# 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**
**of the Securities Exchange Act of 1934**

**Date of Report: 10/24/2021**

**Commission File Number: 001-39777**

## Nanobiotix S.A.
**(Exact Name of Registrant as Specified in its Charter)**

**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 ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

## EXHIBIT INDEX

| Exhibit | Title |
| --- | --- |
| 99.1 | Press Release, dated October 24, 2021 |

**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.

**PORTER NOVELLI**
(Agency)

By: /s/ Emily Papp

Emily Papp
Senior Account Executive

**NANOBIOTIX S.A.**
(Registrant)

By: /s/ Bart Van Rhijn

Bart Van Rhijn
Chief Financial Officer

# NANOBIOTIX Announces 18.1 Month Median Overall Survival for 41 Evaluable Elderly and Frail Patients With HNSCC in Phase I Expansion Evaluating Nbtxr3 as a Single Agent Activated by Radiotherapy

**Data presented by Professor Christophe Le Tourneau at the 2021 Annual Meeting of the American Society for Radiation Oncology**

- **First survival data from Phase I Dose Expansion in tough-to-treat elderly and frail LA-HNSCC patients ineligible for cisplatin and intolerant to cetuximab:**
  - **Median Overall Survival of 18.1 months in evaluable patients (n=41) and median Progression Free Survival of 10.6 months**
  - **Best observed target lesion objective response rate of 85.4% and best observed target lesion complete response rate of 63.4%[1]**
  - **NBTXR3 administration was feasible and well tolerated in population with significant burden of disease and comorbidity**
- **Phase I dose expansion data support and inform the design of upcoming phase III global registration trial in a larger HNSCC population with lower comorbidities overall**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--October 24, 2021--Regulatory News:

NANOBIOTIX (Euronext: NANO – NASDAQ: NBTX – the ‘‘**Company**’’)**,** a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, today announced first ever survival data from its priority head and neck cancer development program at the 2021 Annual Meeting of the American Society for Radiation Oncology (ASTRO).

*As specified by the ASTRO Annual Meeting embargo policy, “information beyond what is included in the abstract, such as updated or additional results, is embargoed until the date and time of scientific presentation or presentation at an ASTRO news briefing, whichever occurs first.” However, Nanobiotix has become aware that ASTRO made a late decision to release the posters at the same time as the abstracts and did not sufficiently update the embargo policy. As a result, the Company is releasing this data in advance of its intended embargo date.*

**New Data from Locally Advanced Head and Neck Squamous Cell Carcinoma (LA-HNSCC) Program**

Data show a median Overall Survival (mOS) of 18.1 months and a median Progression Free survival of (mPFS) of 10.6 months in the evaluable population (n=41) from the dose expansion part of its phase I, multicenter, open-label, non-randomized dose escalation and dose expansion study evaluating NBTXR3 as a single-agent activated by radiotherapy in tough-to-treat elderly and frail LA-HNSCC patients ineligible for cisplatin and intolerant to cetuximab (Study 102 Expansion). In the full population (all evaluable and non-evaluable patients treated; n=54), data showed a 14.1-month mOS and a 9.4-month mPFS. The data suggest that lower mOS and mPFS observed in the full population versus the evaluable population in the study could be related to early death associated with high burden of comorbidity in the non-evaluable population.

Evaluability in Study 102 Expansion was determined based on the patient receiving at least 80% of the intended intratumoral dose of NBTXR3, at least 60 Gy of radiotherapy, and the required imaging to assess the target lesion at baseline and at least once post treatment.

Response rates remained consistent with previously reported results from the dose escalation and dose expansion study, showing a best observed target lesion objective response rate (ORR) of 85.4% and a best observed target lesion complete response rate (CRR) of 63.4%[2].

“I have held the belief that NBTXR3 could have a real impact for patients with solid tumors since reviewing the proof-of-concept data from the phase II/III in soft tissue sarcoma and throughout my participation in Study 102 Expansion,” said study principal investigator Professor Christophe Le Tourneau, senior medical oncologist and head of the Department of Drug Development and Innovation (D3i) at Institut Curie. “This first look at survival data has added to my confidence that NBTXR3 could provide a promising new therapeutic option for the practice. I look forward to leading the upcoming phase III global registration study, and to have the opportunity to evaluate the promise of this innovation in a larger patient population.”

