



## Nanobiotix Provides Business Update and Reports Financial Results for the First Half of 2022

September 28, 2022 8:15 PM EDT

- Pivotal Phase 3 study, NANORAY-312, actively enrolling elderly, LA-HNSCC patients ineligible for cisplatin across ~50 sites as LianBio enrolls first patient and continues to ramp up site activation in Asia and Nanobiotix adds European sites, and begins recruitment in the US
- Recommended Phase 2 dose for I/O combination Study 1100 determined and cohorts in dose expansion phase aligned with planned registration pathway for NBTXR3 plus anti-PD-1 for patients suffering from treatment-resistant recurrent/metastatic head and neck squamous cell carcinoma
- Reported €63.0 million in cash and cash equivalents as of June 30, 2022 which, combined with proposed EIB debt restructuring and existing equity line, is expected to fund development programs into Q1 2024

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 28, 2022-- Regulatory News:

[NANOBOTIX](#) (Euronext: NANO — NASDAQ: NBTX – the “**Company**”), a late-clinical stage biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, provided an update on operational progress and announced its half year financial results for the six-month period ended June 30, 2022.

“I am encouraged by the progress of NANORAY-312 as we, in partnership with LianBio, have been able to activate more than 50 sites globally and recruit our first patients in Europe and Asia,” said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. “We view the evaluation of radiotherapy-activated NBTXR3 as a single agent for the treatment of elderly patients with locally advanced head and neck cancer as the foundation of a potentially industry-leading head and neck cancer treatment franchise, and look forward to advancing toward our second planned registrational program for patients with recurrent and/or metastatic head and neck cancer in the coming months.”

### Recent Operational Highlights, Pipeline Status and Upcoming Milestones

#### Priority Registration Pathway in Locally Advanced Head & Neck Cancer. Local Control as Single Agent Activated by Radiotherapy (RT):

- Randomized first patient in Europe in pivotal Phase 3 study NANORAY-312, evaluating RT-activated NBTXR3 with or without cetuximab in elderly patients with locally advanced head and neck squamous cell carcinoma (LA-HNSCC).
- Strategic partner LianBio enrolled the first patient in Asia in Q3 2022, and continues to ramp up site activations in the region to support planned enrollment of ~100 patients in NANORAY-312.
- Initiated clinical site activation for NANORAY-312 in the United States (US) in Q3 2022, and expect patient enrollment to begin in Q4 22.
- Completed enrollment in Study 102 and provided data as of February 2022 showing on-going median overall survival of 17.9 months in the all-treated population (n=56) and 23.0 months in the evaluable patients (n=44). Data with minimum follow-up of one year for full study population are expected in mid-2023.

#### Priority Pathway in Immunotherapy for Recurrent/Metastatic Head & Neck Cancer. Priming Immune Response in Combination with Anti-PD-1 Treatment:

- Received preliminary feedback from FDA regarding a potential Phase 3 registrational program

for patients with unresectable locoregional recurrent (LRR) or relapsed or metastatic head and neck squamous cell carcinoma (R/M HNSCC) that developed primary or secondary resistance to previous anti-PD-1/PD-L1 therapy, suggesting a single, randomized, controlled trial including a pre-specified comparative analysis of overall response rate (ORR) may be suitable to support an accelerated approval, subject to confirmation of clinical benefit based on overall survival (OS) results from the same trial

- Completed enrollment and determined recommended phase 2 dose (RP2D) at 33% of tumor volume in all three cohorts of Study 1100, a US Phase 1 dose escalation and dose expansion study evaluating RT-activated NBTXR3 in combination with immune checkpoint inhibitors for patients with advanced cancers. The recommended dose is now being evaluated in the dose expansion part of Study 1100 and will serve as the proposed dose for planned registration pathway in patients with inoperable R/M HNSCC that is resistant to prior immunotherapy
- Amended protocol for the Study 1100 to include one cohort focused on patients with R/M HNSCC that is resistant to anti-PD-1; a second cohort focused on patients with R/M HNSCC that is naive to anti-PD-1; and a third cohort focused on patients with lung, liver, or soft tissue metastases from primary non-small cell lung cancer, malignant melanoma, hepatocellular carcinoma, renal cell carcinoma, urothelial cancer, cervical cancer, or triple-negative breast cancer.
- Expect to provide updated data including approximately ~28 patients at medical conference during the fourth quarter of 2022
- Plan to submit protocol for potential registration pathway for NBTXR3 immunotherapy combination to US FDA by Q1 23

Expanding NBTXR3 Opportunity. Collaborating with World-Class Partners to Validate Tumor-Agnostic, Combination-Agnostic Therapeutic Profile:

