



*Small but heading for the big time*

## **Nanobiotix 2014 Review, 2015 Anticipated Milestones and Financial Calendar**

**Nanobiotix moved up to a new level:**

**Major clinical and financial progress, broadening of indications and strategic plans to develop across Europe, Asia and the US**

**Paris, France, January 7th 2014 - NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205)**, a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, provides its activities and achievements during 2014 and an overview of anticipated 2015 events including the financial calendar. The Company made major clinical and financial progress, including broadening of indications and strategic plans across Europe, Asia and the US.

### **Highlights**

- Reported positive results from the Phase I clinical study on NBTXR3 in soft tissue sarcoma (STS) demonstrating a good safety profile and proof of concept
- Received approval to start a pivotal European Phase II/III clinical trial in STS; the last trial before registration which is expected in 2016
- Expanded the clinical development program with new high potential indications in the US and Europe : liver cancers and prostate cancer, in parallel with STS and head & neck trials already underway in Europe
- Announced the Company's partner for Asia, PharmaEngine, and decided to participate in the STS registration trial, potentially shortening the time to market in Asia
- Broadened the Company's international strategy through the creation of a US affiliate to advance internally the development of NBTXR3 in the US for different indications prior to potential partnering
- Strengthened the Company's financial position; a rights issue and a private placement totaled €38.5m [€28.1m + €10.4m]
- Outlook for 2015 : extended clinical pipeline and preparation for commercialization of NBTXR3

Laurent Levy, CEO of Nanobiotix said: *"2014 has been a pivotal year for the Company, with significant progress in clinical development, where we jumped from an early clinical stage to late clinical stage. This has impacted our visibility and exposure from a financial and industrial point of view allowing us to accomplish two capital raises this year. We are now in a position to create value through the expansion of the indications and geographical area of development for the lead product, NBTXR3. As a result, 2015 is expected to be a year of further significant progress with intermediary clinical results, US corporate developments and launch of new indications; all building on the successes of 2014 and preparing for the final steps of CE marking by the end 2016 required before commercial launch."*

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## Overview

### Expansion of clinical development programme

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).

NBTXR3 is the first product of the NanoXray portfolio to reach clinical development. The product comprises nanoparticles which can be injected directly into tumor. 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. Currently, NBTXR3 is classified as a medical device in Europe and a drug in the United States (US).

### **Soft tissue sarcoma (STS): green light to start registration trial**

In June 2014 during ASCO, the Company presented positive Phase I clinical study results for NBTXR3, demonstrating feasibility and safety of intratumoral injection of the product followed by radiotherapy in patients with locally advanced STS. In addition to the feasibility and safety data presented, promising signs of efficacy have been demonstrated.

The positive results led the French National Security Agency for Medicines and Health Products (ANSM) to allow Nanobiotix to enter into a Phase II/III pivotal trial, which is the final step before registration (CE mark).

This study started end 2014 in France and will be broadened out to 25-30 sites in Europe once further authorizations are received.

This international multi-center pivotal study is expected to be completed towards the end of 2016 with interim results in mid-2016.

In the Asia-Pacific region, Nanobiotix's partner, PharmaEngine intends to participate in the pivotal study by opening clinical sites in several Asia-Pacific countries.

In the US, depending on the interim clinical results, expected mid-2016, the Company will decide if doable to expand the development of NBTXR3 through a bridge study in this indication to access this market.

### **Head & Neck cancer: new sites opened in Spain**

NBTXR3 is also in development for elderly patients with locally advanced head and neck cancer. The aim is the decrease of the tumor size and the preservation of the local functions. Nanobiotix is currently conducting a pilot trial for this indication, for which interim results are expected in H1 2015.

Patients are being assessed on their tolerance of the product with the aim of providing better control of the disease and an improved quality of life. In 2014, two new sites were opened in Spain for this pilot trial.

