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<b>EDGAR Submission Header Summary</b>	
Submission Form Type	6-K
XBRL	Non-XBRL Submission
Period of Report	03-17-2021
Filer	Nanobiotix S.A.
CIK	0001760854
CCC	xxxxxxx
Exchanges	NASD
Co-Registrants	
Submission Contact	
Contact Phone Number	
Documents	2

<b>Documents</b>	
6-K	a52397689.htm
Description	Nanobiotix S.A. 6-K
EX-99.1	a52397689ex991.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: March 17, 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):

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**EXHIBIT INDEX**

**Exhibit      Title**

[99.1](#)      [Press Release, dated March 17, 2021](#)

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**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)

March 17, 2021

By: /s/ Philippe Mauberna  
Philippe Mauberna  
Chief Financial Officer

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## NANOBIOTIX Reports Full Year 2020 Financial Results and Highlights Operational Progress

- **Substantial progress in priority development pathway in head and neck cancer with clinical registration plan announced, Fast Track designation granted by US Food and Drug Administration, and new data from phase I dose expansion showing 83% objective response rate in primary lesion.**
- **First clinical data reported phase I immuno-oncology trial showing conversion of anti-PD-1 non-responders to responders.**
- **Extended global capital markets presence with a successful Nasdaq IPO that provided gross proceeds of €93.5 million (\$113.3 million).**
- **Cash, cash equivalents, and short-term investments were €119.2 million at December 31, 2020, supporting robust development plans into the second quarter of 2023.**

PARIS & CAMBRIDGE, Mass.--(BUSINESS WIRE)--March 17, 2021--Regulatory News:

NANOBIOTIX (Paris:NANO) (NASDAQ:NBTX) (Euronext : NANO — NASDAQ: NBTX – the “**Company**”), a late-stage clinical biotechnology company pioneering physics-based approaches to expand treatment possibilities for patients with cancer, reported business highlights and financial results for the fiscal year ending December 31, 2020.

*“2020 was a banner year for Nanobiotix, despite challenges posed by COVID-19. Our company achieved several milestones to advance our priority development pathways in head and neck cancer and immuno-oncology; and our successful Nasdaq IPO positioned us to keep our pace in 2021. We look forward to building on our progress to ensure that we deliver the potential benefits of NBTXR3 to patients with deliberate speed,” commented Laurent Levy, founder and chairman of the executive board of Nanobiotix.*

### **2020 Financial Highlights**

- In 2020 total revenue remained stable compared to 2019 and amounted to €2.5M. €0.05M corresponded to the license and collaboration agreement signed with PharmaEngine, a former partner. €1.9M corresponded to the Research Tax Credit (CIR). There we €0.5M in subsidies from the government of France, of which €0.3M was in the context of partial unemployment and €0.2M went to Curadigm SAS from BPI.
- Research and development expenses decreased from €30.4M in 2019 to €24.3M. This decrease is primarily a result of the Company's cost-control efforts relating to R&D subcontracting and consulting fees, as well as a reduction in the number of Group employees assigned to research and development.
- Selling, general and administrative expenses in 2020 were €14.6M compared to €18.9M in 2019. This decrease is due mainly to the decrease in external costs mainly related to savings due to the COVID-19 pandemic (especially consulting fees) and to the 2019 reclass of the Nasdaq IPO costs.
- Net loss for the year ended December 31, 2020 was €33.6M, or €1.4 per share (basic and diluted), compared to net loss of €50.9 million, or €2.3 per share for the same period in 2019.
- Cash, cash equivalents, and short-term investments were €119.2 million on December 31, 2020.

