# 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: April 28, 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 April 28, 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.

NANOBIOTIX S.A.

(Registrant)

April 28, 2021 By: /s/ Philippe Mauberna

Philippe Mauberna Chief Financial Officer



## PRESS RELEASE

## NANOBIOTIX TO PRESENT FOUR POSTERS INCLUDING UPDATES FROM PRIORITY HEAD AND NECK CANCER AND IMMUNOTHERAPY DEVELOPMENT PATHWAYS AT THE 2021 ANNUAL MEETING OF THE AMERICAN SOCIETY FOR CLINICAL ONCOLOGY

- New data with additional patients and further follow up from study Study 1100, evaluating lead product candidate NBTXR3 in combination with anti-PD-1 in head and neck cancer, lung metastasis and/or liver metastasis
- New data with additional patients and further follow up on safety and response rate from Study 102 dose expansion, evaluating NBTXR3 as a single agent activated by radiotherapy in head and neck cancer
- Long term safety data from complete European phase II/III registration study, Act.In.Sarc, evaluating NBTXR3 as a single agent activated by radiotherapy in soft tissue sarcoma
- "From bench-to-bedside" compilation data encompassing the journey of NBTXR3 from preclinical investigation to clinical evaluation of NBTXR3 as a potentially tumor-agnostic radioenhancer that could prime adaptive immune response for both local and systemic control
- Following the ASCO, Nanobiotix will host an investor event on Friday June, 11 at 8am EST, to review immunotherapy results from Study 1100 with several key opinion leaders

**Paris, France ; Cambridge, Massachusetts (USA) ; April 28, 2021** - <u>NANOBIOTIX</u> (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 that new data from its oncology pipeline will be presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting from June 4-8. Four (4) abstracts have been accepted showcasing lead oncology product candidate, potential first-in-class radioenhancer NBTXR3, across tumor types and in combination with anti-PD-1.

"We look forward to sharing our development progress, particularly from our priority pathways in immunotherapy and head and neck cancer," said Laurent Levy, co-founder and chief executive officer of Nanobiotix. "The data that will be presented at this year's ASCO continue to highlight the potential of NBTXR3 to provide a practice-changing improvement in treatment outcomes for patients with cancer."

The data to be presented in four posters include:

## **Priming Immune Response plus Immunotherapy Combination**

• Abstract #2590: Updated analysis with additional patients and further follow up from Study 1100, a phase I basket study evaluating NBTXR3 activated by radiotherapy in combination with nivolumab or pembrolizumab in locoregional recurrent or recurrent metastatic head and neck squamous cell carcinoma (HNSCC), lung metastasis from any primary tumor and/or liver metastasis from any primary tumor.

### Local Control as a Single-Agent for Patients with Head and Neck Cancer

• Abstract #6051: Updated analysis with additional patients and further follow up from Study 102, a phase I study evaluating NBTXR3 as a single agent activated by radiotherapy in locally advanced HNSCC. Nanobiotix is planning the launch of a global phase III pivotal trial in this indication in 2021 and has received Fast Track designation from the U.S. Food and Drug Administration for the patient population in the phase III study.

## **Local Control as a Single-Agent for Patients with Soft Tissue Sarcoma**

• Abstract #11544: Long-term safety analysis of NBTXR3 from Act.in.Sarc, a European phase II/III registration study evaluating NBTXR3 as a single agent activated by radiotherapy in locally advanced soft tissue sarcoma. NBTXR3 has received a CE marking for this indication under the brand name Hensify®.

## <u>Tumor-Agnostic, Therapeutic Combination-Agnostic Development Potential</u>

Abstract #2591: An analysis of compiled data encompassing the journey of NBTXR3 from preclinical investigation to clinical evaluation as a
potential first-in-class radioenhancer that could improve local control across solid tumor indications, prime adaptive immune response and
combine with immunotherapy.



### **Nanobiotix Investor Event**

Nanobiotix will host a virtual investor event featuring several key opinion leaders after the ASCO Annual Meeting on Friday June 11 at 8am EST. The discussion will focus on the new immunotherapy results from Study 1100. Details will be provided closer to the event at <a href="https://www.nanobiotix.com/">www.nanobiotix.com/</a>.

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### **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 primarily in locally advanced head and neck squamous cell carcinoma (HNSCC). The company-sponsored phase I dose escalation and dose expansion study has produced consistently favorable safety data and early signs of efficacy; and a phase III global registration is planned to launch in 2021. In February 2020, the United States Food and Drug Administration granted the 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.

Nanobiotix has also prioritized a company-sponsored Immuno-Oncology development program—a 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 collaboration strategy with world class partners to expand development of NBTXR3 in parallel with its priority development pathways. Pursuant to this strategy, in 2019 The University of Texas MD Anderson Cancer Center engaged in a broad, comprehensive clinical research collaboration with Nanobiotix 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 and Cambridge, Massachusetts (United States). The company also has subsidiaries in France, Spain, and Germany. Nanobiotix has been listed on Euronext: Paris since 2012 and completed a successful initial public offering (IPO) on the Nasdaq Global Select Market in New York City in December 2020. The company is one of only 7 dual-listed biotech companies with headquarters in France.

Nanobiotix is the owner of more than 30 umbrella patents associated with three (3) nanotechnology platforms: 1) applied to oncology; 2) applied to bioavailability and biodistribution; and 3) applied to disorders of the central nervous system. The lion's share of the company's resources are devoted to the development of its lead product candidate—NBTXR3—which was born from 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 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 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 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) on April 7, 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.

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