Quarterly Report 2019

Q3 July – Sept 2019

Date of publication: 14 November 2019

WntResearch AB (publ) Reg.no. 556738-7864

www.wntresearch.com

THIRD QUARTER (JULY-SEPTEMBER 2019)

- Operating income amounted to MSEK 0 (0)
- Costs amounted to MSEK 7.3 (-5.4)
- The result before and after taxes amounted to MSEK -7.3 (-5.4)
- Earnings per share amounted to SEK -0.29 (-0.25)

THE FIRST NINE MONTHS OF THE YEAR (JANUARY-SEPTEMBER 2019)

- Operating income amounted to MSEK 0 (0)
- Costs amounted to MSEK 17.1 (12.7)
- The result before and after taxes amounted to MSEK -17.1 (-12.7)
- Earnings per share amounted to SEK -0.73 (-0.59)

SIGNIFICANT EVENTS DURING THE THIRD QUARTER

- WntResearch announced an increase of the number of centers in Spain. To speed up the pace even more, Hungary was chosen as the third country to be included in the clinical study.
- WntResearch and Sage group initiated a cooperation to accelerate the work to identify and engage prospective partners in view of the results from the ongoing Phase 2 study on Foxy-5.
- WntResearch announced that information from two pre-clinical studies had been submitted to patent offices to support the Company's patent application for treatment of psoriasis with Box-5.
- WntResearch announced the completion of an update to the study protocol to optimize the outcome of the NeoFox study, and the filing of an application to initiate the study in Hungary.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- 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 when the twentieth patient was included in the NeoFox study. This means that the recruitment target for performing the initial safety assessment has been reached.

RESULT IN BRIEF

kSEK	Q3 2019	Q3 2018	Q1-Q3 2019	Q1-Q3 2018	Year 2018	Year 2017
Operating income	0	0	0	0	0	0
Operating costs	-7,324	-5,362	-17,107	-12,653	-24,206	-33,732
Operating result	-7,324	-5,362	-17,107	-12,653	-24,206	-33,732
Result for the period	-7,324	-5,362	-17,107	-12,653	-24,206	-34,582

COMMENTS FROM OUR CEO

As the third quarter of the year began, our focus was to activate the clinics that had been approved to recruit patients for our clinical phase 2 study. In parallel with the activation of new clinics, several follow-up activities were carried out at centers with low recruitment rate. Subsequently, the cooperation with one of the clinics was terminated.

Since the recruitment rate initially fell short of plan, additional clinics were identified in Spain. In early September, an application to start the first four of those clinics that met our requirements was submitted to the authorities. Soon thereafter, that application was granted. The work to activate these clinics has been conducted in parallel with the application process, and has been progressing according to plan.

Before having a clear and certain indication that things were accelerating in Spain, we decided to submit another application to start the study in Hungary as well. An effective and well-managed process culminated with the submission of the application to the Hungarian authorities at the end of September. We will continue to communicate with the Hungarian authorities during this quarter, while also negotiating contracts with the clinics concerned.

When the first patients in the study had completed their treatment in the second quarter, and we received the first reports from our monitors, we realized that we had to define the study protocol better. This applies in particular to the treatment of patients in connection with the surgical process. To allow patients to benefit from the full potential of Foxy-5, we decided to update the protocol to include adjuvant therapy. This update is pending approval by Spanish authorities. The study now includes more than 20 patients, and the number is growing by the week. The adjuvant therapy is covered by the protocol, but has previously not been laid down in explicit, written instructions.

As our clinical trial was being established, the time had also come to begin looking for prospective cooperation partners. To streamline this effort, we have attracted a highly reputed partner with a global network: the Sage group (Sage). Sage has a market position that allows it to pick and choose those projects it deems to have substantial commercial potential. It is very positive that Sage wants to work with WntResearch; we consider it a seal of quality for our work, and it is important to note that Sage obtains the greater part of its revenue from successful business transactions.

Within the psoriasis area, we are engaged in dialogue about using the open innovation platforms that are avaible through leading dermatology companies; the aim here is to

generate more data related to efficacy signals to supplement our own experiments. At the end of the quarter, we submitted additional data to the patent office in order to strengthen the patent regarding possible treatment for psoriasis patients.

After the end of the quarter, a regrettable incident occurred at a contract research company that we last hired in 2016. The events, that have attracted attention, are not related to our trials which have all been reported without serious side effects. These events have no impact on our operations. During the period when we contracted the company, both announced and unannounced inspections were carried out by the relevant authorities in Germany responsible for ensuring that the operations are carried out in compliance with the legislation in place. We have requested but are yet to receive more information from the authorities concerned.