### **New Indications with High Potential: Liver Cancers and Prostate Cancer**

#### *Liver cancers*

Liver cancers are potentially the largest indication for NBTXR3.

Nanobiotix is already pursuing the non-clinical evaluation phase of NBTXR3 in primary liver cancer, and as part of its expanded development plan, is also evaluating the compound in liver metastases (metastases

arising from colorectal cancers, breast cancer, etc.).

The inclusion of liver metastases would more than double the total potential treatable population of patients for this product.

Nanobiotix plans to initiate clinical trials in this indication in the second half of 2015 and will include patient populations with both Primary liver cancer and liver metastases. For this patient population, the aim of treatment is to increase and prolong patients' survival rates. This program is being supported with a €2.8m grant from Bpifrance through the NICE project..

#### *Prostate cancer*

The Company is also seeking to develop NBTXR3 for patients with high risk prostate cancer, with the aim of providing effective tumor control combined with tumor destruction. It represents a significant potential new market for the product. The planned pilot trial is expected to start in the second half of 2015 and will involve approximately 24-30 patients that are newly diagnosed with high risk prostate cancer.

#### *Potential further indications*

NBTXR3 could be also developed in other indications as the potential is broad especially for esophagus cancer, glioblastoma, cervix cancer, etc.

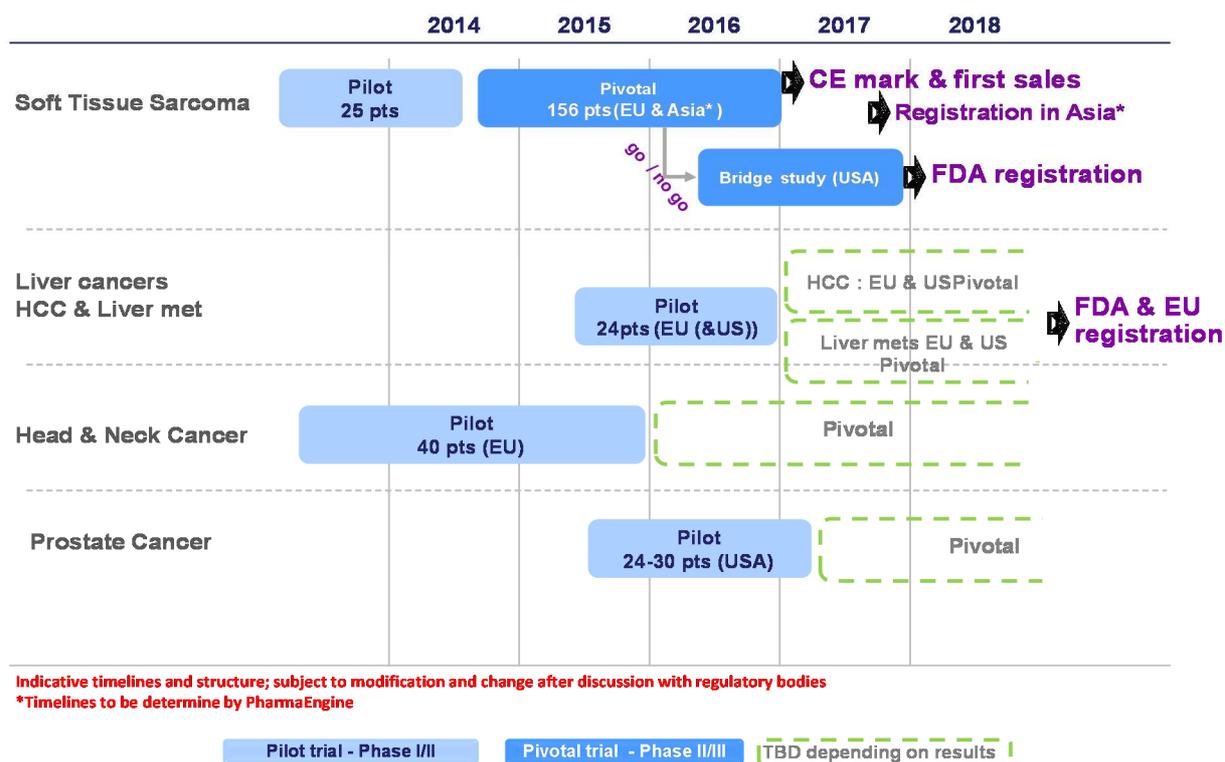
### **Broader International Strategy**

Nanobiotix is pursuing a standalone development and commercialization strategy for its lead product NBTXR3 in Europe.

Following a private placement to a US investor in November 2014, the Company now has the financial means to adopt a similar independent strategy for the development of NBTXR3 in the US.

As part of the international strategy, in September, Nanobiotix opened an affiliate office in Cambridge, MA. The affiliate is headed up by Patrick Tricoli, Vice President Corporate Development for Nanobiotix. Patrick has over 25 years' experience within the pharmaceutical industry and joined Nanobiotix from Sanofi where he held a number of positions in both Corporate and Research and Development departments.

In the Asia-Pacific region, Nanobiotix is already partnered with PharmaEngine. PharmaEngine joined Nanobiotix's pivotal trial for NBTXR3 in STS to accelerate its development in Asia-Pacific.



## Strengthened Financial Position

### Capital raisings

During 2014, the Company completed two capital raises, totaling €38.5m, with the potential for another €24.1m (if all warrants attached to the shares issued during the second capital raise are exercised, and the Company exercises a supplemental tranche).

