Year-end Report, 2019

Q4 October – December 2019

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FOURTH QUARTER (OCTOBER - DECEMBER 2019)

- Operating income amounted to MSEK 0 (0)
- Costs amounted to MSEK 8.0 (11.6)
- The result before and after taxes amounted to MSEK -8.0 (-11.6)
- Earnings per share amounted to SEK -0.31 (-0.54)

YEAR AS A WHOLE 2019 (JAN - DEC 2019)

- Operating income amounted to MSEK 0 (0)
- Costs amounted to MSEK 25.1 (24.2)
- The result before and after taxes amounted to MSEK -25.1 (-24.2)
- Earnings per share amounted to SEK -1.04 (-1.13)

SIGNIFICANT EVENTS DURING THE FOURTH QUARTER

- WntResearch announced that it had emerged that a now criticized contract laboratory had been used by the company in the past. The contracted research was carried out between 2010 and 2016. The contract research company has been certified according to GLP (Good Laboratory Praxis), which is a regulatory certification.
- WntResearch reached an important milestone by including the twentieth patient in the NeoFox study. This means that the recruitment target for performing the initial safety assessment was reached.
- WntResearch announced that a renewed application was submitted to the Hungarian authority, following a positive assessment of the clarifications provided to the ethics committee by the Company. The message that a new application must be submitted, in combination with a lower-than-expected recruitment rate in Spain, induced delays in the reading of study results.
- WntResearch announced few reported side effects from the NeoFox study; Foxy-5 treatment considered safe and well tolerated. The Data Safety Monitoring Board (DSMB) for WntResearch's NeoFox study convened to analyze the reported side effects from the first ten patients, which on average received 7 weeks of treatment with Foxy-5 and underwent surgery. As expected, the results show few side effects, and due to this positive analysis the study can proceed according to plan.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- WntResearch announced with deep sadness that the member of the board Sten Trolle had passed away after a short illness. He was one of the founders of WntResearch, and participated actively in the operations during the first years. Sten Trolle was reelected to the board of WntResearch in 2018.
- WntResearch announced that the Hungarian authority approved the Company's application to start the NeoFox study in 12 clinics in Hungary.

RESULT IN BRIEF

kSEK	Q4 2019	Q4 2018	**Year 2019**	**Year 2018**
Operating income	0	0	0	0
Operating costs	-7,975	-11,553	-25,082	-24,206
Operating result	-7,975	-11,553	-25,082	-24,206
Result for the period	-7,975	-11,553	-25,082	-24,206

COMMENTS FROM OUR CEO

The focus during the fourth quarter has almost exclusively been on the clinical trial and on facilitating the provision of information according to plan. Additional applications have been submitted in both Hungary and Spain to increase the number of clinics and thereby accelerate patient recruitment.

An extended application in Spain was approved, and seven new clinics could be added. We currently have 17 Spanish clinics, most of them with patients included.

By early November, an important milestone was achieved as we included the 20th patient – thus reaching the number required to carry out an initial safety assessment of Foxy-5 administration to patients. At the end of December, the assessment was concluded and the findings were presented to the safety committee, which gave its approval to proceed with the clinical trial according to plan. This stamp of approval will facilitate patient recruitment and enhance the treating physicians' trust.

At the moment there are 37 patients included in the trial, which means an increase by 14 patients since late December.

At the end of the quarter, our application to initiate the study was unexpectedly rejected by the Hungarian authorities. We immediately responded and addressed the reasons for refusal; a second application was submitted, and this was approved very swiftly during the current quarter.

However, in combination with a slow recruitment rate in Spain, the result of the process was that we failed to meet our estimated patient recruitment. Our initial forecast, on which the estimate to potentially be able to begin data evaluation by summer 2020 was based, relied on a quick initiation of patient recruitment in Hungary for safety margin. Due to the Hungarian authority's decision to initially reject the initiation of the study, it is now entirely conditioned on the already included patients not deviating from our assumptions based on historic assessment of risk and WNT5A expression.

Most encouragingly, we find that the time between operation and relaunch of Foxy-5 treatment has decreased following the protocol amendment that was applied during the last quarter. It is difficult to determine the consequences of a longer post-operation interruption of administration (as observed in the patients first included) with any certainty, and future analyses will show.

The criteria we are using for inclusion in the statistical analysis are the stage of the cancer at the onset of treatment and the level of WNT5A expression in the primary tumor. These are necessary parameters to take into account in order to assess how many of the patients included in the study that fulfill the criteria to be included in the statistical analysis.

An initial assessment of level of risk and WNT5A expression will be brought forward and carried

out concertedly with regard to treated patients during Spring 2020. This assessment will be of significant importance in confirming the Company's assumption that approximately 70 percent of patients have a low WNT5A expression as well as that the risk of relapse has been correctly estimated in the clinical diagnosis, that is, 30-60 percent in the patient group. Provided that this is correct, we will be able to analyze and compare the outcome of ctDNA in plasma for 12 patients each in the control and treatment arm respectively, that have undergone surgery at least 3 months prior to analysis; this will be carried out during the Summer of 2020. It still remains to be seen whether this patient base is sufficient to observe an efficacy trend. The Company hopes to be able to include additional patients in February and early March to improve the patient base of the analysis. If the patient base is deemed to be insufficient, there will be analysis made at a regular basis while the patient base increase and the time from surgery increase.

