



NANOBIOTIX Provides First Quarter Operational and Financial Update

May 19, 2022 1:12 AM EDT

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- Received preliminary feedback from FDA informing development of pivotal Phase III protocol for NBTXR3 in combination with anti-PD-1 therapy, protocol submission planned in Q1 2023
- Cash position totaling €70.6 million as of March 31, 2022
- Prioritizing research and development programs to reduce operating expenses and establishing flexible equity financing line that can be accessed at the Company's discretion to extend operating runway into Q4 2023
- Exploring broader debt restructuring to potentially extend operating runway further

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 18, 2022-- Regulatory News:

This replaces the announcement made at 4:40PM EDT/20:40 CEST on May 18 due to the following correction: Updated date in "First Quarter Operational Highlights" section.

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[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 announced operational progress, cash position (unaudited) for the first quarter of 2022, and extension of operating runway into Q4 2023.

First Quarter Operational Highlights

Priority Registration Pathway in Head & Neck Cancer. Local Control as Single Agent Activated by Radiotherapy

- Randomized first patient in pivotal phase III study NANORAY-312 evaluating radiotherapy (RT) activated NBTXR3 with or without cetuximab in elderly patients with locally advanced head and neck squamous cell carcinoma
 - Strategic partner, LianBio, expected to activate first clinical trial site and randomize first patient in Asia in H2 2022
 - US site activation and patient enrollment expected in Q3 2022 in line with prior expectations
- Completed enrollment in Study 102, a phase I study evaluating RT activated NBTXR3 in elderly LA-HNSCC patients ineligible for cisplatin and intolerant to cetuximab and provided data showing on-going median overall survival of 17.9 months in the all-treated population (n=56) and 23.0 months in the evaluable patients (n=44)

- Preparing protocol amendment reducing planned post-treatment follow-up period from 24 months to 12 months to provide a mature dataset while reducing the overall study duration
- Final Study 102 data expected mid-2023

Priority Pathway in Immunotherapy for Advanced Cancers. Priming Immune Response in Combination with Anti-PD-1 Treatment:

- Received preliminary feedback from the U.S. Food and Drug Administration (FDA) regarding a potential Phase III registration program in patients with unresectable relapsed or metastatic Head & Neck Squamous Cell Carcinoma (R/M HNSCC) who developed primary or secondary resistance to previous anti-PD-1/PD-L1 therapy
 - Comments provided by the FDA suggest a single, active-control trial including a pre-specified comparative analysis of overall response rate (ORR) may be suitable to support an accelerated approval, with verification of clinical benefit based on overall survival (OS) results from the same trial
 - Based on guidance provided by FDA, Nanobiotix plans to prepare and submit a protocol and statistical analysis plan for review in Q1 2023
- Expansion Phase added to Study 1100 evaluating NBTXR3 in combination with anti-PD-1 therapy in three cohorts, including one cohort focused on R/M HNSCC patients that are resistant to prior anti-PD-(L)-1 therapy
 - Update expected on Study 1100 in Q4 2022

Expanding NBTXR3 Opportunity. Collaborating with World-Class Partners to Validate Tumor-Agnostic, Combination-Agnostic Therapeutic Profile:

- Published data from a preclinical study conducted in collaboration between The University of Texas MD Anderson Cancer Center (MD Anderson) in the in the Journal of Nanobiotechnology showing that adding NBTXR3 to a combination of radiotherapy, anti-PD-1, and anti-CTLA-4 produced significant antitumor effects against both primary and secondary tumors, improved the mouse survival rate from 0 to 50%, and induced long term antitumor memory, further supporting the hypothesis that the potential immune priming effects of NBTXR3 extends beyond anti-PD-1.
- Researchers from MD Anderson published peer-reviewed clinical case study reporting preliminary data on the first-in-human administration of NBTXR3 for the treatment of pancreatic cancer not eligible for surgery, demonstrating feasibility with no treatment-related toxicity
 - Determination of recommended phase II dose for NBTXR3 in pancreatic cancer expected in H2 2022

“During the first quarter of 2022, we made significant progress in advancing our priority development programs. Having already provided clinical validation of the novel, physics-based MoA of NBTXR3 in soft tissue sarcoma, showed the potential survival benefit as a monotherapy in head and neck cancer, replicated the high response rate across multiple cancer types, and reported data suggesting the potential to combine with and expand the benefits of checkpoint inhibitors to more patients, we remain steadfast in our conviction that NBTXR3 has the potential to radically impact the future of cancer care for millions of patients,” said Laurent Levy, co-founder and chairman of the executive board of Nanobiotix. “To ensure this fundamental value as we continue to see unprecedented deterioration in the capital markets, we are taking proactive steps to adjust our cost structure, reduce spend, and focus our operational activities on building a head and neck franchise. We believe that by beginning with single agent approval in locally advanced head and neck cancer and expanding through combinations across treatment modalities will create a model that can be replicated across solid tumor indications, improving patient outcomes and driving significant value to shareholders.”

