



## **Highlights**

- Expansion of upcoming Radspherin<sup>®</sup> clinical trial to include colorectal cancer patients
- Oncoinvent awarded NOK 4.6 million in innovation funding
- Oncoinvent receives Manufacturer's Authorization for Medicinal Products (GMP certificate)
- Distribution agreement signed with radiopharmaceutical wholesaler
- New findings in preclinical testing requires additional testing of Radspherin<sup>®</sup> before initiation of clinical phase I.

# **Operational review**

During first quarter of 2019 Oncoinvent has reached several significant milestones important for the continued development of Radspherin®. These milestones come as a result of an organization working systematically and with a strong focus in moving the company's lead product, Radspherin® into clinical phase development:

### Expansion of upcoming clinical trial program

It was announced in the first quarter that Oncoinvent would be starting two Radspherin® phase I clinical trials. In addition to the previously announced trial to test Radspherin® in the treatment of peritoneal carcinomatosis in ovarian cancer patients, the company now plans to run a second trial to test Radspherin® in the treatment of peritoneal carcinomatosis in colorectal cancer patients.

### Innovation funding from Innovation Norway

Oncoinvent will receive 4,6 MNOK in innovation funding together with Oslo University Hospital receiving 3,3 MNOK – for a total of 7,9 MNOK to perform a phase I study in colorectal cancer patients suffering from peritoneal carcinomatosis. This financing enables the company to expand the clinical trial program with an additional study developing Radspherin®.

### GMP Certificate

As part of the development strategy for Radspherin® Oncoinvent decided early on that the production technology for Radspherin® is to be viewed as a key core competence and that the company would produce clinical trial material in house in its own manufacturing premises. The GMP (Good-Manufacturing-Practice) certificate from the Norwegian Medicine Agency received in Q1 of 2019 is a significant milestone and



confirmation of the quality of the efforts expended by the company since the inauguration of the production facility. This gives Oncoinvent the necessary capacity and flexibility to fully control the production of Radspherin® for the upcoming clinical trials program.

### Distribution agreement for radiopharmaceuticals

The logistics of Radspherin® distribution to the clinical sites will be of vital importance and will directly impact the success of the upcoming clinical trials. The distribution agreement signed with Institute for Energy Technology (IFE) during Q1 secures a reliable delivery of Radspherin® to participating clinical collaborators and customers.

## New preclinical data with unexpected findings

As part of the preparation for initiating the clinical phase 1 studies, Oncoinvent has performed additional preclinical testing. The company has decided that recent findings require further investigation and consideration. The recent preclinical findings indicate that a fine-tuning of the Radspherin® product composition would be beneficial and would maximize the clinical effectiveness of the product. The company is currently assessing the impact of these latest developments on the start date and completion of the phase 1 clinical trials. The company is currently targeting a start of the phase 1 studies in Q4 2019. More information and an update to the status of the upcoming studies will be provided in the Q2 Quarterly Report.

#### **Financial review**

In the 1<sup>st</sup> quarter of 2019, Oncoinvent had a Net operating loss of minus NOK 12.4 mill compared to NOK 9.6 mill. the previous year. The company received a total of NOK 1.2 mill. (NOK 0.5 mill.) in grants from the Norwegian Research Council during the quarter which included support from the BIA program as well as the Industrial PhD program.

Total operating expenses during the quarter was NOK 13.5 mill. an increase from NOK 10.1 mill. from the same period previous year. The increase was according to plan and is a result of the establishment of a manufacturing organization certified for manufacturing clinical trial material (GMP certification).



Other operating expenses was NOK 7.0 mill. (NOK 6.5 mill.), a small increase from previous year. These expenses are expected to increase as soon as the clinical trials are initiated. The company had NOK 145.1 mill. in cash and cash equivalents at the end of the quarter.

KEY FIGURES		1st QUARTER		YTD		FULL YEAR
AMOUNTS IN NOK		2019	2018	2019	2018	2018
TOTAL REVENUES AND OTHER INCOME		1 230 730	467 713	1 230 730	467 713	10 458 850
Payroll and related expenses		6 569 312	3 547 300	6 569 312	3 547 300	15 617 140
Other operating expenses		6 979 695	6 517 791	6 682 873	6 511 801	29 579 761
TOTAL OPERATING EXPENSES		13 549 007	10 065 091	13 252 185	10 059 101	45 196 901
Finance cost and other income	-	32 656	3 790	- 32 656	3 790	1 686 127
NET OPERATING PROFIT(LOSS) FOR THE PERIOD	-	12 350 933 -	9 593 588	- 12 054 111	- 9 587 598	- 33 051 924
Net Proceeds from equity issue		-	-	_	-	25 000
Cash and cash equivalents, end of period		145 118 078	179 662 158	145 118 078	179 662 158	153 553 317
Total number of shares, beginning of period		13 187 181	13 184 681	13 187 181	13 184 681	13 184 681
Total number of shares, end of period		13 187 181	13 184 681	13 187 181	13 184 681	13 187 181

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The Board of Directors Oncoinvent AS

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