Of the 21 evaluable patients with a best observed overall response of complete response (CR) with a mean follow-up of 16.1 months, 6 patients died for non-oncologic reasons and only one died from disease progression.

NBTXR3 administration was feasible and well-tolerated overall. A total of 8 Grade 3-4 NBTXR3-related adverse events (AEs) were observed in 8 patients, representing 1.3% of all observed AEs. Of these AEs related to NBTXR3, 5 serious adverse events (SAEs) were observed including dysphagia, sepsis, soft tissue necrosis, stomatitis, and tumor hemorrhage. Of the SAEs, one death from sepsis assessed by the investigator as possibly related to NBTXR3, radiotherapy, and cancer was observed.

While the incidence of LA-HNSCC has continued to rise, patients in the elderly and frail LA-HNSCC population have significant unmet needs. Many are not eligible to receive concurrent chemoradiation due to frailty associated with comorbidities. The modified Charlson Comorbidity Index (mCCI) is a measure of comorbidity burden on a patient-by-patient basis, and high mCCI (i.e., mCCI ≥ 4) is correlated with higher risk of death relative to the broader population. In this study, 63% of all patients treated had high mCCI, which is two to three times the prevalence of comorbidity in the overall LA-HNSCC population[3].

Despite the prevalence of high mCCI in Study 102 Expansion, these preliminary data support further evaluation of NBTXR3 activated by radiotherapy as a therapeutic option that may translate to a survival benefit for elderly and frail LA-HNSCC patients. The data also suggest that the potential benefits of the therapy could improve in a population with a lower burden of comorbidity.

“Bringing innovation to the patients that need it most has always been the backbone of our development strategy for NBTXR3,” said Laurent Levy, co-founder and chief executive officer of Nanobiotix. “We started with soft tissue sarcoma—a disease indication notoriously resistant to radiotherapy. After proving we could provide a therapeutic benefit versus radiotherapy alone for patients with locally advanced disease and achieving European market approval, we pivoted to patients with locally advanced head and neck cancer that have substantially limited treatment options. The new survival data we are seeing from Study 102 Expansion bolster our confidence in the promise of NBTXR3 as we near the launch of our pivotal phase III study in head and neck cancer. We have designed this study with the benefit of our learnings from the phase I and look forward to the opportunity to prove that our product candidate can expand treatment possibilities for patients with cancer around the world.”

***

**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 I dose escalation and dose expansion study has produced favorable safety data and early signs of efficacy; and the launch of a phase III global registrational study is planned. 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 planned phase III study.

Nanobiotix has also prioritized an Immuno-Oncology development program—beginning with a Company sponsored phase I clinical study evaluating NBTXR3 activated by radiotherapy in combination with anti-PD-1 checkpoint inhibitors for patients with locoregional recurrent or recurrent/metastatic HNSCC and 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 I and phase II studies to evaluate NBTXR3 across tumor types and therapeutic combinations.

**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. The company also has subsidiaries in Cambridge, Massachusetts (United States), France, Spain, and Germany. Nanobiotix has been listed on the regulated market of Euronext in Paris since 2012 and on the Nasdaq Global Select Market in New York City since December 2020. Nanobiotix is the owner of more than 30 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. Furthermore, many other important factors, including those described in our Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (the SEC) on April 7, 2021 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 7, 2021, each as updated in our Half-Year Financial Report filed with the AMF and the SEC on September 8, 2021 (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] Calculations include one patient marked ** in Figure 1 assessed as Complete Response by principal investigator per eCRF

[2] Calculations include one patient marked ** in Figure 1 assessed as Complete Response by principal investigator per eCRF

[3] Zumsteg ZS, et al., Cancer 2017;123:1345-53

## Contacts

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

**Investor Relations Department**
*Kate McNeil*
*SVP, Investor Relations*
+1 (609) 678-7388
investors@nanobiotix.com

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

**US – Porter Novelli**
Dan Childs
+1 (781) 888-5106
Dan.childs@porternovelli.com