### **Clinical activities and achievements advancing NBTXR3 toward global phase III registration trial in head & neck cancer:**

- **Clinical registration plan for global phase III head and neck cancer study for elderly patients ineligible for platinum-based chemotherapy announced** following feedback from the US Food and Drug Administration (FDA) in January 2020. The FDA also agreed to the chemistry, manufacturing, and controls (CMC) development plan for NBTXR3, to support the future New Drug Application (NDA) for the product candidate and its use in the phase III clinical study.
  - **Fast track designation granted by FDA for the patient population in the global phase III head and neck cancer study** in February 2020.
  - **Preliminary safety and efficacy data from the dose expansion part of phase I study in head and neck cancer reinforcing NBTXR3 as a potential new option for patients** presented in October 2020 at the annual meeting of the American Society for Radiation Oncology (“ASTRO”). Among 31 evaluable patients, overall response rate according to RECIST 1.1 was 83.9% of the evaluable patients, 67.7% had achieved a complete response of the injected lesion.
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#### Clinical activities and achievements advancing I/O combination strategy:

- **First clinical data suggesting NBTXR3 could convert anti-PD-1 non-responders to responders** presented at the 35th Anniversary Annual Meeting of The Society for Immunotherapy of Cancer (SITC) in November 2020. Data from company-sponsored study 1100 provided a strong signal that NBTXR3 activated by radiation therapy in combination with pembrolizumab or nivolumab (anti-PD-1 checkpoint inhibitors) could convert anti-PD-1 non-responders to responders. Eight of nine patients treated on study showed tumor regression, including six of seven prior anti-PD-1 non-responders. Four of the anti-PD-1 non-responders had multiple lesions, and three of the four experienced tumor regression in the non-injected local and/or distant lesions. One patient with prior anti-PD-1 resistance experienced delayed tumor regression, suggesting an adaptive immune response aided by NBTXR3 activated by radiation therapy. The early data also demonstrated that administration of NBTXR3 via intra-tumoral injection had been feasible and well tolerated in all patients (head and neck cancer, lung metastasis, and liver metastasis). One patient in the head and neck cancer cohort experienced 4 severe adverse events related to anti-PD-1, of which 2 events were also reported as possibly related to NBTXR3.
- **Positive new preclinical data from two studies suggesting that NBTXR3 could have a significant impact in immunotherapy** presented at SITC in November 2020. The first study demonstrated that NBTXR3 activated by radiotherapy produced a strong abscopal effect without checkpoint inhibitor combination, stimulated adaptive antitumor immunity and increased TCR repertoire diversity in treated tumors compared to radiation therapy alone. The second study suggested that NBTXR3 plus high dose and low dose radiation (RadScopal™) combined with anti-PD-1 and anti-CTLA-4 could significantly improve the control of both the primary and secondary tumors, extended survival, and reduced lung metastases in an anti-PD-1 resistant lung cancer model. The NBTXR3 combination also promoted anti-tumor response both at molecular and cellular levels and produced long-term anti-tumor memory.

#### Clinical activities and achievements advancing clinical collaboration with The University of Texas MD Anderson Cancer Center and expanding the evaluation of NBTXR3:

- **Activation of first study in the collaboration and first patient injected in pancreatic cancer**, in May 2020 and September 2020, respectively.
  - **Regulatory ‘safe to proceed’ granted for a phase I esophageal cancer study** in October 2020 and was activated in November 2020. The first patient was subsequently injected in January 2021.
  - **Regulatory ‘safe to proceed’ granted for two phase II head and neck cancer studies evaluating NBTXR3 in combination with anti-PD-1** in November 2020. The first clinical study (Study 2020-0541) targets patients with recurrent or metastatic head and neck squamous cell carcinoma with limited PD-L1 expression, or that are refractory to PD-1 blockade. The second clinical study (Study 2020-0354) targets patients with inoperable locoregional recurrent head and neck squamous cell carcinoma amenable to re-irradiation.
  - **Regulatory ‘safe to proceed’ granted for a phase I study in lung cancer amenable to re-irradiation** in October 2020.
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## Corporate activities and achievements enhancing Nanobiotix balance sheet and advancing subsidiary Curadigm:

