



NANOBIOTIX Provides Third Quarter 2023 Operational and Financial Update

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- \$2.5 billion global licensing, co-development, and commercialization agreement expands worldwide potential of novel radioenhancer NBTXR3
- 16.9 months median progression free survival (mPFS) and 23.1 months median overall survival (mOS) following radiotherapy-activated (RT) NBTXR3 in topline Study 102 Phase 1 data in head and neck cancer strengthens hypotheses for pivotal NANORAY-312 trial design
- Promising initial anti-tumor efficacy, median overall survival (mOS) of 23 months, 92% local disease control rate (DCR), favorable safety profile and recommended dose established for NBTXR3 in locally advanced pancreatic cancer
- €50.9 in capital from recent financing including second equity tranche from collaboration partner extends cash runway into 2Q 2025 assuming a milestone
- Successful removal of the EIB cash covenant
- Multiple clinical readouts over the next 18 months and beyond

Conference call and webcast scheduled for Tuesday, November 14, 2023, at 2:00 pm CET / 8:00 am ET

PARIS and CAMBRIDGE, Mass., Nov. 13, 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 third quarter of 2023.

“Our robust NBTXR3 clinical program continues to demonstrate potentially transformative efficacy and well-tolerated safety across indications and patient types, including elderly and vulnerable populations. We are pleased with the encouraging, expanded potential in locally advanced pancreatic cancer supported by initial Phase 1 data from our strategic collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson) presented at this year’s AACR and ESMO annual meetings,” said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. *“Additionally, strong Phase 1 data from Study 102 in locally advanced head and neck cancer demonstrated high and durable activity including a 64% complete response rate, a 16.9 months mPFS and 23.1 months mOS in evaluable patients, which is nearly double the survival reported in historical data. Further, we believe the Study 102 results inform next steps and further strengthen the hypotheses underlying the design of the ongoing global, registrational NANORAY-312 Phase 3 study for NBTXR3.”*

Laurent Levy continued, *“Building on the momentum following our recent global licensing agreement with Janssen, we have raised €50.9 million in capital that includes a public offering and the partial execution of the second equity tranche from Johnson & Johnson Innovation, Inc. With the EIB cash covenant removed, our financial overhang addressed, and our cash runway extended, we are poised to successfully execute through several important catalysts and into the expected timeframe of the NANORAY-312 interim efficacy readout.”*

Third Quarter 2023 Operational Highlights, Subsequent Events, and Pipeline Status and Upcoming Milestones

- Nanobiotix announced on July 10, 2023, that it had entered into a 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. The Company has received:
 - \$30 million upfront cash licensing fee (received after June 30th, 2023)
 - \$5 million first equity tranche received post signing
 - \$20.2 million of \$25 million second equity tranche received in recent capital raise
- The Company remains eligible to receive:
- Remaining \$4.8 million from second equity tranche, subject to certain conditions

- Up to \$30M in-kind regulatory and development support for study NANORAY-312 provided at Janssen's sole discretion
 - 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
- The Company has raised gross proceeds of €50.9 million from a recent financing and second equity tranche from Johnson & Johnson Innovation, Inc. (JJDC) extends cash runway into 2Q 2025 assuming a development milestone. Gross proceeds are expected to increase to €55.5 million following subscription by JJDC to the remaining placement amount of the second tranche of €4.6 million.

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

- 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 H2 2024
 - Initial Phase 3 interim efficacy and safety data expected after 67% of planned PFS events in mid-2025
- Study 102, a Phase 1 dose escalation and expansion trial evaluating RT-activated NBTXR3 in patients ineligible for cisplatin chemotherapy or intolerant to cetuximab
 - Topline safety and efficacy data presented as an oral presentation at the 65th Annual Meeting of the American Society for Radiation Oncology (ASTRO) supporting robust anti-tumor efficacy and well-tolerated profile in elderly patients with a high burden of comorbidity (n=56)
 - 64% CR, 82% ORR in injected-lesion in the evaluable population (n=44) and median duration of response in the NBTXR3-injected lesion not yet reached
 - 16.9 months mPFS and 23.1 months mOS in the evaluable population
 - Exploratory analyses presented at the 2023 Annual Congress of the European Society for Medical Oncology (ESMO) investigating additional signs of efficacy provide further support for hypotheses underlying the ongoing registrational Phase 3 NANORAY-312 study design
 - 42.8 months mOS observed in the 81.8% of evaluable patients who had complete or partial response in the NBTXR3-injected lesion (36/44) compared to 18.1 months in All Patients Treated (n=56)
 - Positive correlation associated with objective response, PFS and OS extension with RT-activated NBTXR3 in the injected lesion

