UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of October 2023

Commission File Number: **001-39777**

Nanobiotix S.A.
(Translation of registrant's name into English)

60 Rue de Wattignies 75012 Paris, France
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F [X] Form 40-F [ ]

On October 4, 2023, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

(c) Exhibit 99.1. Press release dated October 4, 2023

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Nanobiotix S.A.
(Registrant)

Date: October 4, 2023

/s/ Bart Van Rhijn
Bart Van Rhijn
Chief Financial Officer

EXHIBIT 99.1

Nanobiotix Announces the Presentation of the Final Efficacy Analysis From Phase 1 Cohort Expansion Evaluating NBTXR3 in Locally Advanced Head and Neck Cancer Showing Median Progression-Free Survival of 16.9 Months and Median Overall Survival of 23.1 Months

Results presented in an oral presentation by Professor Christophe Le Tourneau, MD, PhD, of Institut Curie, and highlighted in two scientific sessions at the 65th Annual Meeting of the American Society for Radiation Oncology

- Final data from Study 102 Dose Expansion show that radiotherapy-activated NBTXR3 was feasible and well tolerated in elderly patients with a high burden of comorbidity (n=56)
- Consistently high injected-lesion overall response rate of 81.8% and complete response rate of 63.6% in the evaluable population (n=44)
- Median duration of response in the NBTXR3-injected lesion was not reached, suggesting durable anti-tumor efficacy
- Median Progression Free of 16.9 months in the evaluable population per independent review committee at the final readout
- Median Overall Survival was 23.1 months in the evaluable population at the final readout
- Compared with historical data in a similar population showing mPFS of 9 months and mOS of 12 months, these results potentially strengthen the hypothesis and clarify next steps for the ongoing global, registrational Phase 3 study evaluating NBTXR3 for elderly patients with locally advanced head and neck cancer (NANORAY-312)
- Nanobiotix will host a conference call to discuss the data and take questions from participants on Thursday, October 5, 2023

Paris and CAMBRIDGE, Mass., Oct. 04, 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 announced the final readout on primary endpoints from Study 102 Dose Expansion—the expansion part of a Phase 1 dose escalation and dose expansion study evaluating potential first-in-class radioenhancer NBTXR3 for patients with locally advanced head and neck cancer (Study 102). The results were presented by Principal Investigator Professor Christophe Le Tourneau in an oral presentation at the 65th Annual Meeting of the American Society for Radiation Oncology (ASTRO). Additionally, the abstract was selected for inclusion in a scientific highlight session on head and neck cancer and the final results were selected for discussion in a scientific discussion on augmenting the potential of radiation therapy (RT) with novel therapeutics and imaging.

This oral presentation at ASTRO will be followed by a conference call on Thursday, October 5, 2023, at 8:00 AM EDT / 2:00 PM CEST. During the call, Laurent Levy, chief executive officer, will review the Study 102 final data before taking questions from participants.

Study Background

Surgery or definitive cisplatin-based chemotherapy are the current standard of care for patients with locally advanced head and neck squamous cell carcinoma (LA-HNSCC; head and neck cancer). One third of these patients, however, cannot tolerate cisplatin due to complications such as age-related frailty or other medical conditions (comorbidities). Combined with the fact that 20-30% of patients with LA-HNSCC have a high burden of comorbidity[1], and 30% of patients with LA-HNSCC are over the age of 70, this patient population presents a significant unmet need for new therapies that offer tolerable safety and the potential for improved local control.

"The hypothesis we sought to evaluate in Study 102 was that novel radioenhancer NBTXR3—as a single intratumoral injection procedure, that does not interact directly with other drugs, and could potentially improve locoregional control of the primary tumor without adding harmful side effects for elderly patients with head and neck cancer—may provide a promising new therapeutic option," said Professor Christophe Le Tourneau, MD, principal investigator for Study 102. *"The favorable safety profile we have seen throughout the study, along with what we believe is meaningful efficacy, reinforce my confidence in the potential of NBTXR3 for these patients."*

ABSTRACT #55360: Novel Radioenhancer NBTXR3 Activated by Radiotherapy in Cisplatin-ineligible Locally Advanced HNSCC Patients: Final Results of a Phase 1 Trial
Christophe Le Tourneau, Zoltán Takacsi-Nagy, Laetitia Finzi, Xavier Liem, Valentin Calugaru, Victor Moreno, Emiliano Calvo, Sébastien Salas, Bernard Doger, Antoine Dubray-Vautrin, Xavier Mirabel, Nathalie Badois, Anne Chilles, Nicolas Fakhry, Stéphanie Wong Hee Kam, Laetitia Houdas, Anais Debard, Omar I. Vivar, Leonard A. Farber, Maria Lesnik

Study Design

Study 102 was designed as a multicenter Phase 1 study with a dose escalation part followed by a cohort expansion to further test the recommended phase II dose. The escalation part achieved its primary objective, establishing a tolerable safety profile without dose-limiting toxicities and a recommended phase 2 dose (RP2D) at 22% of tumor volume. The completed cohort expansion recruited a total of 56 patients across 20 sites in 4 European countries. In each patient, the primary tumor was injected with NBTXR3, while involved lymph nodes were not injected. The NBTXR3-injected lesion and the non-injected lesion were treated with the same dose of intensity-modulated radiation therapy (IMRT).

The patient population entered the study with negative prognostic factors such as advanced age, and a high burden of comorbidity as measured by the age-adjusted Charlson Comorbidity Index (ACCI ≥ 4)[2]. 61% of patients in the study were aged ≥ 70 years and 67% had ACCI ³ 4. The median duration of follow up was 18.2 months.

