

NANOBIOTIX

EXPANDING LIFE

NANOBIOTIX Provides First Quarter 2023 Operational and Financial Update

May 17, 2023

Reported €30.2 million in cash and cash equivalents as of March 31, 2023

PARIS and CAMBRIDGE, Mass., May 17, 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 reported financial results for the for the first quarter of 2023.

“2023 will be a foundational year for Nanobiotix, and we are energized to further advance late-stage development of our radioenhancer NBTXR3 in head and neck cancer. The recent operational efficiencies implemented last year are working, and we are seeing enrollment progress well in our pivotal Phase 3 study, NANORAY-312, with 122 sites activated in 24 countries to date,” said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. “We remain focused on our near-term milestones including final data for Study 102, and a first look at NBTXR3 in pancreatic cancer as part of our MD Anderson collaboration. We are excited to welcome a new Chief Medical Officer in the third quarter of this year who will help further enhance our clinical development strategy. We believe that the clinical and corporate framework we are establishing will strongly position us for growth and successful execution across our programs in the years ahead.”

Pipeline Status and Expected Upcoming Milestones

- Chief Medical Officer (CMO) candidate with strategically aligned experience in oncology and immuno-oncology is expected to join the organization in Q3 2023

Locally Advanced Head and Neck: Priority Registration Pathway in Locally Advanced Head & Neck Squamous Cell Carcinoma (LA-HNSCC), Local Control as Single Agent Activated by Radiotherapy (RT):

- NANORAY-312 Phase 3 trial evaluating RT-activated NBTXR3 ± cetuximab vs RT ± cetuximab in elderly patients with LA-HNSCC
 - Futility analysis to be conducted following 25% of planned PFS events expected in H1 2024
 - Initial Phase 3 interim efficacy and safety data expected after 67% of planned PFS events in H2 2024
- Study 102 Phase 1 trial evaluating RT-activated NBTXR3 in LA-HNSCC
 - Final safety and efficacy data expected in H2 2023

Recurrent/Metastatic Head and Neck: Priority Pathway in Immunotherapy for Recurrent/Metastatic Head & Neck Squamous Cell Carcinoma (R/M HNSCC), Priming Immune Response Followed by an Anti-PD-1 Treatment:

- Study 1100 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 at a time to be determined
- Phase 3 registrational program for patients with unresectable locoregional recurrent (LRR) or recurrent or metastatic HNSCC resistant to previous anti-PD-1/PD-L1 therapy
 - Company plans to consult with incoming CMO prior to continuing discussions with FDA on potential registration pathway for an NBTXR3-immunotherapy approach, and expects to provide an update in Q3 2023

Pancreatic, Lung and others: Expanding NBTXR3 Opportunity, Collaborating with a World-Class Partner to Validate Tumor-Agnostic, Combination-Agnostic Therapeutic Profile:

- Ongoing collaboration with The University of Texas MD Anderson Cancer Center
 - Preliminary Phase 1b dose escalation safety data in PDAC expected in H2 2023
 - Completion of enrollment in Phase 1b dose expansion trial for PDAC expected in H2 2023
 - Determination of RP2D for NBTXR3 in non-small cell lung cancer (NSCLC) expected in H2 2023
 - Initial Phase 1b/2 data for NBTXR3 in combination with chemotherapy in patients with esophageal cancer expected in 2024

First Quarter Financial Updates

Cash and Cash Equivalents:

Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €30.2 million as of March 31, 2023, will fund its operations into the third quarter of 2023, assuming no additional cash inflows, no business development transaction is consummated and assuming the European Investment Bank does in fact exercise the covenant requiring the Company to have a cash and cash equivalents balance at least equal to the principal of the loan balance currently at €25.3 million.

Next Annual General Meeting of the Company

The Company announced that its next Annual General Meeting ("AGM") will be held on June 27, 2023, at its headquarters, 60 rue de Wattignies, 75012 Paris, France. The notice of meeting of this AGM will be published shortly in the French legal bulletin and will include the agenda, the proposed resolutions as well as instructions to participate and vote in this AGM. All documentation regarding this AGM will be published on the Company's website.

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. The Company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, and Germany. Nanobiotix has been listed on Euronext Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020.

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 already achieved market authorization 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](#).

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," "consider," "anticipate," "think," "aim," "believe," "expect," "intend," "wish," "may," "can," "could," "is designated to," "might," "on track," "plan," "potential," "predict," "objective," "shall," "should," "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 will not reach a final and binding definitive agreement with respect to the development and commercialization of NBTXR3, the risk that the EIB may accelerate the loans under finance contract and its amendment upon the occurrence of one of the events of default; 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" 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 24, 2023, (a copy of which is 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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Attachment

- [2023-05-17 -- NBTX -- 1Q23 Financial Results -- FINAL](#)

