

NOXXON PUBLISHES INTERIM 2019 RESULTS

Top-line data from Phase 1/2 clinical trial with NOX-A12

Berlin, Germany, October 24, 2019, 06.00 p.m. CEST - NOXXON Pharma N.V. (Euronext Growth Paris: ALNOX), a biotechnology company focused on improving cancer treatments by targeting the tumor microenvironment (TME), released today its interim 2019 results for the six months ended June 30, 2019.

Aram Mangasarian, Chief Executive Officer of NOXXON, commented: "NOXXON has made significant progress in the clinical development of our lead drug candidate, NOX-A12, obtaining near-final data from the trial testing NOX-A12 with immunotherapy in metastatic micro-satellite stable pancreatic and colorectal cancer patients and initiating the NOX-A12 and radiotherapy combination trial in first-line therapy for brain cancer patients. We continue to develop relationships with potential partners with the goal to set up an agreement to share the financial resources needed to advance our drug candidate for the treatment of cancer."

Business Overview

NOXXON is focused on advancing clinical trials to test its lead drug candidate, NOX-A12, an anti-CXCL12 agent, in two distinct therapeutic combinations: NOX-A12 + radiotherapy and NOX-A12 + immunotherapy (PD1 checkpoint inhibitors). Each combination approach has a different underlying rationale and mechanism of action.

The combination approach of NOX-A12 + radiotherapy is currently being tested as a first line therapy in a Phase 1/2 trial in newly diagnosed patients with aggressive brain cancer (glioblastoma) who would not benefit from standard of care chemotherapy and whose tumor cannot be fully resected by surgery. The anticipated mode of action of NOX-A12 is the inhibition of a process called "vasculogenesis" which allows the tumor's blood vessels that were destroyed by the radiotherapy to be replaced, which ultimately results in disease recurrence.

The combination of NOX-A12 + immunotherapy has been tested in a Phase 1/2 trial in patients with metastatic pancreatic and colorectal cancer who had failed several lines of standard therapy. Both the NOX-A12 mechanistic data as well as the overall survival figures observed following treatment with the combination of NOX-A12 and anti-PD1 have been highly encouraging for the patient population enrolled in this study. Three patients (15% of the total) with advanced metastatic disease, including metastases in the liver, whose cancer was progressing rapidly at the time of trial entry have survived for more than one year.

Partnering discussions resulted in one of the top-10 global pharmaceutical companies initiating an experimental preclinical evaluation of NOX-A12 in a novel indication. The indication is a serious disease with significant unmet medical need and a market valued at more than one billion euros.

Business Highlights During First Half-Year of 2019

- February 2019: Aachen University Hospital researchers published work showing that blocking the recruitment of macrophages in the liver with an anti-CCL2 molecule, such as NOX-E36, is a promising mechanism for the treatment of liver cancer. This is the second solid tumor for which monotherapy activity of NOX-E36 has been demonstrated after pancreas cancer.
- February 2019: NOXXON filed the clinical trial application with the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*), to start a Phase 1/2 clinical trial combining NOX-A12 with radiotherapy to treat newly diagnosed brain cancer patients who would not benefit from the current standard of care and whose tumor cannot be fully resected by surgery.
- April 2019: An update of clinical results from the Phase 1/2 study of NOX-A12 in combination with Keytruda® (pembrolizumab) in patients with microsatellite-stable, metastatic pancreatic and colorectal cancer was presented at the American Association for Cancer Research (AACR) Annual Meeting. The data confirmed that NOX-A12 is safe and well-tolerated in advanced cancer patients both as a monotherapy and in combination with Merck and Co./MSD's anti-PD1 antibody pembrolizumab. The combination of NOX-A12 and pembrolizumab induced stable disease in 25% of patients and prolonged time on treatment vs. prior therapy for 35% of patients. Overall survival figures were very encouraging for this patient population.
- June 2019: A top-10 pharmaceutical company signed an agreement with NOXXON for the purpose of evaluating NOX-A12 in a novel indication. The pharmaceutical company will fund and conduct preclinical studies to assess NOX-A12 in an indication which is a serious disease with significant unmet medical need. The market for this indication has been valued at more than one billion euros. The studies are anticipated to be completed in Q2 2020, after which the parties may enter negotiations for rights to NOX-A12.

