Press Release

Pharnext takes full stock of its operating, strategic and financial situation

PARIS, France, March 11, 2024, 04:30 pm CET – Pharnext SA (FR001400N1P4 - ALPHA) (the "Company"), an advanced late-clinical stage biopharmaceutical company developing novel therapeutics for neurodegenerative diseases with high unmet medical need, provides a comprehensive overview of operational, strategic and financial issues following recent announcements.

UPDATE ON CLINICAL TRIAL RESULTS

As indicated in press releases on December 11, 2023[1], December 19, 2023[2] and February 28, 2024[3], data from the pivotal Phase III trial (PREMIER trial) of PXT3003, its drug candidate in Charcot-Marie-Tooth type 1A (CMT1A) disease, require refine analysis which is still ongoing.

As a reminder, on the primary efficacy endpoint of the PREMIER trial, the Overall Neuropathy Limitation Scale (ONLS), which measures functional motor disability, patients with mild to moderate CMT1A experienced improvement on both treatment and placebo, rather than the slow deterioration typical of CMT1A's natural progression. This unexpected improvement in the placebo group complicated the interpretation of the results based on this endpoint.

However, other data from PREMIER suggested no deterioration in the condition of patients under treatment, which is a positive sign in the context of a degenerative disease such as CMT1A. In the meantime, the trial reaffirmed the high safety profile of the treatment already established in all previous studies. This safety profile is crucial for the treatment of a chronic disease such as CMT1A.

In addition, pre-specified subgroup analyses of the PREMIER trial suggested an efficacy signal, including a better response in treated patients with a body mass index (BMI) of less than 25, or in patients under 45 years of age.

Finally, analysis of the data revealed that, while the study as a whole was indeed randomized into two arms (PXT3003 and placebo), the distribution of the two treatments within each clinical investigation center was not balanced, contrary to what is normally expected. This major factor may have had a significant impact on the study results.

The Company has therefore contested invoices issued by the contract research organization (CRO) mandated by Pharnext to conduct PREMIER trial, and further actions including legal action are envisaged.

Beyond this, the Company confirms, as announced on February 28, it is waiting for the upcoming results (by summer 2024) from the Phase III trial currently being conducted in China by partner Tasly (through a joint venture owned 30% by Pharnext) which acquired the licensing rights for PXT3003 in China in 2017, with 2 options:

- If results from the study in China are negative, Pharnext will analyze these results and draw the necessary conclusions in conjunction with the Company's shareholders.
- If results from the study in China are positive, showing a statistically significant benefit of PXT3003, Pharnext will continue its dialogue with the FDA and EMA to agree on a registration process for PXT3003 in CMT1A.

Given available data and the favorable outlook if results from the study conducted in China are positive, the Company considers it has sufficient satisfactory elements to maintain its operations, at least until receipt of the said results.

[1] Pharnext reports topline results from the pivotal Phase III clinical trial (PREMIER trial) of PXT3003 in Charcot-Marie-Tooth disease type 1A
[2] Pharnext intends to prepare registration and marketing authorization dossiers for PXT3003, its drug candidate in Charcot-Marie-Tooth disease type 1A
[3] Pharnext progresses in analyzing data from pivotal Phase III study of PXT3003 in Charcot-Marie-Tooth disease type 1A

UPDATE ON NEGOTIATIONS VALUING PXT3003 OPERATING RIGHTS

As announced on November 27, 2023[4], the Company decided to wait for the publication of PREMIER topline results before signing an exclusivity agreement with one of the candidate pharmaceuticals, and valuing PXT3003. At that time, the Company had received 3 main offers, including 1 binding and 2 non-binding, from pharmaceutical companies.

To date, the 3 main candidates are still waiting for final conclusions from the ongoing analyses as well as topline results from the study conducted in China, and none of them has formally declared withdrawal from the process. Even more, working meetings are being scheduled with some candidates to analyze available data. The Company hopes these candidates will be able to update their position in terms of intent and valuation.

UPDATE ON CASH CONSUMPTION AND COST REDUCTION PLAN

In this context, as announced on January 17, 2024[5], the Company embarked on a drastic cost-cutting plan with the aim of reducing cash consumption from operating expenses from an average of €2.0m per month in S1 2023 to an average of €0.5-0.9m per month in S1 2024.

In February 2024, cash consumption by operations was €0.57m.

If results from the study in China are positive, the Company will be able to reactivate some of its expenses, with a relaunch budget estimated at €1.0-1.5m per month and a view to submitting PXT3003 for registration in CMT1A by the FDA and EMA. In this case, the Company plans to pass on all or part of these additional costs to candidates for PXT3003 rights.

As announced on February 15, 2024[6], the Company is working to align its financial resources and commitments with main partners. These discussions have been initiated within the framework of a confidential conciliation procedure opened under the aegis of the Paris Commercial Court at the Company's request.

