study established that intratumoral injection of NBTXR3 followed by radiotherapy has a good safety profile in patients with locally advanced soft tissue sarcoma (STS), who have an important

risk of relapse and few treatment options. Final results also demonstrate treatment feasibility and promising signs of efficacy in patients with advanced Soft Tissue Sarcomas.

These positive clinical results allow Nanobiotix to proceed to the pivotal phase, which is the final step before registration of a CE mark. Enrolling patients for the pivotal study is expected to commence before the end of 2014. Clinical development has been faster than originally expected and therefore, the company has brought forward its initial estimate for achieving CE mark from 2017 to 2016.

### **Head and neck cancer**

Head and neck cancer represents a group of biologically similar cancers that appear in the mouth, the nose, the sinuses and at the top of the aerodigestive tract. This will be the second indication for NBTXR3 in radiation therapy with the aim to improve tumor destruction, and to maintain patients' function and appearance after treatment.

Nanobiotix has continued its progress in the clinical development of NBTXR3 in elderly patients with a pilot trial for head and neck cancers. Patients are being assessed on their tolerance of the product in the context of providing better control of the disease and an improved quality of life.

### **Liver cancers**

In 2014, Nanobiotix pursued the non-clinical evaluation phase of NBTXR3 in a third indication, primary liver cancer with a view to initiating a clinical trial of NBTXR3 in patients suffering from liver cancer. In this population of patients, the aim of using the product is to increase and prolong patients' survival rates. This programme is being supported with a €2.8m grant from Bpifrance through the NICE project. This non-clinical evaluation phase should be finalized in H2 2014.

### **NBTXR3 Partnerships**

In Europe, Nanobiotix is focusing its resources on potential CE mark of NBTXR3 in 2016.

For the development and commercialization of NBTXR3 in Asia-Pacific region, Nanobiotix has been in partnership with the Taiwanese company, PharmaEngine.

For NBTXR3's development in the United States, Nanobiotix is still evaluating its different options of partnering the product.

## **Other product development**

### **NBTX-IV**

NBTX-IV is the second product generated from Nanobiotix's proprietary NanoXray platform for administration intravenously to target deep-seated tumors and lymph nodes which may have been invaded locally by cancer cells. The aim is to enhance radiotherapy energy to destroy cancer cells and to reduce the subsequent escape of malignant cells in neighbouring tissue cells or lymph nodes. Target indications include lung carcinoma, rectal cancer or locally advanced prostate cancer.

In 2013, the product was selected by the National Cancer Institute (NCI) for preclinical characterization and that process continues into 2014. The resulting data will support Nanobiotix's filing of an Investigational New Drug (IND) with the FDA.

## **NBTX-TOPO**

This is the third product from the NanoXray platform and is a gel containing NanoXray nanoparticles potentially applicable for all types of post-operative radiotherapy, designed for direct application to the tumor bed, the cavity left following the surgical removal of a tumor. This nanotherapeutic product with embedded radar combines two important functions: a more efficient eradication of remaining cancer cells following the surgical removal of a tumour and a more accurate localization of the tumour bed (post-surgical cavity). Preclinical development commenced at the end of 2013 and is progressing in line with expectations.

### **Supervisory Board and management appointments**

To support these key developments, the Anne-Marie Graffin and Enno Spillner joined the Supervisory Board in H1 2014. Both have considerable understanding of the international healthcare ecosystem and stock markets, and therefore they will be valuable contributors in helping Nanobiotix achieve its ambitious future strategy.

On the operational side, in April, Nanobiotix announced the appointment of Thierry Otin as Head of Manufacturing and Supply. He has over 30 years' experience in the global pharmaceutical industry. His expertise strengthens the manufacturing team as they prepare to industrialize the process as NBTXR3 moves from clinical trials into CE mark which could occur as soon as 2016.

### **Intellectual property and promotion of Nanomedicine**

#### **Scientific article publication about the NBTXR3 concept**

Researchers from Nanobiotix have written an article that highlights the universality of the concept upon which NBTXR3 is based. The scientific article entitled "*Hafnium oxide nanoparticles: toward an in vitro predictive biological effect?*" was accepted and published in Radiation Oncology in June 2014 (Source: Marill et al. *Radiation Oncology* 2014, 9:150).

This is a new scientific recognition of the generalizability of our technology.

