NANOBIOTIX Provides Business Update and Reports Half Year 2024 Financial Results

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- RT-NBTXR3 followed by anti-PD-1 demonstrated favorable safety profile, disease control and tumor response in patients both naïve and resistant to anti-PD-1, suggesting that NBTXR3 may prime the immune system before checkpoint therapy
- Several clinical milestones expected over the next 12-18 months including updated data in pancreatic, and head and neck cancer, and initial data in esophageal and lung cancer
- €66.3 million in cash and cash equivalents as of June 30, 2024, with a cash runway extended into Q4 2025

PARIS and CAMBRIDGE, Mass., Sept. 18, 2024 (GLOBE NEWSWIRE) -- NANOBIOTIX (Euronext: NANO - NASDAQ: NBTX - the **"Company")**, a late-clinical stage biotechnology company pioneering nanoparticle-based approaches to expand treatment possibilities for patients with cancer and other major diseases, provided an update on operational progress and announced its half year financial results for the six-month period ended June 30, 2024.

"We continue to make strong progress advancing our nanoparticle-based therapeutic approach with lead candidate NBTXR3, which is part of our global licensing agreement with Janssen Pharmaceutica NV, a Johnson & Johnson company. The agreement is designed to realize significant therapeutic and market opportunities in solid tumor cancers worldwide, starting with lung and head and neck. We also continue to establish additional expansion opportunities across multiple cancer settings as part of our ongoing collaboration with MD Anderson," said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. "The potential of NBTXR3 to prime immune activity before an anti-PD-1 inhibitor was further reinforced with new data from Study 1100 announced at the Annual Meeting of American Society for Clinical Oncology (ASCO) showing disease control and tumor response in patients with head and neck cancer that are naïve or resistant to prior anti-PD-1 therapy. We expect several clinical milestones over the next 12-18 months that, would further advance and broaden the potential patient population for NBTXR3 including updated data in pancreatic and head and neck cancer, and initial data in esophageal and lung cancer."

First Half 2024 Operational Highlights, Pipeline Status and Expected Milestones

Strengthened Supervisory Board with the nominations of Dr. Margaret A. Liu and Ms. Anat Naschitz as board observers, 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, and Ms. Naschitz brings world-class expertise in raising and deploying capital to support disruptive innovation for the benefit of patients, healthcare professionals and investors.

Achieved a NANORAY-312 operational milestone as part of global exclusive licensing, co-development, and commercialization agreement with Janssen Pharmaceutica NV, a Johnson & Johnson company, for the investigational, potential first-in-class radioenhancer NBTXR3 and subsequently received the $20 million payment.

Locally Advanced Head and Neck Squamous Cell Carcinoma (LA-HNSCC): *Local Control as Single Agent Activated by Radiotherapy (RT)*

- **NANORAY-312**, a pivotal, global, randomized Phase 3 trial evaluating RT-activated NBTXR3 ± cetuximab vs RT ± cetuximab in elderly patients ineligible for cisplatin chemotherapy
  - Interim analysis to be reported after both the requisite number of events has occurred and the last patient is recruited, expected by 1H2026
  - Ongoing transfer of the sponsorship to Janssen to facilitate preparations for potentially positive trial results and subsequent steps
- **Study 102**, a successfully completed Phase 1 dose escalation and expansion trial evaluating RT-activated NBTXR3 in patients ineligible for cisplatin chemotherapy or intolerant to cetuximab. Final results showed topline safety and efficacy data supporting robust anti-tumor activity and a well-tolerated profile in elderly patients with a high burden of comorbidity (n=56)

Non-Small Cell Lung Cancer (NSCLC)

- Janssen-led randomized Phase 2 study evaluating NBTXR3 + chemoradiation followed by anti-PD-L1 for patients with **inoperable, stage 3 NSCLC**
  - Study may proceed letter received from the Food and Drug Administration (FDA)

- First patient randomized is the next expected milestone

Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma (R/M HNSCC)*: Priming Immune Response Followed by an Anti-PD-1 Treatment:*