Business Highlights After June 30, 2019

- July and August 2019: NOXXON raised €1.5 million through two capital increases.
- September 2019: NOXXON initiated recruitment of newly diagnosed brain cancer patients in a Phase 1/2 clinical trial combining NOX-A12 with radiotherapy.
- September 2019: NOXXON presented more mature top-line data from the NOX-A12 clinical trial in metastatic microsatellite stable pancreatic and colorectal cancer patients at the European Society of Medical Oncology (ESMO) Meeting. Three patients (15% of the total) have now survived over one year despite having failed at least three prior lines of therapy. It should also be noted that these patients experienced rapid cancer progression as the best response to their last therapy just prior to entering the NOX-A12 trial. This data provides further support to the concept that the combination of NOX-A12 + anti-PD1 immunotherapy is able to modify the biology of the tumor to the benefit of the patient.
- October 2019: NOXXON announced initiation of treatment of the first brain cancer patient in the Phase 1/2 clinical trial combining the CXCL12 inhibitor NOX-A12 with radiotherapy.

First-half 2019 Financial Results (IFRS)

NOXXON Pharma did not generate any revenues in the first half of 2019 (H1 2019). The Group does not expect to generate any revenues from its product candidates in development until the company either signs a licensing agreement or obtains regulatory approval and commercializes its products or enters into collaborative agreements with third parties.

The increase in other operating income to €274 thousand in H1 2019 (vs. €77 thousand in H1 2018) was mainly due to the sale of raw materials and a partial waiver of management and supervisory board members concerning their receivables from remuneration due from the Group in 2019, which generated higher other operating income than the sale of assets held for sale in H1 2018.

NOXXON dedicated its resources to research and development (R&D) and general and administrative (G&A) expenses. R&D expenses slightly decreased to €1,062 thousand in H1 2019 (vs. €1,189 thousand in H1 2018). The decrease was mainly driven by lower personnel expenses, patent costs and consulting services.

The decrease in G&A expenses to €1,238 thousand in H1 2019 (vs. €1,359 thousand in H1 2018) was mainly driven by lower personnel expenses, lower public and investor relation expenses, partly offset by higher legal, consulting and audit fees.

Foreign exchange losses in the amount of €2 thousand remained at par in H1 2019 and in H1 2018 as a result of unchanged volume of purchases denominated in currencies other than euro in H1 2019.

Finance income increased to €75 thousand in H1 2019 (vs. €59 thousand in H1 2018). Finance income in H1 2018 and H1 2019 was due to the fair value adjustments of warrants issued and outstanding and was entirely non-cash related.

No finance cost was reported in H1 2019 (vs. €1,637 thousand in H1 2018). Finance cost in H1 2018 was related to the Yorkville equity line financing and included the consideration incurred in connection with the amendment of the Issuance Agreement with Yorkville, the conversions of outstanding notes in equity as well as the issuance of notes and the recognition of warrants. Finance cost in H1 2018 was entirely non-cash related.

As a result of the above factors, NOXXON's net loss decreased to €1,954 thousand in H1 2019 (vs. €4,051 thousand in H1 2018). The net cash used in operating activities amounted to €2,687 thousand in H1 2019 and €1,757 thousand in H1 2018, respectively.

Consolidated income statement

In € thousands	for the six months ended	
	June 30, 2019	June 30, 2018
Other operating income	274	77
Research and development expenses	(1,062)	(1,189)
General and administrative expenses	(1,238)	(1,359)
Foreign exchange losses	(2)	(2)
Loss from operations	(2,028)	(2,473)
Finance cost	(0)	(1,637)
Finance income	75	59
Loss before income tax	(1,953)	(4,051)
Income tax	(1)	(0)
Net loss	(1,954)	(4,051)

Outlook

Having obtained and published more mature data from the NOX-A12 clinical trial in metastatic microsatellite stable pancreatic and colorectal cancer patients in September 2019, NOXXON believes that further clinical trials in these indications are warranted. The company's goal is to find industrial partners to provide an anti-PD1 therapy and financial support to conduct a trial. Since finalizing such a partnership is taking more time than anticipated and some of the discussions have not advanced as hoped – in particular with regards to financial support of further trials – the company has broadened the range of potential industrial partners in discussions.

