



NANOBIOTIX Provides Business Update and Financial Results for the First Half of 2023

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- Global licensing, co-development, and commercialization agreement with Janssen Pharmaceutica NV (“Janssen”) expands worldwide potential of novel radioenhancer NBTXR3
- Upfront payment and first equity tranche received by Nanobiotix post H1 2023 from agreement with Janssen extends cash runway into the first quarter of 2024 and second quarter if the cash covenant of the European Investment Bank (EIB) was not applicable
- Bolstering of clinical oncology development and commercialization capabilities with appointment of Louis Kayitalire, MD as chief medical officer (CMO)
- Final Phase 1 safety and efficacy data in head and neck cancer, and initial Phase 1 dose escalation data in pancreatic cancer for NBTXR3 expected in the coming weeks
- Reported €21.6 million in cash and cash equivalents as of June 30, 2023
- Reached agreement in principle with the EIB to remove the cash covenant in its entirety, subject to certain conditions

Conference call and webcast scheduled for Wednesday, September 27, 2023, at 2:00 pm CEST / 8:00 am EDT

PARIS and CAMBRIDGE, Mass., Sept. 26, 2023 (GLOBE NEWSWIRE) -- [NANOBIOTIX](#) (Euronext: NANO — NASDAQ: NBTX – the “**Company**”), a late-clinical stage biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today provided an update on operational progress and announced its half year financial results for the six-month period ended June 30, 2023.

“To date, this has been a truly transformative year for Nanobiotix following the successful execution of a global licensing, co-development and commercialization agreement for NBTXR3, the appointment of Dr. Kayitalire, an industry-veteran in oncology as CMO, and the ongoing advancement of trials designed to establish the clinical foundation of NBTXR3 in multiple solid tumor indications. Collectively, these achievements continue to propel late-stage development of NBTXR3 forward, expand our patient reach, and ultimately position us to realize the paradigm changing potential of NBTXR3 worldwide,” said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. “With our balance sheet strengthened following the upfront payment and first equity tranche from Janssen, we are poised to successfully execute across our upcoming clinical milestones. We expect topline Phase 1 escalation and expansion efficacy and safety data from study 102 in locally advanced head and neck cancer, and initial Phase 1 dose escalation safety data in pancreatic cancer from our ongoing collaboration with MD Anderson before the end of this year.”

First Half 2023 Operational Highlights, Pipeline Status and Upcoming Milestones

- Nanobiotix announced on May 5, 2023, that it had entered into final contract negotiations following agreement to a non-binding term sheet for development and commercialization of NBTXR3 with a major global pharmaceutical company. Following this first semester 2023, these negotiations culminated with the signing of a global exclusive licensing, co-development, and commercialization agreement with Janssen, a Johnson & Johnson company, for the investigational, potential first-in-class radioenhancer NBTXR3. The Company is eligible to receive:
 - \$30M upfront cash licensing fee (received after June 30th, 2023)
 - \$30M in-kind regulatory and development support for study NANORAY-312 provided at Janssen’s sole discretion
 - \$30 million in equity subject to certain conditions

- First tranche, \$5 million (received after June 30th, 2023)
- Second tranche, up to \$25 million subject to a future qualified financing¹
- Success-based payments of up to \$1.8B and tiered double-digit royalties on net sales of NBTXR3
- Additional success-based potential development and regulatory milestone payments of up to \$650 million, in the aggregate, for five new indications that may be developed by Janssen at its sole discretion
- And up to \$220 million, in the aggregate, per indication that may be developed by Nanobiotix in alignment with Janssen
- Nanobiotix strengthened global development capabilities with the appointment of industry veteran Louis Kayitalire, MD as CMO. Dr. Kayitalire brings proven success in the research, development, registration, and commercialization of therapeutics in oncology
- Successful shareholder approval and issuance of 959,637 shares for subscription by Johnson & Johnson Innovation – JJDC, Inc. for an initial tranche equal to \$5 million representing 2.65% of the issued shares of the Company