- Published data from a preclinical study conducted in collaboration between The University of Texas MD Anderson Cancer Center (MD Anderson) in the International Journal of Nanobiotechnology showing that adding NBTXR3 to a combination of radiotherapy, anti-PD-1, and anti-CTLA-4 produced significant antitumor effects against both primary and secondary tumors, improved the mouse survival rate from 0 to 50%, and induced long term antitumor memory. These data further the hypothesis that the potential immune priming effects of NBTXR3 could extend beyond anti-PD-1.
- Researchers from MD Anderson published a peer-reviewed clinical case study reporting preliminary data on the first-in-human administration of NBTXR3 for the treatment of pancreatic cancer not eligible for surgery, demonstrating feasibility with no treatment-related toxicity. Determination of the recommended Phase 2 dose (RP2D) for NBTXR3 in pancreatic cancer is expected by the end of 2022.
- Data from a Phase 1b/2 head and neck cancer study in Asia evaluating NBTXR3 combined with concurrent weekly low-dose cisplatin-containing chemoradiation showed that, in 12 evaluable patients with stage 4 disease, the combination therapy was feasible, had a favorable safety profile for patients with LA-HNSCC, produced a 100% disease control rate, and an overall response rate of 58.3%.
- Data from a Phase 1b/2 rectal cancer study in Asia evaluating NBTXR3 combined concurrent chemoradiation showed that, in 31 evaluable patients with unresectable disease, the

combination in the preoperative setting was feasible, had a favorable safety profile, and enabled 96% of evaluable patients to undergo R0 surgery. The combination therapy produced a 100% disease-control rate, a 35.5% overall response rate, and a 20% pathological complete response rate in 25 patients who underwent surgery.

"Building on initiatives begun in 2021, Nanobiotix committed in the first half of 2022 to further reduce operating costs and better align financial resources with strategic priorities" said Bart Van Rhijn, chief financial officer of Nanobiotix. "Midway through the year, we can see that the focused execution in our clinical development programs was matched by a similar focus on strengthening our financial position, and the success is equally apparent."

### Financial Results for the First Half of 2022

**Revenue and Other Income:** Revenue and other income remained stable for the six months ended June 30, 2022 at €1.3 million, compared to approximately the same figure for the six months ended June 30, 2021. The Company has mainly benefited from the research tax credit, granted by the French government to encourage companies to conduct technical and scientific research.

**Research and Development ("R&D") Expenses:** R&D expenses consist primarily of preclinical, clinical and manufacturing expenses related to the development of NBTXR3. These expenses for the six months ended June 30, 2022, were €16.6 million, compared to €15.5 million for the six months ended June 30, 2021. Purchases, sub-contracting and other expenses increased by €1.2 million for the six month period ended June 30, 2022 as compared to the same period in 2021. This increase reflects the Company's focus on advancing its clinical trial development priorities, specifically the global Phase 3 registrational trial, NANORAY-312.

**Selling, General and Administrative ("SG&A") Expenses:** SG&A expenses consist primarily of administrative employee-related expenses, legal and other professional fees, patent filing and maintenance fees, and insurance. Total SG&A expenses for the six months ended June 30, 2022, were €9.6 million, compared to €10.2 million for the prior-year six-month period.

Purchases, fees and other expenses decreased by €0.9 million for the six month period ended June 30, 2022 as compared to the same period in 2021, illustrating the Company's focus on enhancing operational efficiencies and optimizing capital allocation for continued investment in priority development pathways.

**Net loss:** Net loss attributable to common shareholders for the six months ended June 30, 2022 was €26.4 million, or €0.76 per share. This compares to a net loss attributable to common shareholders of €30.4 million, or €0.88 per share, for the same period in 2021.

**Cash and Cash Equivalents:** Cash and cash equivalents as of June 30, 2022, were €63.0 million, compared to €83.9 million as of December 31, 2021.

**Financial Guidance:** In September 2022, the Company reached an agreement in principle to restructure its existing debt obligations with the European Investment Bank (EIB). Once finalized and executed with the EIB, the amendment to the debt restructuring is expected to extend the Company's operating runway through the end of 2023. Combined with committed capital available through its previously announced, untapped equity line of credit, Nanobiotix expects to be able to fund its current R&D and clinical programs into the first quarter of 2024.

These results are represented in the condensed consolidated financial statements as of June 30, 2022 and have been subjected to a limited review by the Company's statutory auditors.

### Availability of the half-year financial report

The 2022 half-year financial report has been filed with the French Financial markets authority (Autorité des marchés financiers). It is available to the public on the company's website, [www.nanobiotix.com](http://www.nanobiotix.com).

### Financial Agenda

November 9th, 2022: Third Quarter Corporate and Financial Update

### About NBTXR3

NBTXR3 is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles administered via one-time intratumoral injection and activated by radiotherapy. The product candidate's physical mechanism of action (MoA) is designed to induce significant tumor cell death in the injected tumor when activated by radiotherapy, subsequently triggering adaptive immune response and long-term anti-cancer memory. Given the physical MoA, Nanobiotix believes that NBTXR3 could be scalable across solid tumors that can be treated with radiotherapy and across different therapeutic combinations.

