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Documents	
6-K	a52488245.htm
Description	Nanobiotix S.A. 6-K
EX-99.1	a52488245ex99_1.htm
Description	Exhibit 99.1
GRAPHIC	euronext.jpg
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**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: 9/8/2021

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 8, 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 PROVIDES BUSINESS UPDATE AND REPORTS FINANCIAL RESULTS FOR THE FIRST HALF OF 2021

- Positive data from Study 102 Expansion reported in H1 2021 included an overall objective response rate of 82.5% and a complete response rate of 62.5% in highly vulnerable, elderly patient population, providing continued support for the planned initiation of a pivotal phase III global registration study in locally advanced head and neck squamous cell carcinoma in late Q4 2021
- Following positive data from ongoing Study 1100 presented in H1 2021 showing that NBTXR3 in combination with anti-PD-1 resulted in tumor regression in 76.9% of evaluable patients regardless of prior anti-PD-1 exposure, Nanobiotix intends to initiate discussions with regulatory authorities in H2 2021 regarding the potential registration pathway for this immunotherapy combination
- Reported €102.3 million in cash and cash equivalents as of June 30, 2021

Paris, France; Cambridge, Massachusetts (USA); September 8, 2021 - 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, provided an update on operational progress and announced its half year financial results for the six-month period ended June 30, 2021.

First Half Operational Highlights, Pipeline Status and Upcoming Milestones

Priority Pathway in Head & Neck Cancer, Local Control as Single Agent Activated by Radiotherapy: Leveraging proof-of-concept demonstrated in a successful Phase II/III study and subsequent EU marketing authorization for soft tissue sarcoma, Nanobiotix is currently evaluating NBTXR3 as a single agent activated by radiotherapy in other solid tumor indications with an initial focus on locally advanced head and neck squamous cell carcinoma (LA-HNSCC).

- Updated data from Study 102 Expansion, a phase I dose expansion study evaluating NBTXR3 as a single agent activated by radiotherapy in LA-HNSCC presented at the 2021 Annual Meeting of The American Society for Clinical Oncology (ASCO) continue to support NBTXR3 administration as feasible and well-tolerated in highly vulnerable elderly LA-HNSCC patients with high unmet medical needs and significant burden of disease. At a median follow up of 8.1 months, evaluable patients (n=40) demonstrated a high primary tumor ORR of 82.5% and a 62.5% CRR.¹ These results are consistent with those observed in the dose escalation part of the study and suggest durability of effect.
- Expect to report an analysis of progression free survival (PFS) and overall survival (OS) from 41 evaluable patients in Study 102 at a medical conference during the fourth quarter of 2021.
- Initiation of NANORAY-312, a pivotal phase III global registration study evaluating NBTXR3 as a single-agent activated by radiotherapy for patients with LA-HNSCC expected late in the fourth quarter of 2021.

Priority Pathway in Immunotherapy for Advanced Cancers, Priming Immune Response in Combination with Anti-PD-1 Treatment: Given early data showing anti-cancer immune activity triggered by its physical mechanism of action, Nanobiotix is evaluating the potential for NBTXR3 to improve current approaches to immunotherapy by combining NBTXR3 with anti-PD-1 therapies in advanced cancers to potentially increase the number of patients that respond to treatment and improve outcomes for patients regardless of their prior exposure to immune checkpoint inhibitors.

- Updated data from Study 1100, a phase I basket study evaluating NBTXR3 activated by radiotherapy (RT) 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 showed tumor regression in 76.9% of evaluable patients (n=13) regardless of prior anti-PD-1 exposure. Data from this ongoing study show NBTXR3 plus radiotherapy could potentially stimulate immune response and convert anti-PD-1 non-responders into responders.

¹ These percentages include one patient recorded by the principal investigator in the Clinical Observation Record as Unconfirmed Complete Response.

