# 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: 03/30/2022**

**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 March 30, 2022 |

**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

Account Supervisor

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

By: /s/ Bart Van Rhijn

Bart Van Rhijn
Chief Financial Officer

# NANOBIOTIX Provides Business Update and Reports Full Year 2021 Financial Results

- **New data from Expansion Study 102 in high-risk, LA-HNSCC patients highlights potential clinical benefit of NBTXR3 showing a median Overall Survival reaching 23 months in evaluable patients; Data with minimum follow-up of one year for full study population anticipated in mid-2023**
- **Pivotal Phase III study, NANORAY-312, now actively enrolling elderly, LA-HNSCC patients ineligible for cisplatin across multiple European sites with US site activation anticipated in mid-2022**
- **Expansion Phase to be added to Study 1100 evaluating NBTXR3 in combination with anti-PD-1 therapy in three cohorts, including two cohorts focused on R/M HNSCC patients that are either naïve to anti-PD-(L)-1 therapy or resistant to prior anti-PD-(L)-1 therapy and combining other eligible patients with lung and/or liver metastasis from anti-PD-(L)-1 resistant advanced cancers into a third cohort**
- **Reported €83.9 million in cash and cash equivalents as of December 31, 2021**
- **Conference call and webcast scheduled for Thursday, March 31 at 2:00 P.M. CET/8:00 A.M. EDT**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--March 30, 2022--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, provided an update on operational progress and reported financial results[1] for the year ended December 31, 2021.

"2021 was a year of acceleration for Nanobiotix as we took important steps towards validating of the broad potential therapeutic benefit of NBTXR3 and reinforced our team." said Laurent Levy, co-founder and chairman of the executive board of Nanobiotix. "Our clinical program evaluating first-in-class radioenhancer, NBTXR3, yielded compelling new data suggesting that our lead therapeutic candidate may improve treatment outcomes for patients both as a single-agent activated by radiotherapy for local diseases and as a combination therapy with anti-PD-1 for systemic disease. We also achieved the launch of our pivotal phase III study, NANORAY-312-a critical milestone as we advance toward global registration in head and neck cancer. 2022 has already seen the enrollment of our first European patients in NANORAY-312, and we expect the first patients in the U.S. and Asia this year. In parallel, we continue to make consistent progress in our Company-led immunotherapy pathway, along with the additional studies evaluating NBTXR3 across tumor indications and therapeutic combinations led by strategic collaborators. We are steadfast in our commitment to bring the potential benefits of NBTXR3 to millions of patients around the world, and in 2022 we will focus on executing our ongoing studies, defining our registration strategy in immunotherapy, and generating more evidence to support the broad applicability of our technology."

*[1] Financial data taken from the Company's consolidated financial statements for the fiscal year ending December 31, 2021, which were approved by its executive board and reviewed by its supervisory board on March 30, 2022. The statutory auditors of the Company have completed their audit work on the 2021 financial statements, but have not issued their audit report yet. Such reports should be publicly available in the Company's 2021 universal registration document and 2021 annual report on Form 20-F.*

**2021 Operational Highlights, Pipeline Status and Upcoming Milestones**

*Priority Pathway in Head & Neck Cancer, Local Control as Single Agent Activated by Radiotherapy*

- Data from Expansion Study 102, a phase I study evaluating NBTXR3 as a single agent activated by radiotherapy (RT) in high-risk, elderly locally advanced head and neck squamous cell carcinoma (LAHNSCC) patients ineligible for cetuximab and intolerant to cisplatin, was presented at the 2021 Annual Meeting of the American Society for Radiation Oncology (ASTRO 21) continued to support NBTXR3 administration as feasible and well-tolerated. At a median follow up of 9.5 months, evaluable patients (n=41) demonstrated 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%.
- A recent review of data from Expansion Study 102 shows, as of February 22, 2022, an on-going median overall survival (mOS) of 17.9 months in the all treated population (n=56) and 23.0 months in evaluable patients (n=44) demonstrating continued improvement relative to the analysis presented at ASTRO 21 and consistent with data reported from the dose escalation phase of Study 102.
- Expansion Study 102 is now fully enrolled with 44 evaluable patients. The last treatment visit for the final patient is expected in Q2 2022 and data reflecting one year of follow-up are expected in mid-2023
- NANORAY-312, a pivotal phase III global registration study evaluating NBTXR3 as a single-agent activated by RT for elderly patients with LA-HNSCC intolerant to cisplatin initiated in Q1 2022 and actively enrolling patients across multiple European sites with U.S. site activation anticipated in mid-2022.