#### **US patent**

A new patent has been granted in the US, which strengthens the protection of NanoXray. This adds to the broad platform of intellectual property already in place.

#### **Nanomedicine promotion**

Nanobiotix continues to promote nanomedicine as a whole, which it achieves through the CEO, Laurent Levy, who is also Vice Chairman of the European Technology Platform on Nanomedicine (ETPN).

### **Outlook and summary**

With the €28.1m capital raising, the inclusion of Nanobiotix on the CAC® PME Index, the acceleration of the commercialisation plans for NBTXR3 in STS, the successful final results of the STS pilot study presented at the ASCO annual congress and the significant progress made in other development areas, H1 2014 has surpassed expectations.

For the remainder of the year, the company expects to see further progress at the clinical and preclinical level, with a major focus being the preparation of the registration phase of the company's lead product. During the period shareholders will be updated on the company's strategic plans to expand its geographical reach beyond Europe.

**Laurent Levy**

**CEO, Nanobiotix**

## Financial Review (IFRS)

The detailed financial statement of revenues and costs is laid out below:

(€ '000)	6 months period closed	
	June 30 2014	June 30 2013
Operating revenue	91	92
Other revenue	906	574
<i>Subsidies</i>	240	61
<i>Research Tax Credit</i>	666	513
<b>Total revenue</b>	<b>997</b>	<b>666</b>
Cost of sales	-	-
R&D costs	-3,362	-2,739
General costs	-1,785	-1,809
Costs associated with payments in shares	-54	-408
<b>Core operating loss</b>	<b>-4,203</b>	<b>-4,289</b>
Income from cash	67	24
Gross cost of debt	-28	-13
<b>Net cost of debt</b>	<b>39</b>	<b>11</b>
Other financial income	0	-
Other financial expenses	-2	-1
<b>Core pre-tax loss</b>	<b>-4,166</b>	<b>-4,279</b>
Tax	-	-
<b>Net loss</b>	<b>-4,166</b>	<b>-4,279</b>
Profit and loss recognized directly in shareholders' equity	-113	-
<b>Global results</b>	<b>-4,280</b>	<b>-4 279</b>
Diluted earning per share	-0.35	-0.39

### Financial Review

Similar to the previous half year periods, the operating revenue corresponds to the pro-rata share of the upfront payment received by the Company in August 2012, within the framework of the licensing contract signed with a Taiwanese company, PharmaEngine, for the development and marketing of NBTXR3 in the Asia-Pacific region.

This upfront payment amounts to €811k generating revenues of €91k for the first semester of 2014, which is fully in line with company expectations.

Total revenue also includes subsidies amounting to €240k compared to €61k in June 2013, predominantly arising from Bpifrance as part of the NICE project. In the meantime, research tax credit reimbursement has increased following the higher R&D expenses level in correlation with clinical and preclinical development.

Operational costs amounted to €5,201k (H1 2013: €4,955k).

R&D costs have risen to €3,362k (H1 2013: €2,739k) as expected with the strengthening of clinical studies for the lead product NBTXR3 in the STS indication and the preparation of the pivotal phase.

General costs remained stable at €1 785k (H1 2013: €1 809k) reflecting the strong internal cost control maintained.

The core operating loss was €4.2m (H1 2013: €4.3m). The total net loss amounted to €4.1m (H1 2013: €4.3m).

The cash balance has been carefully managed during the period and as at 30 June 2014, was €27m (H1 2013: €8m), driven up by the €28.1m capital increase completed in March 2014.

**-Ends-**

**Next financial press release: revenue for the third quarter of 2014 on November 14, 2014.**

**About NANOBIOTIX:** [www.nanobiotix.com/fr](http://www.nanobiotix.com/fr)

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer. The company's first-in-class, proprietary technology, NanoXray, enhances radiotherapy energy to provide a new, more efficient treatment for cancer patients. NanoXray products are compatible with current radiotherapy treatments and are meant to treat a wide variety of cancers via multiple routes of administration.

Nanobiotix's lead product NBTXR3, based on NanoXray, is currently under clinical development for soft tissue sarcoma and locally advanced head and neck cancer. The company, based in Paris, France, has partnered with PharmaEngine for clinical development and commercialization of NBTXR3 in Asia.

Nanobiotix is listed on the regulated market of Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP).

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