NANOBIOTIX Provides Business Update and Reports Full Year 2023 Financial Results

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- Global licensing, co-development, and commercialization agreement with Janssen Pharmaceutica NV ("Janssen") expands worldwide potential of novel radioenhancer NBTXR3
- Prolonged survival in Study 102 reinforces pivotal NANORAY-312 trial design in head and neck cancer; initial efficacy and favorable safety profile supports potential of NBTXR3 in pancreatic cancer; determined RP2D for MD Anderson lung study
- Multiple clinical readouts expected in 2024 including immunotherapy combination data from Study 1100, and data from MD Anderson program
- €75.3 million in cash and cash equivalents as of December 31, 2023 with cash runway into Q3 2025 including the $20 million first development milestone due from Janssen
- 2023 Universal Registration Document filed with the French financial market authority and the 2023 Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission

Conference call and webcast scheduled for April 25, 2024 at 8:00 A.M. EDT / 2:00 P.M. CEST

PARIS and CAMBRIDGE, Mass., April 24, 2024 (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, 2023, and announced the filing of its universal registration document (URD) for the financial year ended December 31, 2023 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, 2023 with the U.S. Securities and Exchange Commission (SEC).

"2023 was an incredible year of progress for Nanobiotix and our NBTXR3 program. This past summer, we entered into a global licensing, co-development and commercialization agreement with Janssen Pharmaceutica NV, a Johnson & Johnson company, to expand NBTXR3, a potential first-in-class radioenhancer with universal application across solid tumors. NBTXR3 is designed to amplify anti-tumor activity and minimize healthy tissue exposure by directly acting inside the tumor. We continue to see compelling data generated in hundreds of patients to date and across eight different tumor types supporting a well-tolerated safety profile and robust efficacy," said Laurent Levy, co-founder of Nanobiotix and chairman of the executive board. "During 2023, we reported prolonged survival from Study 102 in head and neck cancer further reinforcing the design of our ongoing pivotal NANORAY-312 trial. In 2024, we expect immunotherapy combination data from our Study 1100 trial in head and neck cancer, as well as chemotherapy combination data in esophageal cancer from our MD Anderson collaboration."

"Since June, we have secured $114 million in gross funding, which includes an equity offering, an investment from Johnson & Johnson Innovation, - JJDC, Inc. ("JJDC"), and a NANORAY-312 operational milestone. With our balance sheet strengthened, cash runway extended, the EIB cash covenant removed, and financial overhang addressed, we are strongly positioned to further advance and maximize the therapeutic potential of NBTXR3 within the solid tumor treatment landscape," said Bart Van Rhijn, chief financial officer of Nanobiotix.

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

- Entered into a global exclusive licensing, co-development, and commercialization agreement with Janssen, for the investigational, potential first-in-class radioenhancer NBTXR3 (announced July 10, 2023)
  - The Company has secured:
    - $30 million upfront cash licensing fee
    - $5 million first equity tranche received post signing
    - $25 million second equity tranche (final payment received December 2023)
    - $20 million for NANORAY-312 operational milestone (due to be received May 2024)
  - The Company remains eligible to receive:

        - 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 $1.8 billion 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
- Raised a total of $64 million gross in a recent equity sale (inclusive of first and second equity tranches totaling $30 million from JJDC)
- LianBio's NBTXR3 rights in Asian markets transferred to Janssen including all rights and responsibilities and the potential for Nanobiotix to receive up to a remaining $205 million in milestones
- Strengthened global development capabilities with the appointment of industry veteran Louis Kayitalire, MD as Chief Medical Officer (CMO). Dr. Kayitalire brings proven success in the research, development, registration, and commercialization of therapeutics in oncology (September 5, 2023)

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 progression free survival (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
    - Successfully completed study and presented topline safety and efficacy data 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% overall response rate (ORR) in injected-lesion in 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
    - Additional signs of efficacy in an exploratory analysis presented at the 2023 Annual Congress of the European Society for Medical Oncology (ESMO) further support underlying hypotheses for the ongoing registrational Phase 3 NANORAY-312 study design
        - 42.8 months median overall survival (OS) observed in the 82% 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

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:

- **Pancreatic Cancer**: Phase 1b study (NCT04484909) of RT-activated NBTXR3 after cytotoxic chemotherapy for patients with locally advanced pancreatic cancer (LAPC)
    - Feasibility and promising, durable anti-tumor efficacy of RT-activated NBTXR3 supported by 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
        - 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 1b 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
- **Four ongoing studies in:** Advanced solid tumors with lung or liver metastases, recurrent or metastatic head and neck cancer, inoperable non-small cell lung cancer (NSCLC), and esophageal cancer.

