



NANOBIOTIX Provides Business Update and Reports Full Year 2022 Financial Results

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- Pivotal Phase 3 trial NANORAY-312 ongoing globally with 104 sites activated in 25 countries to date; interim efficacy analysis after 67% of planned progression free survival (PFS) events expected in H2 2024, as planned
- Final data from Study 102 in head and neck cancer expected in H2 2023
- First pancreatic cancer data expected from MD Anderson trial in H2 2023
- Chief Medical Officer with strategically aligned multidisciplinary experience in oncology expected to join the company in Q3 2023
- Reported €41.4 million in cash and cash equivalents as of December 31, 2022
- 2022 Universal Registration Document filed with the French financial market authority and the 2022 Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission

Conference call and webcast scheduled for Tuesday, April 25 at 2:00 P.M. CEST/8:00 A.M. EDT

PARIS and CAMBRIDGE, Mass., April 24, 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, provided an update on operational progress and reported financial results for the year ended December 31, 2022, and announced the filing of its universal registration document (URD) for the financial year ended December 31, 2022 with the French financial market authority (Autorité des marchés financiers or AMF), as well as of the Annual Report on Form 20-F for the financial year ended December 31, 2022 with the U.S. Securities and Exchange Commission (SEC).

“2022 was a year that saw a leap forward in our ambition of bringing our lead nanotherapeutic candidate, NBTXR3, to elderly patients with head and neck cancer through the recruitment of the first patients across all major regions in our pivotal Phase 3 study, NANORAY-312,” said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. “This past year also tested our agility. Against continued volatility in the capital markets, our team was proactive in prioritizing critical development programs, driving efficiencies to reduce expense and extending our operating runway without hampering our development capability. Moreover, while our team rightly focused on delivering our near-term priorities, we also continued to build our leadership for the future with the addition of our Global Chief Clinical and Medical Affairs Officer, Leonard A. Farber, M.D., and the establishment of our multi-national, multi-disciplinary Scientific Advisory Board. I am confident that the momentum we built in 2022 has positioned us for continued success in 2023 and am grateful to all involved in supporting our mission.”

2022 Operational Highlights, Pipeline Status and Upcoming Milestones

- Strengthened executive leadership with appointment of Leonard Farber, M.D., as Chief Clinical and Medical Affairs Officer
- Established Nanobiotix Scientific Advisory Board with leading global radiation, medical and surgical oncologists involved in oncology treatment decision-making, clinical trial investigation and patient recruitment to further support clinical development of NBTXR3
- Chief Medical Officer (CMO) candidate with strategically aligned experience in oncology and immuno-oncology is expected to join the organization in Q3 2023

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
 - Initiation across core geographical sites in Europe, Asia (in collaboration with LianBio), and the United States with 104 sites activated across 25 countries
 - Futility analysis to be conducted 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 Phase 1 trial evaluating RT-activated NBTXR3 in LA-HNSCC
 - Completed enrollment in expansion phase
 - Interim update in February 2022 reported ongoing median overall survival of 17.9 months in the all-treated population (n=56) and 23.0 months in evaluable patients (n=44)
 - Final safety and efficacy data expected in H2 2023

Priority Pathway in Immunotherapy for Recurrent/Metastatic Head & Neck Squamous Cell Carcinoma (R/M HNSCC), Priming Immune Response Prior to 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
 - Completed enrollment in the escalation phase, established recommended Phase 2 dose (RP2D) and initiated enrollment in expansion cohorts
 - Phase 1 escalation data update presented at the Society for Immunotherapy of Cancer (SITC) 2022 annual conference; Objective reduction in target lesion/s, seen in 71% of evaluable patients, resulted in durable control in both anti-PD-1 naive and resistant lesions including 8 patients achieving over 6 months disease control and 5 patients with over 12 months
 - Study 1100 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
 - Received preliminary feedback from FDA suggesting a single, randomized, controlled trial including a pre-specified comparative analysis of overall response rate (ORR) may support accelerated approval, subject to confirmation of clinical benefit based on overall survival (OS) results from the same trial
 - 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

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

- Ongoing collaboration with The University of Texas MD Anderson Cancer Center
 - Determined RP2D for NBTXR3 in pancreatic ductal adenocarcinoma (PDAC) and demonstrated positive preliminary qualitative efficacy data
 - 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 an immunotherapy in patients with esophageal cancer expected in 2024

Full Year 2022 Financial Results

Revenue and Other Income: No revenue was recognized for the year ended December 31, 2022. The limited revenue during the year ended December 31, 2021, was mainly derived from the charging-back of external contract research organization costs incurred on behalf of former partner PharmaEngine in connection with the now terminated license and collaboration agreement.