*Priority Pathway in Immunotherapy for Advanced Cancers, Priming Immune Response in Combination with Anti-PD-1 Treatment:*

- Preclinical data was presented at the 2021 Annual Meeting of the Society for the Immunotherapy of Cancer (SITC) showing RT-activated NBTXR3 increased CD8+ T cell infiltration and modulated the T cell receptor repertoire, suggesting stronger immune priming triggered by the therapy compared to radiotherapy alone.
- Updated data from Study 1100, a phase I basket study evaluating NBTXR3 activated by RT in combination with nivolumab or pembrolizumab in locoregional recurrent or recurrent metastatic HNSCC (LRR or R/RM HNSCC), lung and/or liver metastasis from any primary tumor presented at ASTRO 21 demonstrated a disease control rate of 81% (n=16) in the evaluable patient population, including 73% in patients with prior primary or secondary resistance to anti-PD-1. In the evaluable population, 3 complete responses and 5 partial responses were reported. Some delayed tumor responses and/or abscopal effects were reported, suggesting NBTXR3 may potentially prime an immune response.
- Reporting of recommended Phase II dose for each cohort is expected in 2022 along with the initiation of a new expansion Phase of Study 1100 evaluating NBTXR3 in combination with nivolumab or pembrolizumab in a cohort of patients LRR or R/M HNSCC resistant to prior anti-PD-(L)-1 therapy, a cohort of LRR or R/M HNSCC patients naïve to anti-PD-(L)-1 therapy, and cohort of patients resistant to prior anti-PD-(L)-1 therapy with lung, liver or soft tissue metastasis from select solid tumors.
- Expect to provide updated Study 1100 data at a medical conference during the fourth quarter of 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 is expected to begin enrolling patients in NANORAY-312 in China in H2 2022 as the first of up to five registrational studies covered by the collaboration.
- Presented preclinical data, developed in collaboration with The University of Texas MD Anderson Cancer Center (MD Anderson), at SITC 21 suggesting the combination of RT-activated NBTXR3, antiPD-1, anti-LAG3, and anti-TIGIT significantly elevated the activities of anti-tumor immune response in both irradiated and unirradiated tumors, improving local and distant tumor control and increasing survival rate.
- Published data from a preclinical study conducted in collaboration between MD Anderson in the International Journal of Radiation Oncology, Biology, Physics (Red Journal) supportive of the hypothesis that RT-activated NBTXR3 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.
- Initiated fifth collaborator-led clinical study at MD Anderson Cancer Center.
- Published peer-reviewed clinical case study reported preliminary data on the first-in-human administration of NBTXR3 for the treatment of pancreatic cancer not eligible for surgery, demonstrating feasibility with no treatment-related toxicity.
- Determination of recommended phase II dose for NBTXR3 in pancreatic cancer expected in 2022.

**Full Year 2021 Financial Results**

Cash and Cash Equivalents: As of December 31, 2021, Nanobiotix had €83.9 million in cash and cash equivalents, compared to €119.2 million as of December 31, 2020. This net decrease of €35.3 million primarily reflects €51.8 million of net cash flows used in operating, investing and financing activities of Nanobiotix which was partially offset by 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 €3.4 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 and is expected to receive in 2022 an additional $1.0 million in administrative fees and, upon a second regulatory approval of an NBTXR3-containing product, a final payment of $5.0 million.

Based on the current operating plan and financial projections, Nanobiotix anticipates that the cash and cash equivalents of €83.9 million as of December 31, 2021, will fund its operations into the second quarter of 2023.

Revenue: Full year 2021 revenue totaled €9.7k compared to €50.0k for the year ended December 31, 2020. The revenue generated in 2021 was primarily related to the Company's now concluded collaboration with PharmaEngine, Inc. Other income includes research tax credits which increased from €1.9 million in 2020 to €2.5 million in 2021 due mainly to an increase of research and development expenses.

Research and Development ("R&D") Expenses: R&D expenses consist primarily of preclinical, clinical, and manufacturing expenses related to the development of NBTXR3 and totaled €30.4 million for the twelve-month period ended December 31, 2021, as compared to €24.3 million for the twelve months ended December 31, 2020. The increase in net R&D expenses was primarily due to increases in development costs related to the Company's priority pathways, including preparation and initiation of its pivotal Phase III registration study, NANORAY-312, continuation of Expansion Study 102 and its ongoing immunotherapy combination Study 1100 as well as increases in personnel related expenses, including share-based compensation.