Preclinical trials have been conducted within psoriasis and Box-5. Previous results have shown elevated levels of WNT5A in the damaged skin of psoriasis patients. Few preclinical models are considered to be useful for determining the efficacy of novel drugs, and Box-5 has been tested with a model which is recommended by many research teams. In an early study, we were able to demonstrate elevated WNT5A levels in this model. In continued experiments where Box-5 was compared with a control group, it was discovered that the model needed to be optimized. At the same time, it was found that Box-5 did not have a negative effect on the disease. According to a preliminary assessment of the results from new experiments where the treatment schedule had been optimized, Box-5 likely has no effect in this model. In recent days, we have also received results from another study conducted by an external party, which does not demonstrate a treatment response from Box-5 either.

The overall results from these studies leads the Company to consider them not attractive for commercial cooperation. The Company will therefore put the project and further work relating to this indication on hold, and instead focus its entire effort towards the phase 2 study and Foxy-5.

We are continuing our preclinical work on Foxy-5 interactions with so called checkpoint inhibitors. The studies conducted in collaboration with the University of Copenhagen have been analyzed in detail without being able to verify the previously observed tendency to potentiate efficacy. The study, however, unambigously demonstrates that Foxy-5 does not have a negative impact on the efficacy of checkpoint inhibitors. It is known that different tumour types vary greatly in their expression of checkpoint molecules, both with regard to the kind of molecules and to expression levels.

Complementary studies on a number of new tumour cell types will be conducted during the current quarter to shed light on how the Company should handle this project in the future.

To summarize, this quarter did include some disappointment, but it also offered a positive development for the NeoFox study, which is the Company's main priority project. We also received a very encouraging piece of news this quarter: that NeoFox is now approved in Hungary as well. Intensive work is currently underway to activate these clinics and proceed with our study to reach our goal of demonstrating a positive effect from Foxy-5 in patients with colon cancer.

Peter Morsing, Chief Executive Officer

WntResearch in brief

WntResearch is developing an entirely new kind of cancer drug, which inhibits the tumour cells' ability to spread through the body and metastasize. The majority of cancer deaths are due to metastases, and there are no therapies available that can prevent that. Foxy-5, the Company's most advanced drug candidate, is a peptide that mimics the body's own WNT5A protein. In preclinical trials, Foxy-5 has demonstrated ability to suppress the mobility and invasive power of cancer cells, and thus to inhibit metastasis. Phase 1 studies on patients with colon, prostate and breast cancer have demonstrated a good safety profile and favourable pharmacokinetics, and early data indicates biological activity. A clinical Phase 2 multicenter study on patients with colon cancer is presently underway, aiming to study the anti-metastasizing efficacy of Foxy-5. WntResearch's share is listed on Spotlight Stock Market. For more information, please visit: www.wntresearch.com

OPERATIONS

ONGOING ACTIVITIES

The Phase 2 study with Foxy-5, called the NeoFox study, is conducted in patients with colon cancer that are considered to have a high risk of relapse after their primary tumours have been surgically removed. To optimize the effect of Foxy-5 on tumour spread, treatment is initiated at the time of diagnosis. The chosen criteria for patients to be included in the study are considered to be fairly highly indicative of the stage of the tumour and the risk of metastasis. At the start of treatment, it is not known whether patients have a high or low expression of WNT5A in their primary tumour. It is the levels of WNT5A in the surgically removed primary tumours that will determine whether or not the patients will be included in the statistical evaluation.

The treatment with Foxy-5 will continue for a maximum of 12 weeks, but will be terminated earlier in the event that a patient starts chemotherapy within this time period. The study will compare the effect of Foxy-5 with a control group without Foxy-5 treatment. Foxy-5-treated patients will be monitored and analyzed in two groups: one group with low and one group with high expression of WNT5A. Even those patients who have a high expression of WNT5A will complete the treatment and be analyzed as a stand-alone group, as it is important to study the safety and the possible efficacy of Foxy-5 in this group as well.