The first fund raising was completed in March 2014 and raised €28.1m based on the share price of €10.60. There was a significant demand for shares from investors in Europe and thus the placement was expanded, with an additional 15% of new equity made available, corresponding to the full exercise of the extension clause.

More recently, in November, the company attracted a new investor from the US, Capital Ventures International, with a private placement of new shares with warrants associated for a total amount of €10.4m (at €15.99 per share). A potential supplemental amount of up to €14.1m if all warrants are exercised (€21.63 per share) and a commitment to purchase an additional tranche of up to €10 million at the Company's discretion, subject to certain conditions, may be received.

The underlying rationale for this second capital raising was to i) enable the Company to expand the indications and the geographical area for its lead product NBTXR3 ii) provide the financial visibility to drive a standalone strategy in US until reconsidering partnering options and iii) structure capital through a new US based shareholder.

The foregoing transactions are described in more detail in the press releases published by the Company at the time of their completion.

### Capital Market Index

Nanobiotix is included in the Next Biotech Index in Europe and to the CAC® PME Index which tracks the performance of 20-40 French PEA PME eligible companies. Nanobiotix' inclusion on the PME index is helpful

in raising the Company's profile and the stock's visibility.

### **Stock market performance**

Major progress made by Nanobiotix in 2014 led to a significant increase of its market capitalization. January 2<sup>nd</sup>, 2015: € 247 million against € 52 million January 2<sup>nd</sup>, 2014.

### **Outlook for 2015**

Nanobiotix is in a strong financial position to pursue its standalone strategy in both Europe and US.

In 2015, further clinical progress is expected:

The head and neck pilot trial is expected to report intermediary results at the end of H1 2015. In the second half of 2015, the liver cancers and high risk prostate cancer programs are anticipated to enter the clinical stage.

The STS pivotal trial will report interim data in the first half of 2016, and the full read out is expected at the end of 2016.

In view of this the Company has already started to work on the most appropriate industrialization, commercialization and reimbursement routes for expected CE mark at the end of 2016.

The company is also preparing for the future by expanding its pipeline with two other NanoXray products (NBTX-TOPO and NBTX-IV) and beyond.

The company expects to grow its affiliate in US in order to sustain the first product and corporate development.

