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Documents	2

Documents	
6-K	a52500197.htm
Description	Nanobiotix S.A. 6-K
EX-99.1	a52500197ex991.htm
Description	Exhibit 99.1

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: 9/28/2021

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 September 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.

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 Red Journal Publication of Preclinical Data Showing Radioenhancer NBTXR3 May "Reprogram" the Tumor Microenvironment to Overcome Anti-PD-1 Resistance and Evoke Abscopal Effect

Data Published in the November 2021 Edition of the International Journal of Radiation Oncology, Biology, Physics (Red Journal)

- ***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***

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--September 28, 2021--Regulatory News:

NANOBIOTIX (Euronext : NANO — NASDAQ: NBTX – the ''**Company**''), a late-clinical stage biotechnology company pioneering nanophysics-based approaches to expand treatment possibilities for patients with cancer, today announced the publication of preclinical findings with the University of Texas MD Anderson Cancer Center (MD Anderson) in the *International Journal of Radiation Oncology, Biology, Physics (Red Journal*). These data support the further exploration of potential first-in-class, solid tumor-agnostic, therapeutic combination-agnostic radioenhancer NBTXR3 as a new therapeutic option seeking to induce significant tumor cell death when activated by radiotherapy, prime immune response, and overcome resistance to anti-PD-1.

View the full publication here: https://www.redjournal.org/article/S0360-3016(21)00860-9/fulltext

"Patients across the oncology landscape are in urgent need of innovation that can make a difference," said Laurent Levy, co-founder and chief executive officer of Nanobiotix. *"We are proud to collaborate with MD Anderson as we seek to validate the broadly applicable, local and systemic potential benefits of NBTXR3. The* Red Journal *provides a critical platform for the advancement of radiation oncology, and we believe this publication represents an important contribution to the academic and medical research communities as we seek to expand treatment possibilities for millions of patients with cancer."*

Background

Immune checkpoint inhibitors (ICIs) such as anti-PD-1 have shown tremendous promise for the treatment of some patients with metastatic tumors. Oncologists have hypothesized the possibility of combining ICIs with radiotherapy (RT) to control the irradiated tumor and turn those tumors into a "self-vaccine" that could improve systemic control of distant metastases as well. To date, however, most patients with cancer have shown resistance to anti-PD-1, limiting the effect of this combination.

This preclinical mouse model study conducted in collaboration between MD Anderson and Nanobiotix hypothesized that NBTXR3 could "reprogram" the tumor microenvironment in local and distant tumors, overcoming resistance to anti-PD-1 when activated by radiotherapy (RT) in mouse models of metastatic lung cancer.

Key Findings on the Triple Combination of NBTXR3 plus Radiotherapy plus Anti-PD-1 in the Mouse Model

- NBTXR3 improved tumor treatment in both anti-PD-1 sensitive and resistant models
- NBTXR3 promoted the activities of several antitumor immune pathways
- NBTXR3 increased cell death in irradiated tumor and facilitated immune response in unirradiated tumors
- NBTXR3 delayed the growth of targeted and distant tumors, improved survival rates, and reduced spontaneous metastases

Conclusion

This study supports further exploration of the triple combination of NBTXR3 plus RT plus anti-PD-1 as a new therapeutic option for the treatment of both primary and metastatic lung cancer, and the potential of this combination to achieve the promise of transforming irradiated tumors into "self-vaccines." These results could support significance for the radioenhancer's clinical application, as the strong activation of an effective immune response in anti-PD-1 resistant tumors may expand treatment possibilities for the majority of patients who do not respond to anti-PD-1 therapy.

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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 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 Euronext: 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, 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 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) under number D.21-0272 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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