- Expect to provide updated data including approximately 16 evaluable patients at medical conference during the fourth quarter of 2021
- Plan to initiate discussions with FDA regarding potential registration pathway for NBTXR3 immunotherapy combination in H2 2021
- On-track to report recommended Phase II dose for each cohort in 2022

Expanding NBTXR3 Opportunity, Collaborating with World-Class Partners to Validate Tumor-Agnostic, Combination-Agnostic Therapeutic Profile:

- Formed strategic partnership with LianBio to develop and commercialize NBTXR3 across tumor types and therapeutic combinations in China and other Asian markets. LianBio will participate in the Nanobiotix global phase III HNSCC registrational study by enrolling approximately 100 patients. In addition to the phase III head and neck cancer study, LianBio has committed to enrolling patients in four additional registrational studies conducted by Nanobiotix across indications and therapeutic combinations. Nanobiotix received a \$20 million upfront payment and is entitled to receive up to an aggregate of \$220 million in potential contingent, development and commercialization milestone payments along with tiered, low double-digit royalties based on net sales of NBTXR3 in the licensed territories.
 - Initiated fifth collaborator-led study at The University of Texas MD Anderson Cancer Center (MD Anderson). MD Anderson Collaboration now includes three Phase I and two Phase II clinical studies, including:
 - Phase I study evaluating NBTXR3 activated by radiation therapy (RT) for patients with non-small cell lung cancer (NSCLC) amenable to re-irradiation;
 - Phase I study evaluating NBTXR3 in combination with chemotherapy for patients with esophageal cancer;
 - Phase I study evaluating NBTXR3 as a single agent activated by RT for patients with pancreatic cancer; and
 - Two Phase II studies, each evaluating NBTXR3 in combination with anti-PD-1 for patients with head and neck cancer (inoperable locoregional recurrent amenable to reirradiation and recurrent metastatic with limited PD-L1 expression or refractory).
 - Presented preclinical data, developed in collaboration with MD Anderson, further suggesting that NBTXR3 could prime adaptive immune response and combine with several immune checkpoint inhibitors at the first American Association of Cancer Research (AACR) Virtual Special Conference on Radiation Science and Medicine. This data demonstrated that a combination therapy including NBTXR3, anti-PD-1, anti-TIGIT, and anti-LAG3 augmented anti-tumor response in both irradiated and unirradiated tumors, improving local and distant tumor control and increasing survival rate. The survivor mice were immune to re-injections of tumor cells, maintained significantly higher percentages of memory immune cells and stronger anti-tumor immune activities than control.
 - Reported first clinical results in rectal cancer including recommended phase II dose from the complete phase Ib part of a phase Ib/II study evaluating NBTXR3 activated by radiotherapy with concurrent chemotherapy at the 2021 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI 2021). The data showed that the intra-tumoral injection of NBTXR3 was feasible and well tolerated at all dose levels. More than 70% of patients showed objective tumor response and approximately 90% of patients underwent total mesorectal excision (surgery), and 17.6% achieved pathological complete response.
 - Initiated one-year collaboration between Sanofi and Nanobiotix subsidiary, Curadigm, to establish proof-of concept for Curadigm's Nanoprimer as a combination product that could improve treatment outcomes for gene therapy product candidates.
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“Given our clinical and operational progress in the first half of 2021, we believe we are on track to deliver on the promise of NBTXR3 as a potential first-in-class, solid tumor-agnostic, combination-agnostic product candidate that could change treatment paradigms in oncology,” said Laurent Levy, co-founder and chairman of the executive board of Nanobiotix. “As we prepare for the initiation of our pivotal phase III study later this year, we are highly encouraged by the consistently strong findings from our phase I expansion study in head and neck cancer presented earlier this year and eagerly anticipate reporting progression free survival and overall survival data from this study in the fourth quarter. Taken together with data we have reported on the potential of NBTXR3 in immunotherapy and the series of studies initiated by MD Anderson exploring NBTXR3 across additional solid tumor types and therapeutic combinations, we continue to achieve critical milestones on our journey to improve outcomes for patients throughout oncology.”

