NANOBIOTIX Provides Business Update and Reports Full Year 2024 Financial Results

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- Global development program for JNJ-1900 (NBTXR3) proceeding as planned, with opportunity to address one of the largest untapped markets in oncology through lead programs in head and neck cancer and lung cancer
- Disciplined financial strategy toward long-term sustainability and growth continues to strengthen financial position through focused allocation of capital, the receipt of a planned milestone payment, the transfer of sponsorship for NANORAY-312, and an amendment to the global licensing agreement for JNJ-1900 (NBTXR3)
- Curadigm, a next generation nanotherapeutic platform designed to reshape drug design and development across multiple therapeutic classes and disease areas, has launched
- Cash runway extended into mid-2026 and reduction of operational cash burn expected beyond mid-2026 with €49.7 million in cash and cash equivalents as of December 31, 2024
- Clinical data readouts in 2025 from Phase 1 and 2 studies in RM-HNSCC, pancreatic cancer, NSCLC amenable to re-irradiation, melanoma and esophageal cancer

Conference call and webcast scheduled for April 3, 2025 at 8:00 A.M. EDT / 2:00 P.M. CEST

PARIS and CAMBRIDGE, Mass., April 02, 2025 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO - NASDAQ: NBTX - the "Company"), a late-clinical stage biotechnology company pioneering nanotherapeutic approaches to expand treatment possibilities for patients with cancer and other major diseases, provided an update on operational progress, reported financial results for the year ended December 31, 2024, and announced the filing of its universal registration document (URD) for the financial year ended December 31, 2024 with the French financial market authority (*Autorité des marchés financiers* or AMF), as well as of the annual report on Form 20-F for the financial year ended December 31, 2024 with the U.S. Securities and Exchange Commission (SEC).

Operational Highlights

- Addressing One of the Largest Untapped Markets in Oncology with JNJ-1900 (NBTXR3)[1]
  - Lead programs in head and neck cancer and lung cancer proceeding as planned
    - Ongoing Pivotal Phase 3 LA-HNSCC Study (NANORAY-312)
      - Aligned on intent to transfer the global NANORAY-312 sponsorship from Nanobiotix to Janssen Pharmaceutica NV, a Johnson & Johnson Company ("Johnson & Johnson") in 2Q2024 to begin preparations for interim analysis.
      - Completed the NANORAY-312 US sponsorship transfer from Nanobiotix to Johnson & Johnson, in 4Q2024, with intent to transfer NANORAY-312 globally to Johnson & Johnson by 3Q2025.
    - Ongoing Randomized Phase 2 Study in Unresectable Stage 3 NSCLC (CONVERGE)
      - First patient dosed in the Johnson & Johnson-sponsored Phase 2 randomized CONVERGE study evaluating JNJ-1900 (NBTXR3) for patients with unresectable stage 3 non-small cell lung cancer ("NSCLC") in 1Q2025
  - Multiple early-stage studies across solid tumor types beyond the lead programs continue to progress
    - RM-HNSCC (Phase 1 Study 1100 sponsored by Nanobiotix)
      - Presented new data showing disease control and tumor response in patients treated with JNJ-1900 (NBTXR3) followed by anti-PD-1 as a second-or-later line (2L+) therapy for patients with recurrent or metastatic ("RM") head and

neck squamous cell carcinoma (“HNSCC”) in 2Q2024

- Locally Advanced or Borderline Resectable Pancreatic Cancer (Phase 1 Study MDA 2019-1001 sponsored by The University of Texas MD Anderson Cancer Center)
  - Completed a Phase 1 study evaluating JNJ-1900 (NBTXR3) for patients with locally advanced or borderline resectable pancreatic cancer in 4Q2024 and investigators recommended that the encouraging oncologic outcomes coupled with a favorable safety profile warrant further exploration in a randomized study
  - US FDA approved a protocol amendment to the completed Phase 1 pancreatic cancer study in 4Q2024 enabling the launch of a new cohort designed to evaluate JNJ-1900 (NBTXR3) combined with standard-of-care concurrent chemoradiation (“CCRT”) and recruitment is ongoing
- NSCLC Amenable to Re-irradiation (Phase 1 Study MDA 2020-0123 sponsored by MD Anderson)
  - Completed the dose escalation part of a Phase 1 study evaluating JNJ-1900 (NBTXR3) for patients with inoperable, recurrent NSCLC amenable to re-irradiation (“reRT”) and established the recommended Phase 2 dose (RP2D) at 33% of gross tumor volume in 4Q2024
  - Presented first data from the Phase 1 NSCLC reRT study showing a favorable safety profile and early signals of efficacy in 1Q2025

