

## NOXXON REPORTS H1 2021 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Positive results from two cohorts of Phase 1/2 clinical trial with NOX-A12 in brain cancer; full readout expected in Q1 2022**
- **Appointment of Scientific Advisory Board with top US and EU pancreatic cancer experts**
- **Appointment of 3 new Supervisory Board members with remarkable experience**
- **Strengthening the Company's balance sheet by raising a total of €9.3 million ensuring financial visibility into June 2022**

**Berlin, Germany, October 22, 2021, 08:00 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), announces its financial results and business highlights for the six months ending June 30, 2021, and provides an outlook for the rest of the year.

**Aram Mangasarian, CEO of NOXXON commented:** "I am delighted to report on the strong progress NOXXON has made in 2021 so far by delivering on its unique approach to target the tumor microenvironment and enhance the way cancers are treated. We continue to develop our lead asset NOX-A12 in two indications with extremely high unmet medical needs, namely brain and pancreatic cancer. The impressive clinical data generated so far indicate the great potential of NOX-A12 to treat and improve the outcomes for patients in these extremely difficult indications."

"We have also significantly strengthened our Supervisory Board by adding three new board members with outstanding and highly relevant experience in business development, corporate law, and finance. On the business development front, I am delighted that MSD/Merck has renewed its confidence in NOXXON by entering a new collaboration agreement to develop NOX-A12 in combination with its market leader PD-1 inhibitor Keytruda. All these recent developments make us confident in our ability to deliver great value to shareholders in the months and years to come," **added Aram Mangasarian.**

### **H1 2021 Business Highlights**

- **Scientific Advisory Board (SAB)**  
Top US and EU pancreatic cancer experts joined NOXXON's SAB in February 2021: Dr. Elena Gabriela Chiorean, Dr. Eileen O'Reilly, Prof. Dr. Thomas T. W. Seufferlein, Dr. Daniel D. Von Hoff and Dr. José Saro (Chair) have long-standing clinical expertise, cutting-edge scientific knowledge, and a track record of successfully developing new drugs.
- **Supervisory Board**  
Appointment of 3 highly distinguished new members to the Supervisory Board in June 2021:
  - Dr. Martine J. van Vugt, Senior Vice President Corporate Strategy and Development at Genmab, with 20 years of successful biotechnology industry experience, an inventor of two successfully commercialized cancer drugs (Darzalex® and Tepezza®) and an expert in corporate transactional and licensing operations.

- o Gregory Weaver, CFO of atai Life Sciences, with over 25 years in the life sciences industry ranging from start-ups to publicly traded commercial stage companies, has raised over US\$1.5 billion in financing transactions, managed 3 IPOs, and has extensive M&A and business development experience.
- o Susan Coles, General Counsel and Head of Finance at Vivet Therapeutics, is a specialist in corporate law with over 25 years of experience in international collaborations and corporate/commercial activities, including more than 15 years in the life sciences sector.

## **H1 2021 Financial Highlights**

For the reporting period, the Group – NOXXON Pharma N.V. and NOXXON Pharma AG – has not generated any revenues. The Group does not expect to generate any revenues from any product candidates that it develops until the Group either signs a licensing agreement or obtains regulatory approval and commercializes its products or enters into collaborative agreements with third parties.

In H1 2021, the Group generated K€142 in other operating income from the sale of raw materials and services as well as other income.

Operating costs increased by 213% in H1 2021 over the same period last year, most of this increase being driven by research and development (R&D) expenses, accounting for 81% of operating costs. The R&D expenses increased by 421% in H1 2021 over the same period last year as NOXXON continued to make progress with the clinical stage assets. General and administrative (G&A) expenses increased by 14% to support operational activities. These operating costs led to €5.9 million in net cash outflow from operations.

The Group was successful in strengthening its balance sheet by raising a total of €9.3 million in net proceeds from multiple sources, including €6 million via private placement.

These activities and fund raising in H1 2021 led the Group to report €13.7 million in cash and cash equivalents, in addition to having available secured financing of €10.45 million (nominal) drawable at the Company's discretion. These available resources mean that NOXXON has sufficient financial visibility into June 2022.

## **H1 2021 and Year-to-Date Clinical Highlights**

NOXXON had a busy and productive H1 2021 period on the R&D front with significant progress made on its lead asset, NOX-A12.

- NOX-A12 + radiotherapy in glioblastoma (GBM) Phase 1/2 study (GLORIA) in patients newly diagnosed with aggressive brain cancer is ongoing. All patients have been recruited in the low, mid and high dose cohorts (200, 400 or 600 mg NOX-A12 per week), and will have completed 6 months of therapy in Q1 2022. Data from two dose cohorts (low and medium) showed that:
  - o Five out of six patients showed reductions in tumor size with maximal reductions baseline ranging from 2% to 71%, including two objective responses (reduction larger than 50%);
  - o Five of six patients achieved reduced blood flow to the tumor compared with baseline;
  - o Comparison of pre-treatment to on-therapy tumor tissue from one patient in the low dose cohort revealed that NOX-A12 effectively suppresses the target.