- **Multiple clinical milestones in 2024:**
    - Initial Phase 1b/2 data in esophageal cancer
    - Completion of enrollment in Phase 1b dose expansion trial in pancreatic cancer

Full Year 2023 Financial Results

Revenue and Other Income: Revenues of €30.1 million was recognized in 2023. No revenue was recognized for the year ended December 31, 2022. Total other income increased significantly to €6.2 million for the year ended December 31, 2023, compared to €4.8 million for the year ended December 31, 2022, respectively, mainly due to supply and services recharge in the framework of the clinical supply with LianBio.

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 €38.4 million for the twelve-month period ended December 31, 2023, as compared to €32.6 million for the twelve months ended December 31, 2022. The increase in net R&D expenses was primarily due to increases in development costs related to the Company's priority development pathways, including continuation of its pivotal Phase 3 registration study, NANORAY-312 and its ongoing immunotherapy combination Study 1100.

Selling, General and Administrative ("SG&A") Expenses : SG&A expenses increased by €4.2 million, or 23%, from €17.9 million for the year ended December 31, 2022, to €22.0 million for the year ended December 31, 2023. This year-over-year increase reflects growth in employee costs, and non-recurring activities including equity issuance legal costs and license agreement execution related services fees.

Net loss: Net loss attributable to shareholders was €39.7 million, a year over year reduction of 30%, or €1.08 per share, for the twelve-month period ended December 31, 2023. This compares to a net loss of €57.0 million, or €1.64 per share for the year ended December 31, 2022.

Cash and Cash Equivalents: As of December 31, 2023, Nanobiotix had €75.3 million in cash and cash equivalents, compared to €41.4 million as of December 31, 2022.

Financial Guidance: Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €75.3 million as of December 31, 2023 will fund its operations into the third quarter of 2025 including the $20 million development milestone mentioned above.

The supervisory board of the Company has reviewed the financial statements 2023 on April 19, 2024 and the Company's statutory auditors has finalized their audit and issued on April 24, 2024 a clean opinion on both statutory and consolidated financial statements 2023.

Availability of the Full Year 2023 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 2023 URD includes its:

- 2023 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 Thursday, April 25, 2024, 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): 1-888-886-7786

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 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 2023, Nanobiotix announced a license agreement for the global co-development and commercialization of NBTXR3 with Janssen Pharmaceutica NV.

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 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 25 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.

For more information about Nanobiotix, visit us at www.nanobiotix.com or follow us on LinkedIn and Twitter.

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 use of proceed therefrom, and the period of time through which the Company's anticipates its financial resources will be adequate to support operations. 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 risks related to Nanobiotix's business and financial performance, which include the risk that assumptions underlying the Company's cash runway projections are not realized. 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, 2024 under "Item 3.D. Risk Factors", in Nanobiotix's 2023 universal registration document filed with the AMF on April 24, 2024 and subsequent filings Nanobiotix makes with 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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Statements of consolidated operations

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

	For the year ended December 31,	
	2023	**2022**
Revenues and other income		
Revenues	30,058	—
Other income	6,150	4,776
Total revenues and other income	**36,207**	**4,776**
Research and development expenses	(38,396)	(32,636)
Selling, general and administrative expenses	(22,049)	(17,857)
Other operating and income expenses	(2,542)	(985)
Total operating expenses	**(62,986)**	**(51,478)**
Operating income (loss)	**(26,779)**	**(46,702)**
Financial income	2,002	3,533
Financial expenses	(14,803)	(13,863)
Financial income (loss)	**(12,801)**	**(10,329)**
Income tax	(120)	(10)
Net loss for the period	**(39,700)**	**(57,041)**
Basic loss per share (euros/share)	**(1.08)**	**(1.64)**
Diluted loss per share (euros/share)	**(1.08)**	**(1.64)**

Statements of consolidated financial position

(Amounts in thousands of euros)

	As of December 31,	
	2023	**2022**
Total non-current assets	**6,558**	**7,412**
Cash and cash equivalents	75,283	41,388
Total current assets	**87,339**	**52,358**
TOTAL ASSETS	**93,897**	**59,769**
Net loss for the period	(39,700)	(57,041)
Total shareholders' equity	**(1,843)**	**(27,045)**
Total non-current liabilities	**45,866**	**48,878**
Total current liabilities	**49,873**	**37,936**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	**93,897**	**59,769**

Attachment

- 20240424-NBTX-PR-FY2023_Financial_Results-EN.html