Financial Results for the First Half of 2021

Cash and Cash Equivalents: Cash and cash equivalents as of June 30, 2021, were €102.3 million, expected to support development plans into the first quarter of 2023. This amount includes the €16.5 million (\$20.0 million) upfront payment associated with the LianBio collaboration announced in May 2021. As previously announced, PharmaEngine was eligible for and received a €2.1 million (\$2.5 million) payment following the announcement of the LianBio collaboration and has received €3.3 million (\$4.0 million) in conjunction with the completion of various administrative steps in connection with the winding-up of the collaboration. PharmaEngine will be eligible to receive an additional \$1.0 million in administrative fees, a final payment of \$5 million upon a second regulatory approval of an NBTXR3-containing product as well as low-single digit royalties for a limited period following approval in the region.

Revenue: Revenue for the first half of 2021 totaled €9.7 thousand compared to €36.9 thousand for the first half of 2020. Revenue for the six months ended June 30, 2021 and June 30, 2020 mainly corresponded to the charging back of cost incurred in connection with the Company previous collaboration with PharmaEngine, Inc.

Research and Development (“R&D”) Expenses: R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of NBTXR3. These expenses for the six months ended June 30, 2021, were €15.5 million, compared to €13.1 million for the six months ended June 30, 2020. Purchases, sub-contracting and other expenses increased by €2.3 million for the six months ended June 30, 2021 as compared with the same period in 2020. This increase reflects the impact of COVID-19 pandemic in 2020 and the Company's focus on advancing its clinical trial development priorities in 2021.

Selling, General and Administrative (“SG&A”) Expenses: SG&A expenses consist primarily of administrative employee-related expenses, legal and other professional fees, patent filing and maintenance fees, and insurance. These expenses for the six months ended June 30, 2021, were €10.2 million, compared to €6.8 million for the prior-year six-month period. This increase of €3.4 million was primarily due to expenses relating to partnership agreements as well as consulting fees, legal & compliance expenses following the Company's Nasdaq listing, and recruitment expenses.

Net loss: Net loss attributable to common shareholders for the six months ended June 30, 2021 was €30.4 million, or €0.88 per share. This compares to a net loss attributable to common shareholders of €20.6 million, or €0.91 per share, for the same period in 2020. The €9.8 million increase in net loss compared to the first half of 2020 was primarily driven by the €5.4 million in operating expenses associated with the termination of the PharmaEngine agreement during the first half of 2021.

These results are represented in the condensed consolidated financial statements as of June 30, 2021, approved by the executive board of the Company on September 8, 2021, and reviewed by the supervisory board of the Company on the same date, and have been subjected to a limited review by the Company's statutory auditors.

Availability of the half-year financial report

The 2021 half-year financial report has been filed with the French Financial markets authority (Autorité des marchés financiers). It is available to the public and can be consulted on the company's website, www.nanobiotix.com.

Updated Financial Agenda

October 20th, 2021: Third Quarter Corporate and Financial Update

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 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, 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”, 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), as well as those set forth in the half-year financial report filed with the AMF 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.

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Nanobiotix S.A.

Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share amounts)

	For the six month period ended	
	June 30, 2021	June 30, 2020
Revenues and other income		
Revenues	10	37
Other income	1,309	1,411
Total revenues and other income	1,319	1,448
Research and development expenses	-15,506	-13,077
Selling, general and administrative expenses	-10,176	-6,755
Other operating income and expenses	-5,414	—
Total operating expenses	-31,096	-19,832
Operating income (loss)	-29,778	-18,384
Financial income	2,511	234
Financial expenses	-3,152	-2,428
Financial income (loss)	-640	-2,194
Income tax	-2	-1
Net loss for the period	-30,420	-20,579
Basic loss per share (euros/share)	(0.88)	(0.91)
Diluted loss per share (euros/share)	(0.88)	(0.91)

Condensed Consolidated Balance Sheet Data
(unaudited)
(in thousands)

	As of	
	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Total non-current assets	8,045	8,782
- Cash and Cash equivalents	102,336	119,151
Total current assets	115,870	125,248
TOTAL ASSETS	123,915	134,030
- Net loss for the period	-30,420	-33,590
Total shareholders' equity	41,431	70,468
Total non-current liabilities	44,445	44,522
Total current liabilities	38,038	19,041
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	123,915	134,030