### **Financial Calendar**

Nanobiotix will announce its financial and operating results according to the following indicative calendar:

- February 27, 2015 - Annual Turnover
- April 30, 2015 - Annual results
- May 15, 2015 - Turnover of the first quarter
- July 15, 2015 - Half yearly turnover
- August 31, 2015 - Half yearly results
- November 13, 2015 - Turnover of the third quarter
- Before June 30, 2015 - Annual General Assembly Paris, France

**-Ends-**

### **Notes to Editors**

#### **Terms of the Private Placement in November 2014**

A total of 650,000 ordinary shares (the "New Shares") were issued to CVI in the private placement, representing around 4.85% of the outstanding shares prior to the private placement.

In accordance with the 17th resolution of Nanobiotix' general shareholders meeting held on June 18, 2014, the price of the placement has been set at €15.99 per New Share. This price represents a 15% discount to the volume weighted average price (VWAP) of the last 5 trading days preceding the pricing date.

One warrant is attached to each New Share, entitling CVI to subscribe, at any time and in one or more installments until June 30, 2016, for one additional share per warrant, i.e. a maximum of 650,000 additional ordinary shares (the "Additional Shares") at a price

of € 21.63 per share (i.e., 115% of the arithmetic average of the VWAP of the Company's shares on each of the five (5) trading days immediately preceding the pricing date). The warrants will be immediately detached (détachés) from the New Shares as from their issuance and will be credited in registered form (nominatif). The Company may require CVI to exercise the warrants if the daily VWAP of the Company's ordinary shares shall exceed 150% of the exercise price of the warrants, i.e., € 32.45, for any twenty (20) out of thirty (30) consecutive trading days before the expiration of the warrants.

The warrants' exercise price will be automatically adjusted downwards (but not to be less than 95% of the arithmetic average of the VWAP of the Company's shares on each of the five (5) trading days immediately preceding the pricing date) in the event of any subsequent new issue of shares or securities giving access to the capital of the Company on the basis of a price per share lower than the exercise price of the warrants (excluding any options or other incentive shares to employees and executives of the group not to exceed 5% of the capital).

Finally, CVI has committed (subject to certain conditions) to purchase a third tranche of up to 10 million € of additional ordinary shares, not to exceed 650,000 shares, if the Company shall decide in its discretion to issue them to CVI in the period from November 25, 2015 to March 31, 2016, at a price equal to 85% of the arithmetic average of the VWAP of the Company's shares on each of the five (5) trading days immediately preceding their issue date, but in no event greater than the VWAP of the Ordinary Shares on the trading day immediately preceding the applicable date.

### About NANObIOTIX: [www.nanobiotix.com](http://www.nanobiotix.com)

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late 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 with a view to provide a new, more efficient treatment for cancer patients. NanoXray products are compatible with current radiotherapy treatments and are meant to treat potentially a wide variety of cancers including Soft Tissue Sarcoma, Head and Neck Cancer, Liver Cancers, Prostate Cancer, Breast Cancer, Glioblastoma, etc., 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 has partnered with PharmaEngine for clinical development and commercialization of NBTXR3 in Asia.

The company, based in Paris, France, opened an affiliate office in the Boston area of the US in September, 2014.

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

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### Important Information

This press release contains certain forward-looking statements concerning Nanobiotix and its business, including the Company's strategy, plans for the global development of the Company's products, investment plans and calendar for regulatory events, the market potential for certain products, as well as other forward looking information and statements. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, such forward-looking statements are, by their nature, subject to a number of important risks and uncertainties, such as those described in the in the reference document of Nanobiotix registered on November 25, 2014 with the AMF under number R.14-071 (a copy of which is available on [www.Nanobiotix.com](http://www.Nanobiotix.com)) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates, and actual results or events may differ materially from those expressed or implied in the forward-looking statements. These forward-looking statements are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or some of such risks, or other events, could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from the plans, objectives and expectations expressed or implied in such forward-looking statements. Forward-looking statements speak only as of the date on which they are made, and Nanobiotix

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