- **Study 1100**, a Phase 1 dose escalation and expansion trial evaluating RT-activated NBTXR3 followed by an anti-PD-1 as a second-or-later line treatment in patients with advanced cancers
  - Completed dose escalation part – ongoing dose expansion part. New data in R/M HNSCC Naïve or Resistant to Anti-PD-1 presented at ASCO:
    - Favorable safety and feasibility in 68 heavily pre-treated patients with R/M-HNSCC (Intention-to-Treat population; "ITT")
    - 48% overall response rate (ORR) in evaluable anti-PD-1 naïve patients (n=25); 28% ORR in evaluable anti-PD-1 resistant patients (n=25) as per RECIST 1.1
    - 76% disease control rate (DCR) in evaluable naïve patients; 68% DCR in evaluable resistant patients as per RECIST 1.1
    - Preliminary review of survival data in ITT anti-PD-1 naïve patients (n=33) showed mPFS of 7.3 months and mOS of 26.2 months
    - ITT anti-PD-1 resistant patients (n=35) showed mPFS of 4.2 months and mOS of 7.8 months
- Initial data from immunotherapy resistant patients with multiple primary tumors expected in 2025
- Data supports further evaluation in randomized clinical trials which may include a potential registrational pathway for NBTXR3 in combination with an immunotherapy.

Pancreatic, Lung and Others: *Expanding NBTXR3 Opportunity Through a Strategic Collaboration with The University of Texas MD Anderson Cancer Center to Validate Tumor-Agnostic, Combination-Agnostic Therapeutic Profiles*

Five ongoing clinical trials in advanced solid tumors:

- **Advanced Solid Tumors with Lung or Liver Metastases**: Phase 1/2 study (NCT05039632) of RT-activated NBTXR3 plus an anti-PD-1/L-1 immune checkpoint inhibitor
- **Recurrent or Metastatic Head and Neck Cancer**: Phase 2 study (NCT04862455) of RT-activated NBTXR3 in combination with anti-PD-1
- **Inoperable Non-Small Cell Lung Cancer (NSCLC)**: Phase 1 study (NCT04505267) of single agent RT-activated NBTXR3
  - Dose escalation completed and dose expansion ongoing. Established RP2D after determination of injection feasibility and observation of a favorable safety profile.
- **Esophageal Cancer**: Phase 1 study (NCT04615013) of RT-activated NBTXR3 in combination with chemotherapy
- **Pancreatic Cancer**: Phase 1b study (NCT04484909) of RT-activated NBTXR3 after cytotoxic chemotherapy for patients with locally advanced pancreatic cancer (LAPC)

Multiple expected clinical milestones:

- Updated Phase 1b dose escalation data in pancreatic cancer expected 2H2024
- Initial Phase 1 dose escalation data in inoperable, recurrent NSCLC amenable to re-irradiation expected 1H2025
- Completion of dose escalation in Phase 1b/2 trial in esophageal cancer expected in 2024, initiation of dose expansion part, and presentation of first data in 2025

Half Year 2024 Financial Results

Revenue and Other Income: Revenue and other income has increased for the six months ended June 30, 2024, to €9.3 million, compared to €3.3 million for the six months ended June 30, 2023, primarily resulting from services and product supply revenue linked to the exclusive licensing, co-development, and commercialization agreement with Janssen Pharmaceutica NV executed on July 7, 2023.

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, 2024, were €22.0 million, primarily driven by an increase of the clinical development activities in NANORAY-312, compared to €17.8 million for the six months ended June 30, 2023.

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, 2024, were €10.8 million, compared to €10.9 million for the prior-year six-month period.

Net loss: Net loss attributable to common shareholders for the six months ended June 30, 2024, was €21.9 million, or a €0.46 basic loss per share. This compares to a net loss attributable to common shareholders of €28.1 million, or €0.80 basic loss per share, for the same period in 2023.

Cash and Cash Equivalents: Cash and cash equivalents as of June 30, 2024, were €66.3 million, compared to €75.3 million as of December 31, 2023.

Based on the current operating plan and financial projections, we anticipate that the cash and cash equivalents of €66.3 million as of June 30, 2024, will now fund our operations into Q4 2025, compared to Q3 2025 in prior guidance.

Availability of the Half Year 2024 Financial Reports

The 2024 half-year financial report has been filed with the French financial market authority (Autorité des marchés financiers). It is available to the public on the Company's website, www.nanobiotix.com.

About NBTXR3

NBTXR3 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 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 any solid tumor that can be treated with radiotherapy and across any therapeutic combination, particularly immune checkpoint inhibitors.

Radiotherapy-activated NBTXR3 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 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, 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 across tumor types and therapeutic combinations. In 2023, Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

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 our 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 24, 2024 under "Item 3.D. Risk Factors", in Nanobiotix's 2023 universal registration document filed with the AMF on April 24, 2024, in Nanobiotix' 2024 semi-annual report under the caption "Supplemental Risk Factor" filed with the SEC on Form 6-K and with AMF on September 18 2024, 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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