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 dose expansion data update anticipated 1H 2024
- 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 NBTXR3 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 NBTXR3 in combination with anti-PD-1 (NCT04862455)
 - Inoperable Non-Small Cell Lung Cancer (NSCLC): Phase 1 study of RT-activated NBTXR3 (NCT04505267)
 - Pancreatic Cancer: Phase 1 study of RT-activated NBTXR3 after cytotoxic chemotherapy for patients with locally advanced pancreatic cancer (LAPC), (NCT04484909)
 - Preliminary Phase 1b dose escalation safety data (July 30, 2023 cutoff) presented at American Association for Cancer Research (AACR) 2023 Special Conference on Pancreatic Cancer support feasibility and promising, durable anti-tumor efficacy of RT-activated NBTXR3
 - Tolerable safety with local endoscopic injection in 15 patients
 - 92% (12/13) injected tumor disease control rate in evaluable patients
 - 21 months mOS from diagnosis in evaluable patients
 - Additional preliminary signals of promising anti-tumor efficacy from the ongoing Phase 1 study (September 30, 2023 cutoff) presented at ESMO 2023 potentially help inform clinical trial development
 - Favorable safety profile and recommended dose established
 - 23 months mOS observed in 15 patients
 - Esophageal Cancer: Phase 1 study of RT-activated NBTXR3 in combination with chemotherapy (NCT04615013)
 - Multiple clinical milestones in 2024:
 - Determination of RP2D in NSCLC trial
 - Completion of enrollment in Phase 1b dose expansion trial in pancreatic cancer
 - Initial Phase 1b/2 data in esophageal cancer

Third Quarter Financial Updates

Cash and Cash Equivalents

Nanobiotix reported cash and cash equivalents of €38.7 million (unaudited) as of September 30, 2023.

Based on the current operating plan and financial projections, we anticipate that the cash and cash equivalents of €38.7 million as of September 30, 2023, in conjunction with €50.9 million from the recent financing and partial execution of the second equity tranche from JJDC as well as a development milestone, extends the cash runway into the second quarter of 2025.

The gross proceeds of the Global Offering were €31.8 million including the Underwriter's Option. Adding to this the €19.1 million gross proceeds from the restricted ADSs to be purchased by JJDC in the Concurrent Private Placement, the Company will receive aggregate gross proceeds of

approximately €50.9 million (equivalent to approximately \$53.8 million, based on an exchange rate of €1.00 = \$1.0568, as published by Bloomberg on November 1, 2023), before deduction of underwriting commissions from the Global Offering and estimated offering expenses payable by the Company. Following the approval of the French Ministry of Economy and the subscription by JJDC for the Remaining Placement Amount, the aggregate gross proceeds would increase to approximately €55.5 million (equivalent to approximately \$58.7 million) and would extend the cash runway to the end of the second quarter of 2025 (assuming the development milestone as above and excluding cash inflows from future non-dilutive or dilutive financing opportunities).

Successful Removal of the EIB Cash Covenant

As previously disclosed, the European Investment Bank (the “EIB”) has agreed to the removal of the minimum cash and cash equivalent covenant from the Company’s EIB loan, effective October 13, 2023. As result of the financing with gross proceeds of €50.9 million, the company will prepay the EIB approximately €0.5 million (1% of €50.9M) of the €20.0 million milestone payment required under the EIB loan.

Conference Call and Webcast

Nanobiotix will host a conference call and live audio webcast on Tuesday, November 14, 2023, at 8:00 am ET / 2:00 pm CET, 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 operational progress, provide an update on business activities for the third quarter of 2023, and review the latest data presented at the 2023 Annual Congress of the European Society for Medical Oncology (ESMO), before taking questions from participants.

Details for the call are as follows:

Live (US): 1-888-886-7786

Live France: 0 800 916 834

Live (international): 1-416-764-8658

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 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 since 2012 and on 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.

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 expected closing of the Concurrent Private Placement and the additional shares to be purchased by JJDC subject to regulatory approval. 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 such as market conditions and risks related to Nanobiotix’s business and financial performance. 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, 2023 under “Item 3.D. Risk Factors”, in Nanobiotix’s half-year report, which was filed with the SEC on Form 6-K and with the AMF on September 26, 2023, and subsequent filings Nanobiotix makes with either the AMF or 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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Attachment

- [2023-11-13 -- NTB -- 3Q23 Financial Results -- FINAL](#)