- **Successful IPO on Nasdaq Global Select Market** in December 2020. The offering, including the full exercise of the underwriters' over-allotment option, included a capital increase of 8,395,000 new shares consisting of 6,540,000 ordinary shares in the form of American Depositary Shares (ADSs), each representing one ordinary share, and 1,855,000 ordinary shares placed in certain jurisdictions outside of the United States. The total gross proceeds of the global offering amounted to €93.5 million (\$113.3 million), or net proceeds of €82.8 million (\$100.4 million) after deducting underwriting commissions and other estimated offering expenses.
- **Successful raise of €20 million in placement of ordinary shares with US and EU investors** in July 2020. Nanobiotix placed 3,300,000 new ordinary shares for total gross proceeds of approximately €20.1 million by means of an accelerated bookbuild offering reserved for a specific class of investors in the US and EU.
- **€10M in non-dilutive financing secured** in June 2020. Nanobiotix a total of €10 million from HSBC and Bpifrance for in the form of state-guaranteed loans (Prêts Garantis par l'Etat, or PGE in France).
- **Validation of novel nanoprimer technology from subsidiary Curadigm in RNA therapeutics** with preclinical data presented at the American Association for Cancer Research (AACR) in June 2020. The data showed that the Curadigm nanoprimer could increase the efficacy of RNA-based therapeutics up to 50% by decreasing rapid liver clearance.

## Expected 2021 Milestones

- 2021 – Expect first patient injected in phase III trial for elderly head and neck cancer patients (NANORAY-312).
- Q2 2021 – Presentation of updated phase I dose expansion results in head and neck cancer (Study 102 Expansion)
- Q2 2021- Updated results with new patients and additional follow up in phase I I/O basket study (Study 1100)
- H1 2021 – Expect first patient injected in phase II study of NBTXR3 in combination with anti-PD-1 for patients with recurrent/metastatic head and neck cancer
- H1 2021- Expect first patient injected in phase II study of NBTXR3 in combination with anti-PD-1/L1 for patients with inoperable head and neck cancer
- H1 2021 – Expect first patient irradiated in phase I lung reirradiation study (first patient injected H2)
- H2 2021 – Expect launch of post-registration study in soft tissue sarcoma to launch in EU
- Additional news on other clinical trials and preclinical programs

Next financial press release: revenue for Q1 2021 on April 30, 2021

Annual General Meeting will be held on April 28, 2021.

## 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) and is currently staffed by 90 employees (70 in France, 20 in the US). 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) nanomedicine 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 is 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](http://www.nanobiotix.com) or follow us on LinkedIn and Twitter

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## 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 that subsequent studies and clinical trials may not generate favorable data notwithstanding positive preclinical 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 our prospectus filed with the U.S. Securities and Exchange Commission on December 11, 2020 under the caption “Risk Factors” and those set forth in the universal registration document of Nanobiotix registered with the French Financial Markets Authority (Autorité des Marchés Financiers) under number R.20-010 on May 12, 2020 (a copy of which is available on [www.nanobiotix.com](http://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.*

The consolidated financial statements for the fiscal year ending December 31, 2020 have been approved by the Company’s executive board and reviewed by the supervisory board on March 17, 2021. The Company’s statutory auditors have completed their audit work on the 2020 financial statements, but they have not issued their audit report yet.

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**Consolidated Income Statement:**

<b>In K€</b>	<b>2020</b>	<b>2019</b>
<b>Total revenue and other income</b>	<b>2.512</b>	<b>2.541</b>
<b>Sales</b>	<b>50</b>	<b>68</b>
Service	50	40
Other sales	-	28
<b>Other revenue</b>	<b>2.462</b>	<b>2.473</b>
Research Tax Credit	1.927	2.437
Subsidies	526	20
Other	10	17
Research & Development (R&D) costs	(24.330)	(30.411)
Selling, General and Administrative (SG&A) costs	(14.611)	(18.909)
<b>Operating loss</b>	<b>(36.428)</b>	<b>(46.779)</b>
Financial loss	2.847	(4.133)
Income tax	(9)	(3)
<b>Net loss for the period</b>	<b>(33.590)</b>	<b>(50.915)</b>

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