

Small but heading for a big time

# Nanobiotix 2013 Review: Significant Corporate and Clinical Progress

**Paris, France, January 7th 2013**- **NANOBIOTIX (Euronext : NANO – ISIN: FR0011341205)**, a clinicalstage nanomedicine company pioneering NanoXray, a novel approach for the local treatment of cancer, summarises its activities and progress made during 2013 and announces its prospective financial communications calendar for the fiscal year 2014.

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### I. Key clinical steps for the NanoXray pipeline

The NanoXray pipeline progressed significantly over the past 12 months. Lead product NBTXR3 achieved clinical proof-of-concept and NBTX-IV and NBTX-TOPO reached major preclinical milestones.

#### June 2013: NBTXR3 clinical proof-of-concept, first product from the NanoXray pipeline

NBTXR3 nanoparticles are designed to absorb X-rays in order to significantly enhance the radiation dose within cancer cells.

The French National Agency for Medicines and Health Products (ANSM) gave its approval to Nanobiotix to launch a phase I clinical trial of NBTXR3 in patients with Soft Tissue Sarcoma (STS) to assess the feasibility of the concept and the patients' tolerance to the product.

In June 2013, Nanobiotix published positive interim results from the phase I trial establishing the proof-ofconcept of NBTXR3 by demonstrating adequate distribution of the nanoparticles within the tumors for over five weeks of radiation therapy along with patient tolerance to the product.

Achieving the proof-of-concept is a key step in the clinical development of NBTXR3, the first product from the NanoXray pipeline, and represents the first stage of Nanobiotix's transition as a novel therapeutic in humans.



#### June 2013: Start of a second indication for NBTXR3 product, head and neck cancers

Following the positive interim results of NBTXR3 in patients with advanced Soft Tissue Sarcoma, the ANSM gave its approval to start a new clinical trial for the product in patients with locally advanced head and neck cancers (cancers of the oral cavity or of the oropharynx).

These types of cancer are a major challenge to treat as the current standard of care, combining chemotherapy and radiotherapy, has a very high relapse rate.

This indication is of a high strategic interest as it embodies a new method of treatment that could mean the avoidance of highly disabling surgery for patients.

#### June 2013: Initiation of the preclinical development of the second NanoXray product, NBTX-IV, in the US

NBTX-IV product was selected by the National Cancer Institute's (NCI) Nanotechnology Characterization Laboratory (NCL), in the US, for characterization studies.

The results from the studies will support Nanobiotix's filing of an Investigational New Drug (IND) application for the US Food and Drug Administration (FDA) authorization towards product registration in the US market.

#### July 2013: Bpifrance public funding for the development of NBTXR3 in a third indication, liver cancer

Nanobiotix received a grant of €2.8 M awarded through Bpifrance's Strategic Industrial Innovation (ISI) program, to accelerate the clinical and industrial development of the Company's lead product NBTXR3 in a new indication, liver cancer (hepatocellular carcinoma).

This grant supports the broader launch of NICE (Nano Innovation for CancEr), a consortium consisting of five public and private partners including Nanobiotix. Its mission is to build a platform to accelerate the development and industrialization of nanomedicine in France.

#### December 2013: Launch of the preclinical development of NBTX-TOPO product

The third product from the NanoXray platform, NBTX-TOPO, is a gel containing NanoXray nanoparticles. This nanotherapeutics 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). NBTX-TOPO is potentially applicable for all types of post-operative radiotherapy.



#### **II. Strengthening management and corporate governance**

• February 2013: Appointment of Dr Alain Herrera to the Supervisory Board

A pioneer in industrial oncology, Dr. Alain Herrera has an outstanding experience in the pharmaceutical industry and business development. He notably headed the Oncology business at Sanofi-Aventis for ten years, where he was Vice President for the Global Oncology Business Strategy and Development (2007-2008) and Head of the Global Oncology Franchise (1998-2007). Dr Herrera contributed as such to the worldwide registration of many anti-cancer products. His previous responsibilities within the pharmaceutical industry include the roles of Chairman of Chiron Therapeutics Europe, Managing Director at Pierre Fabre Oncology Laboratories and Head of the Oncology Platform at Roger Bellon (Rhône Poulenc). In addition to these roles, Dr. Herrera has been a Hematologist Consultant at Antoine Beclere Hospital since 1991.