Total other income increased significantly to €4.8 million for the year ended December 31, 2022, compared to €2.6 million and €2.5 million for the years ended December 31, 2021, and 2020, respectively, mainly due to higher research tax credit.

Research and Development (“R&D”) Expenses : R&D expenses consist primarily of preclinical, clinical, and manufacturing expenses related to the development of NBTXR3 and totaled €32.6 million for the twelve-month period ended December 31, 2022, as compared to €30.4 million for the twelve months ended December 31, 2021. The increase in net R&D expenses was primarily due to increases in development costs related to the Company’s priority pathways, including initiation of its pivotal Phase 3 registration study, NANORAY-312, continuation of Expansion Study 102 and its ongoing immunotherapy combination Study 1100 as well as increases in personnel related expenses.

Selling, General and Administrative (“SG&A”) Expenses : SG&A expenses decreased by €1.6 million, or 8.1%, from €19.4 million for the year ended December 31, 2021, to €17.9 million for the year ended December 31, 2022. This year-over-year decrease reflects the Company’s efforts to rationalize SG&A and internalize certain functions.

Net loss: Net loss attributable to shareholders was €57.0 million, or €1.64 per share, for the twelve-month period ended December 31, 2022. This compares to a net loss of €47.0 million, or €1.35 per share for the year ended December 31, 2021. Our operating loss decreased from €52.6 million in 2021 to €46.7 million in 2022; this operating loss improvement was offset mainly by a negative €6.9 million one-time debt valuation impact in 2022 as well as higher debt interest charges, together with €3.1 million lower foreign exchange gains.

Cash and Cash Equivalents: As of December 31, 2022, Nanobiotix had €41.4 million in cash and cash equivalents, compared to €83.9 million as of December 31, 2021.

Financial Guidance: Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €41.4 million as of December 31, 2022, in conjunction with its previously announced equity line financing will fund its operations into the third quarter of 2023.

Going Concern: We have prepared our consolidated financial statements assuming that we will continue as a going concern. We experienced net losses of €57.0 million in 2022 and a net decrease in cash and cash equivalents of €42.5 million in 2022. At December 31, 2022, our accumulated deficit was €227.3 million and we had negative working capital of €22.7 million. We expect to continue to incur significant expense related to the development and manufacturing of nanotechnology product candidates such as NBTXR3 and conducting clinical studies. Additionally, we may encounter unforeseen difficulties, complications, development delays and other unknown factors that require additional expense. As a result of these expenditures, we expect to continue to incur significant losses in the near term. Additionally, the EIB loan contain covenants that require maintenance of minimum cash and cash equivalent balances that limit the availability of cash resources to pursue operational needs.

The Company’s covenant obligations entail that the current cash and cash equivalents are only sufficient to fund our operating expenses into the third quarter of 2023. Violation of the covenant would result in immediate repayment of all or part of the loan outstanding (if and when requested by the EIB), together with accrued interest, prepayment fees and all other accrued or outstanding amounts. However, Nanobiotix has obtained a 15 million euros temporary waiver, until July 31, 2023, and has reached an agreement in principle with the EIB to automatically extend it until January 31, 2024 should a business development partnership, collaborative or strategic alliance have become effective before July 31, 2023. If the company secures this extension period, or if the company obtains appropriate funding prior, the Company is not expected to be in breach of this temporary waiver as of July 31, 2023.