- Disciplined Financial Strategy Toward Long-Term Sustainability and Growth
  - Received $20M first milestone payment related to NANORAY-312 from Johnson & Johnson in May 2024
  - Executed amendment to global licensing agreement for JNJ-1900 (NBTXR3) in 1Q2025, removing the vast majority Nanobiotix funding obligation for NANORAY-312 and releasing Johnson & Johnson from select future potential milestone payments, while safeguarding Nanobiotix’s path to sustainable cashflow through hundreds of millions in potential milestone payments related to lead programs expected in the coming years
  - Extended cash runway to mid-2026 with a meaningful reduction in cash burn expected immediately and moving forward through and beyond mid-2026
  - Actively exploring preferably non-dilutive financing options to further extend cash visibility into 2027

- Other Operational Highlights
  - Strengthened Supervisory Board with the nominations of Dr. Margaret A. Liu and Ms. Anat Naschitz as board observers in 3Q2024, two key additions intended to further equip the Company for sustainable long-term growth.
    - Dr. Liu brings a wealth of experience in US and international academia, pharmaceuticals, biotechnology and public policy
    - Ms. Naschitz brings world-class expertise in raising and deploying capital to support disruptive innovation for the benefit of patients, healthcare professionals and investors
  - Launched the Curadigm Nanoprimer Platform, the Company’s next lever for growth, in 4Q2024
    - The platform consists of nanoparticles designed with specific physico-chemical

properties that allow temporary occupation of the liver cells responsible for therapeutic clearance. This mechanism is intended to increase the blood bioavailability and subsequent accumulation of therapeutics in the targeted tissues, potentially providing the opportunity to increase the efficacy or decrease the toxicity of intravenously administered medicines. As such, it is a potentially ideal technology to be used by both Nanobiotix and potential partners.

[1] Potential first-in-class radioenhancer "NBTXR3" was licensed to Johnson & Johnson by Nanobiotix in 2023 and renamed "JNJ-1900" for the purposes of Johnson & Johnson-led clinical development.

"2024 was a productive year focused on strong clinical execution and establishing a foundation for the next stage of growth. We expanded into lung cancer with the dosing of the first patient in the CONVERGE Phase 2 trial evaluating the potential of JNJ-1900 (NBTXR3) to enhance the treatment of first-line Stage III lung cancer patients." said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. *"Conviction in the broad potential of JNJ-1900 (NBTXR3) was further bolstered by the prolonged survival and well-tolerated safety reported across three key programs including Phase 1 data from Study 1100 evaluating NBTXR3 in combination with an anti-PD-1 in recurrent or metastatic head and neck cancer, as well as initial data supporting expansion potential in pancreatic and lung cancer as part of our MD Anderson collaboration. We also introduced our next generation first-in-class nanotherapeutic platform, Curadigm, late in 2024, which we expect to drive additional long-term value. With our financial position strengthened and new data this year in head and neck, lung, pancreatic, and esophageal cancer, we believe Nanobiotix is strongly positioned for impact in 2025 and beyond."*

Full Year 2024 Financial Results

Revenue and Other Income: Negative Revenues of €7.2 million were recognized in 2024, compared to €36.2 million for the year ended December 31, 2023, in which year significant revenue was recorded in connection with the execution of the license agreement with Janssen as well as the recognition of a development milestone. The negative non-cash revenue impact recognized in 2024 results from the transfer of NANORAY-312 study sponsorship to Janssen, signed at the end of 2024, which amounts to negative €19.3 million and is driven by a one-time recognition of a net liability towards Janssen to reflect this new situation. This one-off, non-cash negative revenue item, that results from application of IFRS 15 revenue recognition accounting principles, is partially offset by Other Revenues that do positively impact Nanobiotix's cash position including: Sales of Clinical Products and goods to Janssen for €5.9 million, Technology Transfer Services billed to Janssen for €1.8 million, Research Tax Credit for €3.3 million and other income related to collaboration and supply services agreement in Asian territory for €1.0 million.