NOXXON initiated the Phase 1/2 combination trial of NOX-A12 with radiotherapy in front-line, inoperable brain cancer (glioblastoma) patients who are shown by biomarker analysis to be resistant to the current standard of care chemotherapy. If the data from this study show positive results, the company will seek advice from competent authorities under the orphan drug designation in the United States and Europe to identify the most efficient manner to complete development in this indication.

The company's partnering objective for this combination is to identify industrial partners that will finance additional clinical trials in brain cancer and other indications where radiotherapy is core to the standard of care. NOXXON anticipates that at least partial top-line clinical data from this trial will be required to sign a partnership in this area.

NOXXON is encouraged by the support of the neuro-oncology community and the strong pull exerted to test NOX-A12 + radiotherapy in the brain cancer setting. In parallel, US-based university consortia are seeking their own funding to test NOX-A12 combined with radiotherapy in adult and pediatric brain cancers. For the clinical trials to proceed, should the consortia be successful in raising funds, NOXXON would need to consider production and supply of NOX-A12.

The ongoing evaluation by a leading international pharmaceutical company of NOX-A12 in a novel indication has created a potentially significant opportunity for NOXXON. It is anticipated that the preclinical work and analysis of the results will be completed in Q2 2020, after which the parties may enter negotiations for rights to NOX-A12.

NOXXON continues to evaluate other indications and therapeutic combinations in which to test NOX-A12 and NOX-E36 as well as the relative priority of such indications for the overall corporate strategy.

Based on its present requirements resulting from the Group's updated business plan focusing on clinical development of its lead product candidate NOX-A12 for the treatment of advanced solid tumors, the Group will require additional cash resources of approximately € 2.5 million, to provide the Group with sufficient working capital for the twelve months following the date of these interim financial statements. The Group will be required to raise these additional funds, alternative means of financial support or conduct a partnering deal for one of its product candidates during February 2020 with a cash inflow be available during the month of February 2020 in order to continue its operations.

Management is pursuing various financing alternatives to meet the Group's future cash requirements, including seeking additional investors, pursuing industrial partnerships, or obtaining further funding from existing investors through additional funding rounds, pursuing a merger or an acquisition. The management of NOXXON is pursuing all of these avenues in parallel with the assistance of experienced external support. Based on the options available and a past history of timely funding the operations of the Group, management is confident to be able to raise additional capital, preferably in the form of equity or an industrial partnership.

The interim results can be downloaded from the [NOXXON website](#).

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About NOXXON

NOXXON's oncology-focused pipeline acts on the tumor microenvironment (TME) and the cancer immunity cycle by breaking the tumor protection barrier and blocking tumor repair. By neutralizing chemokines in the tumor microenvironment, NOXXON's approach works in combination with other forms of treatment to weaken tumor defenses against the immune system and enable greater therapeutic impact. Building on extensive clinical experience and safety data, the lead program NOX-A12 has delivered top-line data from a Keytruda® combination trial in metastatic colorectal and pancreatic cancer patients in December 2018 and further studies are being planned in these indications. In September 2019 the company initiated an additional trial with NOX-A12 in brain cancer in combination with radiotherapy. The combination of NOX-A12 and radiotherapy has been granted orphan drug status in the US and EU for the treatment of certain brain cancers. The company's second clinical-stage asset NOX-E36 is a Phase 2 TME asset targeting the innate immune system. NOXXON plans to test NOX-E36 in patients with solid tumors both as a monotherapy and in combination. Further information can be found at: www.noxxon.com

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