Prioritizing Registration Programs and Reducing Operating Expenses

Nanobiotix is pursuing various initiatives to reduce operating costs while maintaining targeted research efforts focused on the continued execution of its pivotal phase III study in LA-HNSCC, the continuation of I/O combination Study 1100, and the development of a registration pathway in I/O combination therapy while leveraging its on-going strategic collaboration with MD Anderson to validate the feasibility of future development opportunities. In prioritizing late-stage programs and strategic collaborations, the company plans to deprioritize direct funding in several areas, including:

- **Modifying or postponing additional company-sponsored clinical trials**, including planned amendments to Study 102 reducing follow-up time from 24 to 12 months and postponement of post-marketing studies previously planned in soft tissue sarcoma
- **Reducing on-going and previously planned preclinical research**, including development activities related to the Company's subsidiary, Curadigm
- **Adjusting planned manufacturing activities to support revised preclinical and clinical development activities**
- **Adapting infrastructure**, including reducing satellite office facilities and implementing a temporary hiring-freeze

These initiatives are expected to reduce the Company's cash burn by approximately €12-15 million, which will be reflected in Nanobiotix' financial outlook for 2022 and 2023.

First Quarter Financial Updates

Nanobiotix reported cash, cash equivalents, and short-term investments totaling €70.6 million as of March 31, 2022, compared to €83.9M as of December 31, 2021. To supplement its financial resources, Nanobiotix has established an equity financing line with Kepler Cheuvreux. This line of financing will provide optionality and create near-term flexibility, if needed, as the company continues efforts to reduce operating expenses and, potentially, restructure its existing debt facilities. Based on the current operating plan and financial projections, Nanobiotix anticipates that the available capital will fund its operations into, at least, the fourth quarter of 2023.

Implementing Equity Line Financing to Strengthen Financial Flexibility

In accordance with the terms of this agreement, Kepler Cheuvreux committed to underwrite up to 5,200,000 shares representing, for information purposes, an issued amount of approximately €25m¹, over a maximum timeframe of 24 months, provided the contractual conditions are met. Should Nanobiotix choose to use this facility, the shares will be issued based on the volume-weighted average share price on Euronext: Paris for the two trading days prior to issuance, minus a maximum discount 5.0%. In addition to controlling if and when to access capital, including consideration of current share valuation, Nanobiotix has guaranteed access to capital to fund operations along with control over potential dilution despite any sustained turbulence in the broader market, while retaining the right to suspend the implementation of the equity line or terminate this agreement at any time, free of charge.

Agreements have been set up based on and in accordance with the 21st resolution from the annual shareholders meeting of April 28, 2021. Should Nanobiotix choose to use this facility, the number of shares issued under this agreement and admitted to trading will be disclosed on the Company's website. In accordance with the provisions of the General Regulations of the French Financial Markets Authority ("AMF"), this financial operation will not be subject to a prospectus requiring a visa from the AMF.

If this financing line were to be fully used with the issue of 5,200,000 shares, a shareholder holding 1.00% of the capital of Nanobiotix before it is set up, would see their stake reduced to 0.87% of the capital on an undiluted basis and to 0.84% of the capital on a fully diluted basis.

This operation was advised and structured by Vester Finance. Kepler Cheuvreux is the sole underwriter of the facility and is not expected to maintain ownership of any shares issued in conjunction with the equity line.

Conference Call and Webcast

Nanobiotix will host a conference call and live audio webcast on Thursday, May 19, 2022, at 2:00 PM CET/8:00 AM EDT, prior to the open of the US market. During the call, Laurent Levy, chief executive officer, and Bart Van Rhijn, chief financial officer, will briefly review the Company's first quarter results and provide an update on business activities before taking questions from analysts and investors. Investors are invited to email their questions in advance to investors@nanobiotix.com.

Details for the call are as follows:

Live (US/Canada): + 16467413167
 Live France: + 33170700781
 Live (international): + 44 (0) 2071 928338
 Conference ID: 7795306

A live webcast of the call may be accessed by visiting news and events page in the investors section of the company's website at www.nanobiotix.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the company's website for 90 days.

2022 Financial Agenda

- June 23, 2022 – Annual General Meeting, Paris, France
- September 7, 2022 – 2022 Half-Year Corporate and Financial Update
- November 9, 2022 – Third Quarter 2022 Corporate and Financial Update

About NBTXR3

NBTXR3 is a novel, potentially first-in-class oncology product composed of functionalized hafnium oxide nanoparticles administered via one-time intratumoral injection and activated by radiotherapy. 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.

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 is leveraging its proprietary nanoparticle platform, including its lead product candidate, radiotherapy activated NBTXR3, to develop a pipeline of therapeutic options designed to enhance local and systemic control of solid tumors with an initial focus on the treatment of head and neck cancers.

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," "anticipate," "believe," "expect," "intend," "on track," "plan," "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, the development and commercialization of NBTXR3, and the execution of the Company's development and commercialization strategy. 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 preclinical or early clinical result 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. Furthermore, many other important factors, including those described in Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 8, 2022 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 8, 2022 (a copy of which is available on www.nanobiotix.com), as well as other known and unknown risks and uncertainties 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.

¹ On the indicative basis of the weighted average price of the last two trading sessions of the Nanobiotix share on May 17, 2022



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Nanobiotix

Nanobiotix Communications

Brandon Owens

VP, Communications

+1 (617) 852-4835

contact@nanobiotix.com

Nanobiotix Investor Relations

Kate McNeil

SVP, Investor Relations

+1 (609) 678-7388

investors@nanobiotix.com

Media Relations

France – Ulysse Communication

Pierre-Louis Germain

+33 (0) 6 64 79 97 51

plgermain@ulyse-communication.com

US – Porter Novelli

Stefanie Tuck

+1 (917) 390-1394

Stefanie.tuck@porternovelli.com

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