Research and Development ("R&D") Expenses : R&D expenses consist primarily of preclinical, clinical, and manufacturing expenses related to the development of NBTXR3 (JNJ-1900) and totaled €40.5 million for the twelve-month period ended December 31, 2024, as compared to €38.4 million for the twelve months ended December 31, 2023, a year over year increase of 5%. The increase in net R&D expenses was primarily due to an increase of clinical development activities, driven by the costs related to NANORAY-312 and of its Phase 1 multi-cohort trial of RT-activated NBTXR3 followed by anti-PD-1 checkpoint inhibitors (Study 1100), and the full-year impact of R&D positions that were recruited in 2023.

Selling, General and Administrative ("SG&A") Expenses : SG&A expenses were €20.5 million for the year ended December 31, 2024, compared to €22.0 million for the year ended December 31, 2023. This year-over-year decrease of 7% is mainly due to one-off fees incurred in 2023, consisting of license agreement execution and equity issuance related legal expenses and next to one-off fees paid to a financial advisor for €1.9 million in total.

Net loss: Net loss attributable to shareholders was €68.1 million, a year-over-year increase of 72%, or €1.44 per share, for the twelve-month period ended December 31, 2024, which was primarily attributable to the one-off non-cash negative revenue recognition accounting impact. This compares to a net loss of €39.7 million, or €1.08 per share for the year ended December 31, 2023.

Cash and Cash Equivalents: As of December 31, 2024, Nanobiotix had €49.7 million in cash and cash equivalents, compared to €75.3 million as of December 31, 2023.

Financial Guidance: Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €49.7 million as of December 31, 2024 will fund its operations into mid-2026.

The supervisory board of the Company has reviewed the financial statements 2024 on April 2nd, 2025 and the Company's statutory auditors have finalized their audit and issued on March 31, 2025 a clean opinion on both statutory and consolidated financial statements 2024.

"*We have recently fortified our financial position and extended our cash runway into mid-2026 by amending our global agreement with Johnson & Johnson. We expect this action to reduce operational burn with immediate effect and this reduction will continue post mid-2026,"* said Bart Van Rhijn, chief financial and business officer at Nanobiotix. *"This non-dilutive financing solution achieved via the amendment, which we believe signals the increasing shared commitment to JNJ-1900 (NBTXR3), positions us to continue taking the necessary operational and financial steps to ensure the future of our business and our potential to benefit millions of patients around the world with our technology and signifies our continued financial discipline."*

Availability of the Full Year 2024 Financial Reports

The URD and 20-F are available on the Nanobiotix website here. In addition, the URD is available on the AMF website (www.amf-france.org) and the 20-F is available on the SEC website (www.sec.gov).

The Company's 2024 URD includes its:

- 2024 annual financial report including the report on corporate governance
- Reports from the Company's statutory auditors and information on their fees Required information in relation to the Company's share buyback program

Conference Call and Webcast

Nanobiotix will host a conference call and live audio webcast on Thursday, April 3, 2025, at 8:00 AM EDT / 2:00 PM CEST, prior to the open of the U.S. market. During the call, Laurent Levy, chief executive officer, and Bart van Rhijn, chief financial and business officer, will briefly review the Company's year-end results and provide an update on business activities for the full year of 2024 before taking questions from participants.

Details of the call are as follows:

Webcast link: click here
Conference call link: click here

Details of the call are also available in the investors section of the Company's website at www.nanobiotix.com. It is recommended to join 10 minutes prior the event start. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website.

Participants are invited to email their questions in advance to investors@nanobiotix.com.

About NBTXR3 (JNJ-1900)

NBTXR3 (JNJ-1900) is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles that is administered via one-time intratumoral injection and activated by radiotherapy. Its proof-of-concept was achieved in soft tissue sarcomas for which the product received a European CE mark in 2019. The product candidate's physics-based 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 physics-based MoA, Nanobiotix believes that NBTXR3 (JNJ-1900) could be scalable across any solid tumor that can be treated with radiotherapy and across any therapeutic combination, particularly immune checkpoint inhibitors.