UPDATE ON THE COMPANY'S FINANCIAL STRUCTURE

On March 8, 2024, the Company had cash of €0.184m and theoretical capacities of €11.9m under the financing agreement with Global Tech Opportunities 13.

In addition to the cash burn described above, the Company's main commitments are as follows:

- Gross financial debt of €6m mainly comprising the cash agreement between Néovacs and Pharnext (€3m) and the bonds subscribed by Global Tech Opportunities 13 not yet converted into shares (€3m); debts not repayable in cash in the short term;
- Trade payables of around €7m, mainly comprising invoices issued by clinical trial partners.

Around 30% of these debts (by value) are currently being contested by Pharnext, and the conciliation process currently underway aims to renegotiate the amount and maturity of debts borne by the Company. Several of the Company's major creditors, already representing more than 50% of debts (by value) and expected to rise to nearly 80% in the next few weeks, agreed to suspend the payment of their debts, if necessary, pending results from the study in China, which reinforces the principle of going concern in the short term.

The Company will provide regular updates on the subject.

UPDATE ON THE SHAREHOLDERS' MEETING TO BE HELD ON FEBRUARY 15, 2024

On February 15, 2024, the Company's shareholders were convened for a general meeting to discuss the Company's situation and outlooks. As part of discussions, shareholders received the special report issued by the Company's statutory auditors, who warned of their uncertainties regarding the Company's ability to continue as a going concern[7], as well as the management's responses.

[4] Pharnext unveils new calendar for negotiations valuing its drug candidate in Charcot-Marie-Tooth disease type 1A
[5] Pharnext commits to a drastic cost-cutting plan and receives support from its financial partners to further enhance the value of its drug candidate for Charcot-Marie-Tooth disease type 1A
[6] Point à la suite de l'assemblée générale des actionnaires convoquée le 15 février 2024 (French version only)
[7] Stage 2 of the alert procedure

The shareholders' meeting could not validly be held for lack of a quorum, and the conciliation procedure in progress has the effect of suspending the alert procedure initiated by statutory auditors. There are therefore no plans to reconvene the meeting in the short term.

UPDATE ON THE NEXT STEPS IN THE CONCILIATION PROCESS

The current conciliation procedure is open for a period of 3 months, i.e. until May 15, 2024, with a possible extension of 1 month, which should enable the Company to maintain its activities until data from the PREMIER trial are fully analyzed and, above all, until topline results from the study in China are issued.

This period should give the Company time to restructure its liabilities and prepare for the next steps post-announcement of these results.

UPDATE ON PHARNEXT SHARE LISTING

The Company asked Euronext to suspend the listing of its shares with effect from March 6, 2024, pending publication of this press release.

The Company therefore applied to Euronext to resume trading in its shares from the session of March 12, and will continue to inform the market on a regular basis as part of its periodic and ongoing information obligations. In this respect, Pharnext aims to publish its 2023 financial statements by April 30, 2024, at the latest.

Hugo Brugière, Manager of Pharnext, said: "*We have heard requests for a full update on our latest announcements and the situation to date regarding results from clinical trials, discussions with partners, financial situation and next steps.*
The horizon is clearly set, and results from the study conducted in China will be a turning point for Pharnext. If they are positive, we will once again have the opportunity to create a great deal of value. If they are negative, we will decide with the Company's shareholders what we want to do."

Disclaimer
Pharnext arranged (I) financing in the form of convertible bonds financing (OCEAN-BSA) with Global Tech Opportunities 13 which, after receiving the shares resulting from the conversion or exercise of these instruments, will not remain shareholder of the Company, and (II) financing in OS bonds which were subsequently transferred to a trust, which is now responsible for their equitization.
The shares resulting from the conversion or exercise of the above-mentioned securities will generally be sold on the market at very short notice, which may create strong downward pressure on the share price. In the specific case of the trust, the shares are sold on the market in accordance with the terms set out in the trust agreement.
Shareholders may suffer a loss of their invested capital due to a significant fall in the Company's share price, as well as significant dilution due to the large number of securities issued to Global Tech Opportunities 13 and/or the trust.
Investors are advised to exercise extreme caution before deciding to invest in the securities of a listed company that carries out such dilutive financing transactions, particularly when they are carried out in succession. The Company wishes to point out that this is not the first dilutive financing transaction it has undertaken.

About Pharnext
Pharnext is an advanced clinical-stage biopharmaceutical company developing novel therapies for neurodegenerative diseases currently without satisfactory therapeutic solutions. Pharnext has a first-in-class drug candidate, PXT3003, in development for Charcot-Marie-Tooth disease type 1A (CMT1A), a rare, debilitating, inherited peripheral neuropathy. PXT3003 benefits from orphan drug status in Europe and the United States. More information at www.pharnext.com.
Pharnext is listed on the Euronext Growth Stock Exchange in Paris (ISIN code: FR001400N1P4).

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