The Company is also pursuing additional funding through one or more possible new partnerships, collaborative or strategic alliances; or from the use of the equity line (PACEO) signed with Kepler Cheuvreux, financing from institutional or strategic investors, from the capital markets, or a combination of the above. However, the Company cannot guarantee if or when any such transactions will occur or whether they will be on satisfactory terms.

While the Company has taken and will continue to take actions to obtain new funding and manage costs through operating expense reduction plans, as necessary, the above factors indicate substantial risk about the Company’s ability to continue as a going concern as there is no assurance that the Company will be successful in satisfying its future cash needs.

Subsequently, the Executive Board determined it is appropriate to prepare consolidated financial statements as of and for the period ended December 31, 2022, applying a going concern basis, assuming the Company will continue to operate for the foreseeable future. The supervisory board of the Company has reviewed and closed the FY 2022 on April 24, 2023.

Availability of the Full Year 2022 Financial Reports

The URD and 20-F are available on the Nanobiotix website at <https://ir.nanobiotix.com/financial-information/annual-reports>. In addition, the URD is available on the AMF website (www.amf-france.org) and the 20-F is available on the SEC website (www.sec.gov).

The Company’s 2022 URD includes its:

- 2022 annual financial report including the report on corporate governance
- Reports from the Company’s statutory auditors and information on their fees
- Required information in relation to the Company’s share buyback program

Conference Call and Webcast

Nanobiotix will host a conference call and live audio webcast on Tuesday, April 25, 2023, at 8:00 AM EDT / 2:00 PM CEST, 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 year-end results and 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. 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.

NBTXR3 is being evaluated in locally advanced head and neck squamous cell carcinoma (HNSCC) as the primary development pathway. The company-sponsored Phase 1 dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy; and a Phase 3 global registrational study was launched in 2021. 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.

Nanobiotix has also prioritized an Immuno-Oncology development program—beginning with a Company-sponsored Phase 1 clinical study evaluating NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors for patients with locoregional recurrent or recurrent/metastatic HNSCC, or lung or liver metastases from any primary cancer eligible for anti-PD-1 therapy.

Given the Company's focus areas, and balanced against the scalable potential of NBTXR3, Nanobiotix has engaged in a strategic collaboration strategy with world class partners 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 to evaluate NBTXR3 across tumor types and therapeutic combinations.

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. 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," "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. 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 EIB may accelerate the loans under finance contract and its amendment upon the occurrence of customary events of default; the risk that 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.

Contacts

Nanobiotix

Communications Department

Brandon Owens
VP, Communications
+1 (617) 852-4835
contact@nanobiotix.com

Investor Relations Department

Craig West
SVP, Investor Relations
+1 (617) 583-0211
investors@nanobiotix.com

Media Relations

Statements of consolidated operations
(Amounts in thousands of euros, except per share numbers)

	For the year ended December 31,	
	2022	2021
Revenues and other income		
Revenues	—	10
Other income	4,776	2,637
Total revenues and other income	4,776	2,647
Research and development expenses	(32,636)	(30,378)
Selling, general and administrative expenses	(17,857)	(19,434)
Other operating and income expenses	(985)	(5,414)
Total operating expenses	(51,478)	(55,226)
Operating income (loss)	(46,702)	(52,579)
Financial income	3,533	6,360
Financial expenses	(13,863)	(780)
Financial income (loss)	(10,329)	5,580
Income tax	(10)	(5)
Net loss for the period	(57,041)	(47,003)
Basic loss per share (euros/share)	(1.64)	(1.35)
Diluted loss per share (euros/share)	(1.64)	(1.35)

Statements of consolidated financial position
(Amounts in thousands of euros, except per share numbers)

	As of December 31,	
	2022	2021
Total non-current assets	7,412	8,709
Cash and cash equivalents	41,388	83,921
Total current assets	52,358	93,060
TOTAL ASSETS	59,769	101,769
Net loss for the period	(57,041)	(47,003)
Total shareholders' equity	(27,045)	26,790
Total non-current liabilities	48,878	38,134
Total current liabilities	37,936	36,845
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	59,769	101,769

Attachment

- [2023-04-24 -- NBTX -- FY22 Financial Results -- FINAL -- English](#)