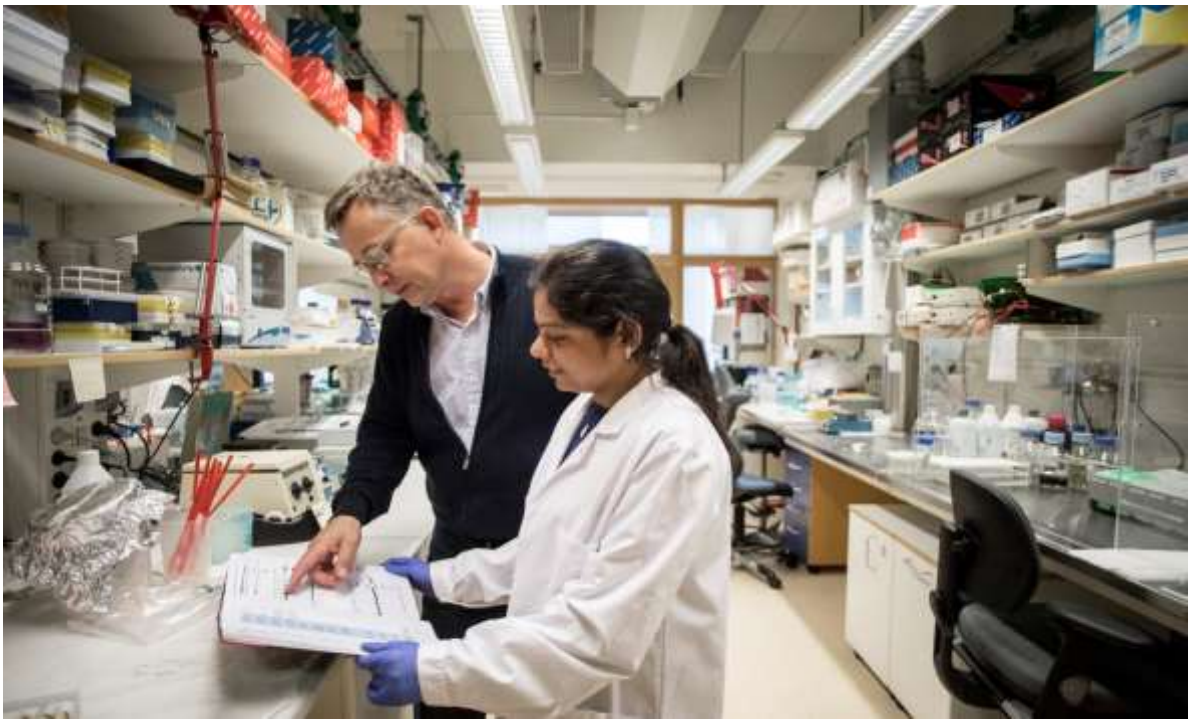
Patients will be followed for a total of 24 months and will be continuously evaluated every three months post surgery. The primary purpose is to document how Foxy-5 impacts time to relapse and the number of patients who experience metastatic relapse. This will be carried out through conventional methods, but also by analysis of circulating tumour DNA (ctDNA). In addition to WntResearch's own study results, published studies on ctDNA have been important for designing the Phase 2 study to be able to demonstrate an anti-metastatic effect of Foxy-5 more quickly, as a proof-of-principle. There is scientific evidence that the analysis of ctDNA in blood provides a much earlier indication of relapse than other available methods; ctDNA has, therefore, been chosen as a surrogate marker for the effect of Foxy-5. Depending on the primary risk level, and based on commonly used endpoints, the majority of all recurrences usually occur within 12-24 months after diagnosis. Since the Phase 2 study is an open study, each follow-up event when the treatments are completed will provide continuous information on the frequency of recurrence in the different study groups.

Combination options with other cancer drugs

Clinical studies have shown unambiguously that treatment with Foxy-5 does not result in any severe side effects. Therefore, Foxy-5 can be used in conjunction with those chemotherapy therapies that dominate today's treatment of cancer patients. The idea is to reduce the tumour burden with the help of chemotherapy, and at the same time counteract metastasis using Foxy-5. In addition, there may be opportunities for combination therapies with the immuno-oncological treatments that are now rapidly gaining ground. WntResearch has recently concluded a collaboration with the Department of Immunology and Microbiology at the University of Copenhagen. The results of these preclinical studies show that Foxy-5 can be given concurrently with immuno-oncological drugs without affecting their effect. These results broaden the treatment possibilities and thus the market for Foxy-5. Additional studies have been initiated to identify further tumour types and thus examine the possible interactions between Foxy-5 and these drugs further.

A collaboration is ongoing with the Uppsala-based biotech company Biovica, which has developed a highly sensitive method to detect thymidine kinase (TK). Thymidine kinase has in several other studies on other forms of tumours been shown to correlate strongly with high rate of relapse. We hypothesize that low levels of WNT5A is correlated to high rate of relapse, and the collaboration aims to investigate whether such a correlation between thymidine kinase, WNT5A and relapse exists. Should this be the case, it would be possible to use TK as a so-called companion diagnostic, that is, a marker to identify patients with high relapse rate, where Foxy-5 would have the greatest impact.

WntResearch is also engaging in other activities that aim to strengthen the company's competitiveness and project portfolio further.



"WntResearch is developing an entirely new kind of cancer drug, based on pioneering research from Lund University that shows that the body's own WNT5A protein plays an important role for the tumour cells' ability to move and spread through the body. Most deaths in cancer can be attributed to tumour spread (metastasis), and the demand for a specific treatment to counteract this process is thus immense."

UPCOMING ANNOUNCEMENTS

Interim report January – March 2020 is presented on 19 May 2020

Interim report January – June 2020 is presented on 13 August 2020

Interim report January – September 2020 is presented on 12 November 2020

Year-end report for 2020 is presented on 25 February 2021

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CONTACT:

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