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

- NANORAY-312, a pivotal, global and randomized Phase 3 trial evaluating RT-activated NBTXR3 ± cetuximab vs RT ± cetuximab in elderly patients ineligible for cisplatin chemotherapy
 - Futility analysis following 25% of planned PFS events expected in H1 24
 - Initial Phase 3 interim efficacy and safety data expected after 67% of planned PFS events in H2 2024
- Study 102, a Phase 1 dose escalation and expansion trial evaluating RT-activated NBTXR3 in patients ineligible for cisplatin chemotherapy or intolerant to cetuximab
 - Final safety and efficacy data expected in the coming weeks

Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma: 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 in patients with advanced cancers
 - Phase 1 data update anticipated between 2H 2023 and 1H 2024
- A potential Phase 3 registrational program for patients with unresectable locoregional recurrent or recurrent/metastatic HNSCC resistant to previous anti-PD-1/PD-L1 therapy
 - Ongoing consultation with newly appointed CMO and our new partner on continuing discussions with the FDA for 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 of RT-activated

NBTR3 plus an anti-PD-1/L-1 immune checkpoint inhibitor (NCT05039632)

- First patient injected in July 2023
- Recurrent or Metastatic Head and Neck Cancer: Phase 2 study of RT-activated NBTR3 in combination with anti-PD-1 (NCT04862455)
- Inoperable Non-Small Cell Lung Cancer (NSCLC): Phase 1 study of RT-activated NBTR3 (NCT04505267)
 - Determination of RP2D for NBTR3 expected in H2 2023
- Pancreatic Cancer: Phase 1 study of RT-activated NBTR3 (NCT04484909)
 - Preliminary Phase 1b dose escalation safety data expected in the coming weeks
 - Completion of enrollment in Phase 1b dose expansion trial expected in H1 2024
- Esophageal Cancer: Phase 1 study of RT-activated NBTR3 in combination with chemotherapy (NCT04615013)
 - Initial Phase 1b/2 data expected in 2024

Financial Results for the First Half of 2023

Revenue and Other Income: Revenue and other income has increased for the six months ended June 30, 2023 to €3.3 million, compared to €1.3 million for the six months ended June 30, 2022. The Company has benefited from an increase of the research tax credit of €0.6 million, granted by the French government to encourage companies to conduct technical and scientific research, and from the collaboration agreement signed with LianBio generating an additional €1.3 million revenue for the six months ended June 30, 2023.

Research and Development (“R&D”) Expenses: R&D expenses consist primarily of preclinical, clinical and manufacturing expenses related to the development of NBTR3. These expenses for the six months ended June 30, 2023, were €17.8 million, compared to €16.6 million for the six months ended June 30, 2022. Purchases, sub-contracting and other expenses increased by €1.5 million for the six-month period ended June 30, 2023, as compared to the same period in 2022. 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, 2023, were €10.9 million, compared to €9.6 million for the prior-year six-month period. Purchases, fees and other expenses increased by €1.1 million for the six-month period ended June 30, 2023 as compared to the same period in 2022, and mainly relates to €1.4 million fees paid to a financial advisor, whereas SG&A payroll cost remained stable as compared to the same period in 2022.

Net Loss: Net loss attributable to common shareholders for the six months ended June 30, 2023 was €28.1 million, or €0.80 per share. This compares to a net loss attributable to common shareholders of €26.4 million, or €0.76 per share, for the same period in 2022.

Cash and Cash Equivalents: Cash and cash equivalents as of June 30, 2023, were €21.6 million, compared to €41.4 million as of December 31, 2022.

Based on the current operating plan and financial projections, we anticipate that the cash and cash equivalents of €21.6 million as of June 30, 2023, in conjunction with the \$30M upfront and \$5M initial equity tranche received subsequently, extends into the first quarter of 2024, which does not take into account any potential future financing, or cash inflow resulting from milestones or future collaborations. For clarity’s sake, if the EIB cash covenant would not be in place, the cash and cash equivalents would be sufficient to fund its operating expenses into the second quarter of 2024.

