# 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: 10/20/2021** 

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  $\boxtimes$  Form 40-F  $\square$ 

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

<u>99.1</u> <u>Press Release, dated October 20, 2021</u>

#### 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: <u>/s/ Emily Papp</u>

Emily Papp Senior Account Executive NANOBIOTIX S.A. (Registrant)

By: <u>/s/ Bart Van Rhijn</u>

Bart Van Rhijn Chief Financial Officer

### NANOBIOTIX Provides Third Quarter Operational and Financial Update

- Published preclinical data in Red Journal supporting the hypothesis that NBTXR3 activated by radiotherapy in combination with anti-PD-1 could effectively control primary and metastatic tumors, evoke abscopal effect, and reduce the possibility of developing distant lung metastases
- Scheduled to present first survival data from priority head and neck cancer program at the 2021 Annual Meeting of the American Society for Radiation Oncology (ASTRO)
- On-track to activate first clinical trial sites in pivotal phase III global registration study, NANORAY-312, in locally advanced head and neck squamous cell carcinoma (LA-HNSCC) in the coming weeks
- Reported €89.8 million in cash, cash equivalents, and short-term investments as of September 30, 2021

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--October 20, 2021--Regulatory News:

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 operational progress and cash position (unaudited) for the third quarter of 2021.

#### Third Quarter Financial Updates

Nanobiotix reported cash, cash equivalents, and short-term investments totaling €89.8 million as of September 30, 2021, compared to €119.2M as of December 31, 2020<sup>1</sup>.

#### Third Quarter Operational Highlights and Upcoming Milestones

- Published preclinical findings with The University of Texas MD Anderson Cancer Center (MD Anderson) in the International Journal of Radiation Oncology, Biology, Physics (Red Journal) supporting continued exploration of NBTXR3 as a potential therapeutic option to induce significant tumor cell death, prime immune response, and overcome resistance to anti-PD-1.
  - Study hypothesized that NBTXR3 in combination with radiotherapy and anti-PD-1 could transform irradiated tumors into "self-vaccines" in anti-PD-1-sensitive and anti-PD-1-resistant mouse models
  - Data supported the hypothesis that the triple combination could effectively control primary and metastatic tumors, evoke abscopal effect, and reduce the possibility of developing distant lung metastases
- Presenting two oral presentations and three poster presentations at the 2021 ASTRO Annual Meeting being held October 24-27, 2021, including:
  - First analysis of progression free survival (PFS) and overall survival (OS) from 41 evaluable patients from Study 102 Expansion, a phase I dose expansion study evaluating NBTXR3 as a single agent activated by radiotherapy in LA-HNSCC
  - Updated data including approximately 16 evaluable patients 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 HNSCC, lung metastasis from any primary tumor and/or liver metastasis from any primary tumor
  - Long-term safety data from the phase II/III Act.In.Sarc Trial of NBTXR3 in locally advanced soft tissue sarcoma
  - Preclinical data on NBTXR3 plus anti-PD-1 in lung cancer model

- Preparing to activate first clinical trial sites for NANORAY-312, a pivotal phase III global registration study evaluating NBTXR3 as a single-agent activated by radiotherapy for patients with LA-HNSCC
  - First site activations in Europe expected in the coming weeks with first patient randomized by early 2022.
  - US site activation and enrollment planned for 2022

#### **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 anticancer 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 a phase III global registrational study is planned to launch 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 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<sup>®</sup>.

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, the development and commercialization of NBTXR3, and the execution of the Company's development and commercialization strategy. 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 preclinical or early clinical result 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 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", those set forth in the universal registration document of Nanobiotix filed with the French Financial Markets Authority (Autorité des marchés financiers or "AMF") under number D.21-0272 on April 7, 2021 (a copy of which is available on www.nanobiotix.com), each as updated in the 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.

<sup>1</sup> It being specified that the company did not generate any revenue during the third quarter of 2021, this following the termination of the PharmaEngine partnership.

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