Radiotherapy-activated NBTXR3 (JNJ-1900) is being evaluated across multiple solid tumor indications as a single agent or in combination with anti-PD-1 immune checkpoint inhibitors, including in NANORAY-312—a global, randomized Phase 3 study in locally advanced head and neck squamous cell cancers. In February 2020, the United States Food and Drug Administration granted regulatory Fast Track designation for the investigation of NBTXR3 (JNJ-1900) activated by radiation therapy, with or without cetuximab, for the treatment of patients with locally advanced HNSCC who are not eligible for platinum-based chemotherapy—the same population being evaluated in the Phase 3 study.

Given the Company's focus areas and balanced against the scalable potential of NBTXR3 (JNJ-1900), Nanobiotix has engaged in a collaboration strategy to expand development of the product candidate in parallel with its priority development pathways. Pursuant to this strategy, in 2019 Nanobiotix entered into a broad, comprehensive clinical research collaboration with The University of Texas MD Anderson Cancer Center to sponsor several Phase 1 and Phase 2 studies evaluating NBTXR3 (JNJ-1900) across tumor types and therapeutic combinations. In 2023 Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 (JNJ-1900) with Janssen Pharmaceutica NV, a Johnson & Johnson company.

About NANOBIOTIX

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's philosophy is rooted in the concept of pushing past the boundaries of what is known to expand possibilities for human life.

Incorporated in 2003, Nanobiotix is headquartered in Paris, France and is listed on Euronext Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020. The Company has subsidiaries in Cambridge, Massachusetts (United States) amongst other locations.

Nanobiotix is the owner of more than 25 patent families associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on LinkedIn and Twitter.

Disclaimer

This press release contains "forward-looking" statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the use of proceed therefrom, and the period of time through which the Company's anticipates its financial resources will be adequate to support operations. Words such as "expects", "intends", "can", "could", "may", "might", "plan", "potential", "should" and "will" or the negative of these and similar expressions are intended to identify forward-looking statements. These forward-looking statements which are based on the Company' management's current expectations and assumptions and on information currently available to management. These forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause actual results to differ materially from those implied by the forward-looking statements, including risks related to Nanobiotix's business and financial performance, which include the risk that assumptions underlying the Company's cash runway projections are not realized. Further information on the risk factors that may affect company business and financial performance is included in Nanobiotix's Annual Report on Form 20-F filed with the SEC on April 2, 2025 under "Item 3.D. Risk Factors", in Nanobiotix's 2024 universal registration document filed with the AMF on April 2, 2025, and subsequent filings Nanobiotix makes with the SEC from time to time which are available on the SEC's website at www.sec.gov. The forward-looking statements included in this press release speak only as of the date of this press release, and except as required by law, Nanobiotix assumes no obligation to update these forward-looking statements publicly.

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Statements of consolidated operations

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

	For the year ended December 31,	
	2024	**2023**
Revenues and other income		
Revenues	(11,609)	30,058
Other income	4,419	6,150
Total revenues and other income	**(7,191)**	**36,207**
Research and development expenses	(40,541)	(38,396)
Selling, general and administrative expenses	(20,527)	(22,049)
Other operating and income expenses	(134)	(2,542)
Total operating expenses	**(61,202)**	**(62,986)**
Operating income (loss)	**(68,392)**	**(26,779)**
Financial income	7,849	2,002
Financial expenses	(7,488)	(14,803)
Financial income (loss)	**361**	**(12,801)**
Income tax	(101)	(120)
Net loss for the period	**(68,132)**	**(39,700)**
Basic loss per share (euros/share)	**(1.44)**	**(1.08)**
Diluted loss per share (euros/share)	**(1.44)**	**(1.08)**

Statements of consolidated financial position

(Amounts in thousands of euros)

	As of December 31,	
	2024	**2023**
Total non-current assets	**5,951**	**6,558**
Cash and cash equivalents	49,737	75,283
Total current assets	**61,466**	**87,339**
TOTAL ASSETS	**67,418**	**93,897**
Net loss for the period	(68,132)	(39,700)
Total shareholders' equity	**(65,704)**	**(1,843)**
Total non-current liabilities	**74,187**	**45,866**
Total current liabilities	**58,934**	**49,873**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**67,418**	**93,897**

Attachment

- 2025-04-02 -- NBTX -- FY24 Financial Results -- FINAL.html