Subsequent to the Company’s licensing agreement executed with Janssen, the Company has entered into discussions with the EIB aiming to remove the cash covenant from the debt financing agreement between the Company and EIB. These discussions have culminated in an agreement in principle on key terms, that would result in the removal of the cash covenant in its entirety, in exchange for an acceleration of payment of a portion of the applicable Milestones Payments calculated using an escalating single digit percentage applied to bracketed funding amounts in the event of an equity funding event and the payment of scheduled PIK interest. Execution of the definitive amendment to the agreements between Nanobiotix and EIB is subject to finalization of necessary documentation and is expected at the beginning of the fourth quarter of 2023, which has the potential to positively influence our cash runway.

The Company’s executive board determined it is appropriate to prepare its half-year 2023 unaudited interim condensed consolidated financial statements on a going concern basis, assuming the Company will continue to operate for the foreseeable future, and to address its liquidity challenges by pursuing activities to generate additional cash inflows and by closely managing its operating expenditures, based on assumptions described in the half-year 2023 financial report.

Availability of the half-year financial report

The 2023 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.

Conference Call and Webcast

Nanobiotix will host a conference call and live audio webcast on Wednesday, September 27, 2023, at 2:00 pm CEST / 8:00 am EDT, prior to the open of the U.S. market. During the call, Laurent Levy, chief executive officer, and Bart van Rhijn, chief financial officer, will briefly review the Company’s half-year results and provide an update on business activities before taking questions from participants.

Details for the call are as follows:

Live (US): 1-877-423-9813

Live France: 0 800 912 848

Live (international): 1-201-689-8573

Call me™ [click here](#)

Participants can use guest dial-in numbers above and be answered by an operator or they can click the Call me™ link for instant telephone access to the event (dial-out). The Call me™ link will be made active 15 minutes prior to scheduled start time. A live webcast of the call may be accessed by visiting 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

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 2021, the Company announced an agreement with LianBio to expand development of NBTXR3 into Greater China and other Asian Markets, and in 2023 Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

About NANOBOTIX

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, among other, Cambridge, Massachusetts (United States).

Nanobiotix is the owner of more than 20 umbrella patents associated with three (3) nanotechnology platforms with applications in 1) oncology; 2) bioavailability and biodistribution; and 3) disorders of the central nervous system. The Company's resources are primarily devoted to the development of its lead product candidate—NBTXR3—which is the product of its proprietary oncology platform and has been granted with a CE marking in Europe for the treatment of patients with soft tissue sarcoma under the brand name Hensify®

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

Cautionary Statement

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 "additional", "aim", "continue", "could", "drive", "enable", "expect", "further", "look forward", "may", "ongoing", "potential", "promise", "realize", "subject to", "success-based", "up to", "will", and "would" or the negative of these and similar expressions. These forward-looking statements, which are based on the management's current expectations and assumptions and on information currently available to management, include statements about the overall development of NBTXR3, including the timing and progress of clinical trials; the development of NBTXR3 pursuant to the license agreement with Janssen (the "Agreement") and the potential payments for which Nanobiotix is eligible under the Agreement; the potential for, and possible size of, the proposed equity investment by Johnson & Johnson – JJDC Inc; and the financial position of Nanobiotix. 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; the risks arising from Nanobiotix's reliance on Janssen to conduct development and commercialization activities with respect to NBTXR3, including the potential for disagreements or disputes under the Agreement; the risk that Janssen may exercise its discretion in a manner that limits the resources contributed toward the development of NBTXR3 under the Agreement or may exercise its faculty to terminate without cause the Agreement; the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data; the risk that the Company and EIB will not reach definitive agreement with respect to the removal of the cash-covenant, and the risk that the 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 24, 2023 under "Item 3.D. Risk Factors", 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 24, 2023, and those set forth in the half-year report filed with SEC on form 6-K and with AMF on September 26, 2023 (copies of which are available on www.nanobiotix.com), 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.

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¹ Nanobiotix may initiate a future capital raise of at least \$50 million as part of which Johnson & Johnson Innovation – JJDC, Inc. (JJDC) has committed to contribute up to \$25 million, subject to a qualified financing. This must occur prior to certain long-term development milestones and December 31, 2027 at the latest. See press release dated July 10, 2023.