



*Small but heading for the big time*

## Nanobiotix: 2015 Annual Results

**Paris, Cambridge, April 29, 2016 – NANOBOTIX (Euronext: NANO – ISIN: FR0011341205)**, a late clinical-stage nanomedicine company pioneering novel approaches for the local treatment of cancer, announces its audited consolidated results for the fiscal year ended December 31, 2015:

- Consolidated cash position as of December 31, 2015 closed at €17 million, confirming the control of all expenses
- Increase of expenses corresponds to progression and expansion of clinical development – five clinical trials running in six indications – and market access activities, according to plan
- Expenses remained in line with expectations

Philippe MAUBERNA, Chief Financial Officer of Nanobiotix commented: *“2015 has been significant as we have made important advances across both the business and clinical fronts, paving the way for 2016 and beyond. Our financial position remains strong and in line with expectations as we enter 2016 - a decisive turning point year for Nanobiotix. We focus our resources on delivering key clinical data that will sustain our future growth.”*

As announced in March 2016, the company has completed a private placement of €21.3 million providing funding until mid-2017.

### Income statement

	2015	2014
<b>Total revenue €</b>	<b>4,015,229</b>	<b>2,770,795</b>
<b>Sales</b>	<b>265,543</b>	<b>967,500</b>
License	183,893	967,500
Other sales	66,179	-
Services	15,471	-
<b>Other revenue</b>	<b>3,749,686</b>	<b>1,803,295</b>
Subsidies	199,838	314,764
Research Tax Credit	3,546,035	1,483,122
Other	3,814	5,408
Cost of sales	-	-
R&D costs	(13,901,898)	(8,075,723)
General costs <i>(market access, G&amp;A, ...)</i>	(5,963,488)	(4,062,591)
Costs associated with payments in shares	(1,291,491)	(252,257)
<b>Core operating loss</b>	<b>(17,141,647)</b>	<b>(9,619,777)</b>
Financial gain / (charges) (*)	138,562	142,522
<b>Core pre-tax loss</b>	<b>(17,003,084)</b>	<b>(9,477,255)</b>
Tax	-	(79,271)
<b>Net Profit &amp; Loss</b>	<b>(17,003,084)</b>	<b>(9,556,525)</b>

\* cost of net financial debt and other financial expenses

## Financial Review

### Total Revenue in 2015 amounts to €4M vs. €2.8M in 2014 mainly due to:

- Sales revenue to PharmaEngine are amounting to €265,5K, providing from the upfront payment received in 2012 and linearized on an annual basis for €184K/year, sales of other services for €66K and Re-invoicing of services for €15K
- Other revenue is amounting to €3.749,7K coming mainly from Research Tax Credit (CIR) that have risen sharply due to higher levels of R&D activities and the preparation to launch in new clinical indications in 2015

### Total Operating expenses reach €21,2M in 2015 vs. €12,4M in 2014:

- R&D expenses at €13.9M (+€5,8M) to support the acceleration of clinical programs (€5M), the manufacturing scale up (€3M) and the preclinical research developments (€3,5M)
- General cost expenses reached €6M (+€1,9M) mainly due to the increase of resources in market access and launch readiness (€0.9M) and the development of Nanobiotix US affiliate (€0.8M)
- Cost associated with share based payment has reached €1,2M which proceeds to an accounting evaluation (non-cash impactful)

Total Headcount reached 60 FTEs in 2015 vs. 49 FTEs in 2014.

Total loss after tax 2015 up to €-17M (vs. €-9.6M FYE 2014) as per budgeted operations development.

FYE 2015 cash balance of €17M as per expectations.

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## 2015: a year of structuring and development expansion

There have been significant clinical and business developments for Nanobiotix in 2015. The Company has built an extensive clinical development program through six indications (versus two in 2014). Expenses remained in line with planned budget. The key highlights of the period are summarised below.

The Company continued to strengthen its R&D to sustain its development.

In perspective of obtaining the CE mark, expected towards the end of 2016, market access activities have begun and additional personnel has been hired to support these programs. The Company also secured a new partnership with CordenPharma, in anticipation of future NBTXR3 production needs, to meet the demand from clinical trials (in Europe and United States) and future commercialization.

In addition, Nanobiotix US affiliate has increased its activities in particular with the preparation of the prostate cancer indication to be started in 2016.

In 2015, Nanobiotix also hired the well-respected Robert Langer as a Scientific Advisor.

### Clinical development – NBTXR3

2015 surpassed expectations with many major clinical developments moving Nanobiotix closer towards demonstrating the use and transferability of NBTXR3's therapeutic approach across different types of cancers.