### About NANBIOTIX

Nanobiotix is a late-stage clinical biotechnology company pioneering disruptive, physics-based therapeutic approaches to revolutionize treatment outcomes for millions of patients; supported by people committed to making a difference for humanity. The company is leveraging its proprietary nanoparticle platform, including its lead product candidate, radiotherapy activated NBTXR3, to develop a pipeline of therapeutic options designed to enhance local and systemic control of solid tumors with an initial focus on the treatment of head and neck cancers.

For more information about Nanobiotix, visit us at [www.nanobiotix.com](http://www.nanobiotix.com) or follow us on [LinkedIn](#) and [Twitter](#).

### Disclaimer

*This press release contains certain "forward-looking" statements within the meaning of applicable securities laws, including the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by words such as "at this time," "anticipate," "believe," "expect," "intend," "on track," "plan," "scheduled," and "will," or the negative of these and similar expressions. These forward-looking statements, which are based on our management's current expectations and assumptions and on information currently available to management, include statements about the timing and progress of clinical trials, the timing of our presentation of data, the results of our preclinical and clinical studies and their potential implications. Such forward-looking statements are made in light of information currently available to us and based on assumptions that Nanobiotix considers to be reasonable. However, these forward-looking statements are subject to numerous risks and uncertainties, including with respect to the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data notwithstanding positive early clinical results and the risks associated with the evolving nature of the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented*

in response to it, the risk that the Company and EIB will not reach definitive agreement with respect to the restructuring of the loan; the risk that the EIB may accelerate the loans under finance contract and its amendment upon the occurrence of customary events of default; the risk that Company may not be able to secure additional capital on attractive terms, if at all. Furthermore, many other important risks factors and uncertainties, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 8, 2022 under "Item 3.D. Risk Factors" and those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers – the AMF) on April 8, 2022, (a copy of which is available on [www.nanobiotix.com](http://www.nanobiotix.com)), as well as those set forth in the half-year financial report filed with the AMF on September 28, 2022, may adversely affect such forward-looking statements and cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

**Condensed Consolidated Statements of Operations**  
(unaudited)

(Amounts in thousands of euros, except per share numbers)

	<u>For the six month period ended</u>	
	<u>June 30, 2022</u>	<u>June 30, 2021</u>
<b>Revenue and other income</b>		
Revenue	—	10
Other income	1,329	1,309
<b>Total revenue and other income</b>	<b>1,329</b>	<b>1,319</b>
Research and development expenses	-16,608	-15,506
Selling, general and administrative expenses	-9,635	-10,176
Other operating expenses	-963	-5,414
<b>Total operating expenses</b>	<b>-27,206</b>	<b>-31,096</b>
<b>Operating income (loss)</b>	<b>-25,877</b>	<b>-29,778</b>
Financial income	2,465	2,511
Financial expenses	-2,940	-3,152
<b>Financial income (loss)</b>	<b>-474</b>	<b>-640</b>
Income tax	-6	-2
<b>Net loss for the period</b>	<b>-26,357</b>	<b>-30,420</b>
<b>Basic loss per share (euros/share)</b>	<b>(0.76)</b>	<b>(0.88)</b>
<b>Diluted loss per share (euros/share)</b>	<b>(0.76)</b>	<b>(0.88)</b>

**Condensed Consolidated Statements of Financial Position**  
(unaudited)

(Amounts in thousands of euros, except per share numbers)

	<u>As of</u>	
	<u>June 30, 2022</u>	<u>December 31, 2021</u>
<b>Total non-current assets</b>	<b>7,765</b>	<b>8,709</b>
Cash and cash equivalents	63,021	83,921
<b>Total current assets</b>	<b>72,859</b>	<b>93,060</b>
<b>TOTAL ASSETS</b>	<b>80,624</b>	<b>101,769</b>
Net loss for the period	-26,357	-47,003
<b>Total shareholders' equity</b>	<b>1,792</b>	<b>26,790</b>
<b>Total non-current liabilities</b>	<b>36,252</b>	<b>38,134</b>
<b>Total current liabilities</b>	<b>42,580</b>	<b>36,845</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>80,624</b>	<b>101,769</b>

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220928006028/en/): <https://www.businesswire.com/news/home/20220928006028/en/>

Nanobiotix

**Nanobiotix Communications**

Brandon Owens

VP, Communications

+1 (617) 852-4835

[contact@nanobiotix.com](mailto:contact@nanobiotix.com)

**Nanobiotix Investor Relations**

*Kate McNeil*  
SVP, Investor Relations  
+1 (609) 678-7388  
[investors@nanobiotix.com](mailto:investors@nanobiotix.com)

*Media Relations*

**France – Ulysse Communication**

Pierre-Louis Germain  
+ 33 (0) 6 64 79 97 51  
[plgermain@ulyse-communication.com](mailto:plgermain@ulyse-communication.com)

**Global – LifeSci Advisors**

Ligia Vela-Reid  
+44 (0) 7413825310  
[Lvela-reid@lifesciadvisors.com](mailto:Lvela-reid@lifesciadvisors.com)

Source: Nanobiotix