The fourth quarter has begun in a positive spirit; we are seeing that patient recruitment is picking up speed, and the goals that we have set for the company are within reach.

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 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 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 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 after completion of treatment will provide continuous information on the frequency of recurrence in the different study groups.

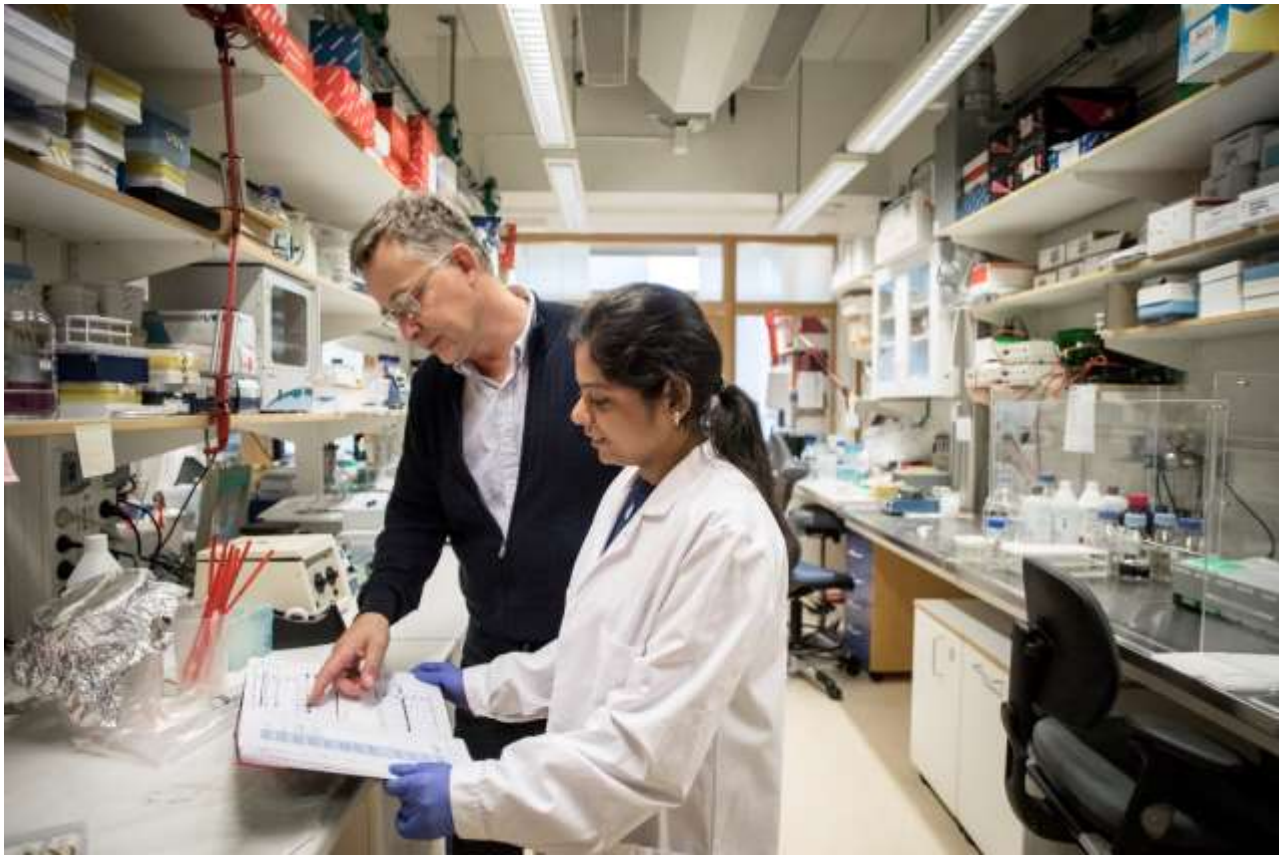
Combination options with other cancer drugs

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 initiated 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.

WntResearch has also entered into a collaboration 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 to 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 engaging in a number of other activities that aim to strengthen the company's competitiveness and project portfolio further.

In order to optimize the value of our portfolio even further, we have initiated a project for our other product, the WNT5A antagonist Box-5. It is well established that plaques in psoriasis patients contain elevated levels of WNT5A. One way of treating psoriasis could thus be to administer the WNT5A antagonist Box-5. Since psoriasis lies beyond the cancer area, further development will be carried out through third-party collaboration.



"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

Year-end report 2019 is presented on 20 February 2020

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 2020 is presented on 25 February 2021

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CONTACT:

Peter Morsing, CEO of WntResearch, email pm@wntresearch.com

Address: WntResearch AB, Medeon Science Park, Per Albin Hanssons väg 41, 205 12 Malmö, Sweden