 September 2013: Appointment of Philippe Mauberna to the Executive Board, CFO of Nanobiotix since May 2013

As an expert in management and the development of financial and operational projects for the pharmaceutical industry, Philippe Mauberna (ISG-INSEAD), has been involved in several international projects (UK, Saudi Arabia, South Africa and Indonesia). Dedicated to the Life Sciences industry for more than 10 years, Philippe has held senior Financial and Operations positions at Astellas Pharma Europe participating in the reinforcement of EMEA commercial effectiveness in Africa and in Europe, most notably this was supporting market authorization for several healthcare products.

Philippe has also been heavily involved in financial projects for start-up launches and innovative SME development. As a consultant, he has provided strategic change management support for European pharmaceutical companies during their development phases.

#### September 2013: Creation of a Communication and Public Affairs Department headed up by Sarah Gaubert

Former advisor to the French Presidency and to several Ministries (Health, Solidarity, Education and Research), Sarah Gaubert, consultant in strategic communications, heads Nanobiotix's newly created Communication and Public Affairs Department.

#### III. Increasing international reputation

- Nanobiotix and Laurent Levy received two prestigious awards
- April 2013: Laurent Levy received the UB Entrepreneurship Award from the University at Buffalo, SUNY. The award is given to individuals that have championed a UB technology to create a highly successful company and whose products will have a beneficial impact on the lives of people worldwide. It recognises Laurent's entrepreneurial aspirations that led to the creation of Nanobiotix in 2003, now one of the leading companies in the field of nanomedicine.



- November 2013: Nanobiotix honoured at the Investor Awards 2013 in the "Young Talent" category. This prize was awarded by Boursorama and Morningstar who jointly organize the largest survey that ranks listed companies by individual and professional investors' preferences. The online survey was conducted with investors by OpinionWay in May 2013. In total, almost 40,000 votes were collected (two-thirds of individuals and a third of professionals).
- Nanobiotix invited to speak at national and international events

Nanobiotix has been invited to speak at national and international events providing the opportunity for the Company to present the innovative NanoXray technology and to meet all of the stakeholders within and beyond the field, including the pharmaceutical industries, medical community, academia and potential investors.

Nanobiotix took part in the following events:

- Future Leaders in the Biotech Industry (BioCentury) April 2013
- BIO International Convention 2013 April 2013
- Clinical Oncology meeting Chicago May-June 2013
- EuroNanoForum June 2013
- CLINAM June 2013
- ASTRO September 2013
- Biotech in Europe Investors Forum (SACHS) October 2013
- BioEurope November 2013
- New York Academia of Science November 2013

#### Renewal of Laurent Levy as Vice-chairman of the European Technology Platform on Nanomedicine (ETPN) for the second year running

The ETPN is an initiative led by industry and set up together with the European Commission. Embracing all stakeholders of the nanomedicine ecosystem from academia and research institutes to SMEs and large industries, the ETPN is dedicated to the organization of the nanomedicine landscape in Europe by identifying the current gaps and needs and setting up Roadmaps and Strategic and Research Agendas (SRAs). In addition to driving the field of nanomedicine in Europe, the ETPN is striving for the efficient translation of R&D results into innovative nanomedicine products.

#### IV. Outlook and conclusion

2013 was a year marked by significant progress in its clinical program; this will continue to be a theme of 2014.

The first intermediate results of the clinical study on head and neck cancers are expected, the trial on liver cancer is anticipated to start in the last quarter of 2014, and the phase I study led in France on soft tissue sarcoma should be finalised.

During the year, Nanobiotix will be focused on accelerating its clinical development outside Europe, with the initiation of two trials led by PharmaEngine in Asia.



The Company also intends to extend its ambitious partnership policy geographically by targeting the US.

The Nanobiotix team is determined to drive the Company's development forward, maintaining the momentum seen in 2013. The Company is fortunate to have strong support from its shareholders to do this and the benefit of a committed internal team.

## V. Financial calendar summary for 2014

Nanobiotix will announce its financial and operating results according to the following anticipated schedule (which may change slightly):

- January 31, 2014 Annual Turnover
- April 12, 2014 Annual results
- May 15, 2014 Turnover of the first quarter
- July 11, 2014 Half yearly turnover
- August 29, 2014 Half yearly results
- November 14, 2014 Turnover of the third quarter
- Before June 30, 2014 Annual General Assembly Paris, France

-Ends-



#### About NANOBIOTIX : <u>www.nanobiotix.com/en</u>

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 NYSE Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP).

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