Based on the data obtained from the initial dose cohorts, an expansion of the study with patients who would not benefit from standard of care chemotherapy is planned. NOXXON believes that the next step in development should be a pivotal trial following the current Phase 1/2 study and targets first market approval in 2025.

- NOX-A12 + immunotherapy. The *Journal for ImmunoTherapy of Cancer* published in October 2021 the final peer-reviewed results of the Phase 1/2 study (OPERA) of NOX-A12 and pembrolizumab in metastatic pancreatic and colorectal cancer patients who failed standard therapy.

## **Outlook for the Remainder of 2021 and 2022**

NOXXON continues to progress its ongoing Phase 1/2 clinical trial of NOX-A12 plus radiotherapy in first-line brain cancer (glioblastoma) patients who are shown by biomarker analysis of their tumor tissue to be resistant to the current standard of care chemotherapy. The clinical trial remains on track to report data from the third cohort (highest dose) in Q1 2022. The Company also continues to advance the regulatory filings for the expansion cohorts to explore additional patient populations and combination therapies in brain cancer.

The operational environment continues to be uncertain due to the COVID pandemic and its consequences and NOXXON remains dependent upon its service providers for drug manufacturing and conducting clinical trials.

NOXXON's long-term strategic plans now include the following trials by indication:

### NOX-A12 + radiotherapy in Brain Cancer:

- Completion of the ongoing Phase 1/2 dose escalation trial is planned for Q1 2022. Thereafter, additional data are expected from expansion arms testing NOX-A12 in another population of brain cancer patients or in combination with other agents.
- Anticipating that the ongoing Phase 1/2 trial data supports further development, NOXXON plans to initiate in 2022 a pivotal trial of NOX-A12 combined with radiotherapy in first-line MGMT promoter-unmethylated glioblastoma patients vs. standard of care, with first market authorization application and approval targeted for 2025.

### NOX-A12 + immunotherapy in Pancreatic Cancer:

- Following the promising results from the OPERA trial, NOXXON has decided to pursue the NOX-A12 + immunotherapy combination in second-line pancreatic cancer with a dosing regimen of NOX-A12 optimized to induce anti-tumor immune responses.
- A two-step approach is planned with a Phase 2 study (OPTIMUS) comparing two NOX-A12 combinations with anti-PD-1 antibody and two different standard of care chemotherapy regimens in second-line patients followed by a pivotal trial comparing the best combination to the standard of care.
- To conduct the OPTIMUS study, NOXXON and MSD (Merck & Co., Inc., Kenilworth, N.J. USA) have entered into a collaboration by which MSD will provide pembrolizumab (Keytruda®) and expert advice for the study protocol.
- As previously announced, first patients are expected to be dosed in Q2 2022. The study completion is expected in early 2024.
- This strategic approach will enable NOXXON to choose the optimal regimen to move forward into a randomized, controlled pivotal study targeting marketing authorization application and approval in 2027.

### NOX-E36 in Oncology:

The second clinical stage asset, NOX-E36, is also being readied for the first clinical trial of NOX-E36 in oncology. Manufacturing of clinical supply has been contracted and clinical trial supply is projected to be available in Q1 2022, and trial initiation is targeted for mid-2022.

The Half-Year Financial Report 2021 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 TME, NOXXON's approach works in combination with other forms of treatment to weaken tumor defenses against the immune system and enable greater therapeutic impact. NOXXON's lead program NOX-A12 has delivered final top-line data from a Keytruda® combination trial in metastatic colorectal and pancreatic cancer patients published at the ESMO conference in September 2020 and in July 2021 the company announced its Phase 2 study, OPTIMUS, to further evaluate safety and efficacy of NOX-A12 in combination with Merck's Keytruda® and two different chemotherapy regimens as second-line therapy in patients with metastatic pancreatic cancer. NOXXON is also studying NOX-A12 in brain cancer in combination with radiotherapy which has been granted orphan drug status in the US and EU for the treatment of certain brain cancers. GLORIA, a trial of NOX-A12 in combination with radiotherapy in newly diagnosed brain cancer patients who will not benefit clinically from standard chemotherapy has delivered interim data from the first two cohorts showing consistent tumor reductions and objective tumor responses. 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. Further information can be found at: [www.noxxon.com](http://www.noxxon.com)

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**About the GLORIA Study**

GLORIA (NCT04121455) is NOXXON's dose-escalation, phase 1/2 study of NOX-A12 in combination with irradiation in first-line glioblastoma (brain cancer) patients with unmethylated MGMT promoter (resistant to standard chemotherapy).

**About the OPTIMUS Study**

OPTIMUS (NCT04901741) is NOXXON's open-label two-arm phase 2 study of NOX-A12 combined with pembrolizumab and nanoliposomal irinotecan/5-FU/leucovorin or gemcitabine/nab-paclitaxel in microsatellite-stable metastatic pancreatic cancer patients.

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