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 were €19.4 million year-ended December 31, 2021, as compared to €14.6 million for twelve-months ended December 31, 2020. The increase in G&A expenses year-over-year was due to increased headcount, consulting fees, legal & compliance expenses resulting from the Nasdaq listing and recruitment expenses.

Net loss: Net loss attributable to shareholders was €47.0 million, or €1.35 per share, for the twelve-month period ended December 31, 2021. This compares to a net loss of €33.6 million, or €1.38 per share for the year ended December 31, 2020.

**Conference Call and Webcast**

Nanobiotix will host a conference call and live audio webcast on Thursday, March 31, 2022, at 8:00 AM EDT / 2:00 PM CET, prior to the open of the U.S. market. During the call, Laurent Levy, chief executive officer, and Bart Van Rhijn, chief financial officer, will briefly review the Company’s fourth quarter results, year-end results, and an update on business activities before taking questions from analysts and investors. Investors are invited to email their questions in advance to investors@nanobiotix.com

Details for the call are as follows:

Live (US/Canada): +1 646-741-3167

Live France: +33170700781

Live (international): +44 (0) 2071 928338

Conference ID: 8169783

A live webcast of the call may be accessed by visiting the investors section of the company's website at www.nanobiotix.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the company's website.

**2022 Financial Agenda**

- May 10, 2022 – First Quarter 2022 Corporate and Financial Update
- June 17, 2022 – Annual General Meeting, Paris, France
- September 7, 2022 – 2022 Half-Year Corporate and Financial Update
- November 9, 2022 – Third Quarter 2022 Corporate and Financial Update

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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 initiated patient enrollment in 2022. 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 dose escalation and dose expansion 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: 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.comor follow us on LinkedInand 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, the Company's anticipated cash runway 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. Particular caution should be exercised when interpreting results relating to a small number of patients or individually presented cased studies, which may not be indicative of outcomes in larger clinical studies. 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 forwardlooking 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.*

**Statements of consolidated operations (unaudited)***
*(Amounts in thousands of euros, except per share numbers)*

| | For the year ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Revenues and other income** | | |
| Revenues | 10 | 50 |
| Other income | 2,637 | 2,462 |
| **Total revenues and other income** | **2,647** | **2,512** |
| Research and development expenses | (30,378) | (24,330) |
| Selling, general and administrative expenses | (19,434) | (14,611) |
| Other operating and income expenses | (5,414) | — |
| **Total operating expenses** | **(55,226)** | **(38,941)** |
| **Operating income (loss)** | **(52,579)** | **(36,428)** |
| Financial income | 6,170 | 201 |
| Financial expenses | (590) | 2,646 |
| **Financial income (loss)** | **5,580** | **2,847** |
| Income tax | (5) | (9) |
| **Net loss for the period** | **(47,003)** | **(33,590)** |
| **Basic loss per share (euros/share)** | **(1.35)** | **(1.38)** |
| **Diluted loss per share (euros/share)** | **(1.35)** | **(1.38)** |

**Financial data taken from the Company's consolidated financial statements for the fiscal year ending December 31, 2021, which were approved by its executive board and reviewed by its supervisory board on March 30, 2022. The statutory auditors of the Company have completed their audit work on the 2021 financial statements, but have not issued their audit report yet. Such reports should be publicly available in the Company's 2021 universal registration document and 2021 annual report on Form 20-F.*

**Statements of consolidated financial position (unaudited)***
*(Amounts in thousands of euros, except per share numbers)*

| | As of December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Total non-current assets** | **8,709** | **8,782** |
| Cash and cash equivalents | 83,921 | 119,151 |
| **Total current assets** | **93,060** | **125,248** |
| **TOTAL ASSETS** | **101,769** | **134,030** |
| Net loss for the period | (47,003) | (33,590) |
| **Total shareholders' equity** | **26,790** | **70,468** |
| **Total non-current liabilities** | **38,134** | **44,522** |
| **Total current liabilities** | **36,845** | **19,041** |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | **101,769** | **134,030** |

**Financial data taken from the Company's consolidated financial statements for the fiscal year ending December 31, 2021, which were approved by its executive board and reviewed by its supervisory board on March 30, 2022. The statutory auditors of the Company have completed their audit work on the 2021 financial statements, but have not issued their audit report yet. Such reports should be publicly available in the Company's 2021 universal registration document and 2021 annual report on Form 20-F.*

## Contacts


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