Major clinical developments included:

- Significant progress and expansion of the STS Phase II/III registration trial ("Act.in.sarc" study) for NBTXR3 in 10 countries
- Positive preliminary results from the head and neck cancer Phase I/II trial with NBTXR3, showing the feasibility of the NBTXR3 injection and a good safety profile of the product in first dose levels
- The launch of liver cancers Phase I/II trial with NBTXR3 in two different populations: HCC and liver metastases
- Nanobiotix also received approval from the US *Food and Drug Administration* (FDA) for the Company's *Investigational New Drug* (IND) application on December 30, 2015 (announced January 2016). This allows Nanobiotix to launch its first clinical study in the US for its lead product NBTXR3 in prostate cancer, a new and very significant indication

Nanobiotix's focus is on developing NBTXR3 in multiple cancer indications for use alongside standard radiotherapy

treatment to increase efficacy at the same dose. The Company's pipeline currently includes soft tissue sarcoma (STS) Phase II/III registration trial, head and neck cancer Phase I/II trial, liver cancers Phase I/II trials, prostate cancer Phase I/II trial, and rectal cancer Phase I/II trial (by PharmaEngine). The trials are running across Europe, USA and Asia.

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## **2016: A critical year to demonstrate the potential of NBTXR3**

2016 got off to a great start for Nanobiotix and its lead product, NBTXR3, with the launch of a new preclinical research program and a successful private placement enabling the Company to remain well funded until mid-2017.

### Immuno-oncology research program

On January 5, 2016, Nanobiotix announced the start of a new preclinical research program in immuno-oncology with its lead product, NBTXR3, which could have the potential to bring a new dimension to cancer immunotherapies. This project is in addition to the Company's core current advanced clinical development program for NBTXR3 as a single agent.

### Financial developments

On March 11, 2016, the Company successfully completed a €21.3 million private placement of new ordinary shares. The new ordinary shares were issued primarily with life sciences specialist investors, the majority of which are from the United States.

### **Forthcoming expected newsflow**

In the coming months, Nanobiotix expects to deliver multiple milestones from its clinical and corporate development activities to validate NBTXR3's potential use as a new standard of care in oncology with the potential to treat a large number of patients across the world.

### Soft tissue sarcoma (STS)

Nanobiotix expects to announce the interim data readout from its STS Phase II/III pivotal study in mid-2016. The interim data readout could allow the filing for CE mark. The Company will present the final data at a later stage after all patients have been treated.

### Expected CE mark end of 2016

Assuming a positive outcome from the STS trial, Nanobiotix could obtain CE mark at the end of 2016, its first market approval.

### Head & neck cancer

Nanobiotix is expecting the first complete set of data from the NBTXR3 head & neck cancer Phase I/II trial in H1 2016. Positive data could allow Nanobiotix to enter registration phase, further expanding the potential market for Nanobiotix's lead product.

In addition, particular attention will be on comparing the data (with the STS data) to analyze at the transferability from one indication to another. This could increase the chance of successful transferability across all solid tumor indications.

### HCC clinical trial and liver metastases clinical trial

The Company expects the first intermediate results from the Phase I/II study in liver cancers (HCC and liver metastases) in the different patient's populations to be announced in H2 2016. The results are expected to show the safety and feasibility on first dose levels and could give another hint about the potential value increase of NBTXR3.

### Prostate cancer

Following the IND granted by the FDA on December 30, 2015, Nanobiotix plans to initiate the Phase I/II prostate cancer trial in the US in 2016. This indication opens additional Medical Value and significantly enlarges the potential

market for NBTXR3. Nanobiotix will communicate the expected timing of the trial this year.

#### Additional development on NBTXR3 in combination with Immuno-oncology

Early in 2016, Nanobiotix started a new research program in immuno-oncology with its lead product NBTXR3. The first preclinical results are expected later this year. These preclinical results should establish the proof of concept for potential combination of NBTXR3 with immuno-oncology approaches across oncology and open new perspectives for potential deals.

The core business of Nanobiotix is to develop NBTXR3 as a single agent with radiotherapy and this year is critical to demonstrate the value potential.

**-Ends-**

**Next financial press release: revenue for Q1 2015 on May 13, 2016.**

**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 solid tumors including soft tissue sarcoma, head and neck cancers, 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, head and neck Cancer, prostate cancer, rectal cancer (PharmaEngine) and liver cancers (HCC and liver metastases). The Company 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). The Company Headquarter is based in Paris, France. Affiliate in Cambridge, United States.

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