Safety

All 56 patients treated received at least 90% of the planned injected volume of NBTXR3 and 91% completed IMRT. 5 patients discontinued IMRT due to treatment-emergent adverse events (TEAEs), of which one TEAE (sepsis) was possibly related to RT and NBTXR3. 10 deaths occurred within 180 days of enrollment, of which 1 death (sepsis) was possibly related to RT and NBTXR3. 80% of these patients (8/10) entered the study with a high burden of comorbidity (ACCI ³ 4). The study concluded that injection of NBTXR3 followed by RT activation was feasible and well tolerated in elderly patients with LA-HNSCC.

Efficacy

The evaluable population in the study included 44 patients. Response was measured in the NBTXR3-injected lesion alone (injected lesion) as per RECIST 1.1, and in the NBTXR3-injected and non-injected lesions together (all lesions). In the injected lesions, data showed an overall response rate (ORR) of 81.8% (36/44) with a complete response rate (CRR) of 63.6% (28/44). In all lesions, data showed an overall response rate of 79.5% (23/44) with a complete response rate of 52.3% (23/44). At the final readout, an independent review committee determined a median Progression-Free Survival (mPFS) of 16.9 months in evaluable patients. Median Overall Survival (mOS) in evaluable patients was 23.1 months. Historical data in a similar population show an expected mPFS of 9 months and mOS of 12 months[3]. Importantly, the median duration of response in NBTXR3-injected lesions was not reached by the end of the study, compared to a median duration of response of 12.4 months in all lesions, suggesting durable antitumor activity from RT-activated NBTXR3.

Next Steps for Nanobiotix Head and Neck Pathway

To date, the Company has provided timing expectations for NANORAY-312 informed by initial hypotheses within the study protocol, including recruitment rate projections and an expected "Time-to-Event" (e.g., tumor progression, death, etc.) for patients based on historical data in a similar population (i.e., 9-month mPFS and 12-month mOS).

After observation of a potentially significant extension in mPFS and mOS versus historical data in the final efficacy analysis of Study 102, and in view of experience with global recruitment ramp up since the beginning of site activation for NANORAY-312, Nanobiotix is adjusting guidance for the NANORAY-312 futility analysis to 2H2024. The Company expects NANORAY-312 to record the appropriate number events for the interim readout in 1H2025, and to deliver the interim efficacy analysis mid-2025.

"Underlying the NBTXR3 global development program is the belief that the universal, physics-based mechanism of our potential first-in-class radioenhancer could significantly increase the dose of radiotherapy within the injected tumor without increasing harmful side effects for patients with cancer," said Louis Kayitalire, MD, chief medical officer at Nanobiotix. *"In my view, the results from Study 102 could represent a significant step toward validating this hypothesis and addressing the unmet needs of patients with head and neck cancer. The signals of safety and efficacy we observed in Study 102, combined with the learnings we have applied in the design of our pivotal Phase 3 study in a similar population, add to my conviction that NBTXR3 has the potential to revolutionize treatment for millions of patients with cancer around the world."*

Conference Call Details

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. 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 2021, the Company announced an agreement with LianBio to expand development of NBTXR3 into Greater China and other Asian Markets, and in July 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 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 been granted with a CE marking 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 "additional", "aim", "continue", "could", "drive", "enable", "expect", "further", "look forward", "may", "ongoing", "potential", "promise", "realize", "subject to", "success-based", "up to", "will", and "would" or the negative of these and similar expressions. These forward-looking statements, which are based on the management's current expectations and assumptions and on information currently available to management, include statements about the overall development of NBTXR3, including the timing and progress of clinical trials including uncertainties as to the timing of NANORAY-312 interim analysis; the extent to which the results from the clinical trial, including the study discussed in this press release, may be replicated in other studies and/or lead to advancement of product candidates to regulatory approval; the development of NBTXR3 pursuant to the license agreement with Janssen (the "Agreement") and the potential payments for which Nanobiotix is eligible under the Agreement; ; and the financial position of Nanobiotix. 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; the risks arising from Nanobiotix's reliance on Janssen to conduct development and commercialization activities with respect to NBTXR3, including the potential for disagreements or disputes under the Agreement; the risk that Janssen may exercise its discretion in a manner that limits the resources contributed toward the development of NBTXR3 under the Agreement or may exercise its faculty to terminate without cause the Agreement; the risk that subsequent studies and ongoing or future clinical trials may not generate favorable data; and 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" 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 and those set forth in the half-year report filed with SEC on form 6-K and with AMF on September 26, 2023 (copies of which are 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

FR – **Ulysse Communication**
Pierre-Louis Germain
+ 33 (0) 6 64 79 97 51
plgermain@ulysse-communication.com

Global – **LifeSci Advisors**
Ligia Vela-Reid
+44 (0) 7413825310
Lvela-reid@lifesciadvisors.com

[1] *Zumsteg et al. Cancer vol. 123,8 (2017);*

[2] *Göllnitz, Irene et al. Cancer Medicine vol. 5,11 (2016)*

[3] *Moye et al., Oncologist. 2015;20(2):159-165*

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/6715743d-b4f9-496b-bc5f-d0d6a7b58b9e

Attachments

- 2023-10-04 -- NBTX -- Final Efficacy Readout on Primary Endpoints from Study 102 Dose Expansion -- FINAL.pdf (https://ml.globenewswire.com/Resource/Download/3814c404-2143-41e5-8c25-509abb7d9fd9)