

QUARTERLY REPORT 3rd QUARTER 2020



Highlights

- Phase 1 clinical trial in patients suffering from peritoneal carcinomatosis from colorectal cancer RAD-18-002 advances to second dose level
- Second clinical site opened for Phase 1 clinical trial for patients with peritoneal carcinomatosis from ovarian cancer, RAD-18-001

Oncoinvent is performing two Phase 1 clinical trials with use of innovative therapy for treatment of peritoneal carcinomatosis from colorectal cancer (RAD-18-002) and ovarian cancer (RAD-18-001), respectively. The primary objective of the two ongoing studies is to identify the optimal dose of Radspherin[®] for treatment of peritoneal carcinomatosis. In addition to determining the safety parameters of the drug, the phase 1 trials will enable us to obtain key biodistribution information and, potentially, initial indication of treatment efficacy.

Operational review

In the third quarter of 2020 Oncoinvent received clearance from the RAD-18-002 trial Safety Monitoring Committee to proceed to the second dosing cohort of 2 MBq in the first-in-human Phase 1 clinical trial with Radspherin® in colorectal cancer patients suffering from peritoneal carcinomatosis.

At the end of the third quarter all necessary preparations were completed in order to open the second clinical trial center at UZ Leuven in Belgium, for the Phase 1 clinical trial in ovarian cancer patients, suffering from peritoneal carcinomatosis (RAD-18-001).

The company sees this as an important step in the development of Radspherin[®] as UZ Leuven has been recognized as a 'Center of Excellence for Advanced Ovarian Cancer Surgery' by the European Society of Gynecological Oncology (ESGO). It is anticipated that recruitment of patients will begin in October.

By the end of the third quarter seven patients have been recruited to the RAD-18-002 study while one patient has been recruited to the RAD-18-001 study. Based on current projections we are on track to complete the dose range finding part of the Phase 1 trial next year and report early patient data from both studies by the end of 2021.



Although COVID-19 has not yet had a significant impact on the Radspherin[®] clinical program, the ongoing pandemic is extensively impacting new and ongoing clinical trials of various medical products irrespective of indication. It has the potential to adversely effect patient recruitment and immediate patient care and is also likely to affect the data collection and analysis in the months to come.

Financial review

Oncoinvent had an EBITDA of minus NOK 12.8 mill. in the 3rd quarter of 2020, compared to minus NOK 8.7 in the 3rd quarter of 2019. Total operating expenses during the quarter was NOK 14.4 mill., an increase from NOK 10.4 mill. the same period in 2019. For the Year-To-Date figures the company had an EBITDA of minus NOK 38.6 mill., compared to minus NOK 29.6 for the same period last year. The increase in expenses are in line with expectations and budget.

The company had NOK 124.7 mill. in cash and cash equivalents at the end of the quarter and expect to have sufficient funds to complete and present the Phase 1 safety data as previously announced.

KEY FIGURES 3rd		ARTER	YTD		FULL YEAR
AMOUNTS IN NOK	2020	2019	2020	2019	2019
TOTAL REVENUES AND OTHER INCOME	1 636 166	1 617 603	4 656 832	3 187 333	11 411 529
Payroll and related expenses	8 018 738	5 994 221	20 837 658	16 691 176	23 883 378
Other operating expenses	6 416 934	4 367 638	22 403 788	16 133 211	26 964 978
TOTAL OPERATING EXPENSES	14 435 671	10 361 859	43 241 446	32 824 387	50 848 356
EBITDA	- 12 799 505	- 8744256	- 38 584 614 -	29 637 054	- 39 436 827
Depreciation and amortization	1 091 326	1 091 642	3 589 361	3 269 164	4 434 609
EBIT	- 13 890 831	- 9 835 898	- 42 173 975 -	32 906 218	- 43 871 436
Finance cost and other income	109 373	- 52 327	152 739 -	68 536	- 1672053
NET PROFIT(LOSS) FOR THE PERIOD	- 13 781 458	- 9888225	- 42 021 236 -	32 974 754	- 42 199 383
Net Proceeds from equity issue	336	-	49 525 224	125 000	125 000
Cash and cash equivalents, end of period	124 732 425	125 562 444	124 732 425	125 562 444	118 337 860
Total number of shares, beginning of period	14 306 904	13 190 411	13 190 411	13 187 181	13 190 411
Total number of shares, end of period	14 310 264	13 190 411	14 310 264	13 190 411	13 190 411

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Oslo, 13. October 2020

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Glossary

Cytoreductive surgery	Cytoreductive surgery is an approach to cancer treatment that aims to reduce the number of cancer cells via resection of primary tumours or metastatic deposits.
GMP	Good manufacturing practices (GMP) are the practices and quality system procedures required by regulatory agencies to ensure that the pharmaceutical products manufactured are of the quality required for their intended use.
HIPEC	Hyperthermic Intraperitoneal Chemotherapy
Intraperitoneal injection	Intraperitoneal injection or IP injection is the injection of a substance into the peritoneal cavity. The method is widely used to administer chemotherapy drugs to treat some cancers, particularly ovarian cancer.
Metastases	Metastasis is the medical term for cancer that spreads to a different part of the body from where it started.
Microparticles	Microparticles are particles between 0.1 and 100 micrometers in size. Commercially available microparticles are manufactured in a wide variety of materials, including ceramics, glass, polymers, and metals. Microparticles have been found to have widespread applications in medicine, biochemistry, colloid chemistry, and aerosol research.
Peritoneal carcinomatosis	Peritoneal carcinomatosis is a type of cancer that occurs in the peritoneum, the thin layer of tissue that covers the peritoneal cavity. The disease develops when cancers of the appendix, colon, ovaries or other organs spread to the peritoneum and cause tumors to grow.
Peritoneal cavity	The space within the abdomen that surrounds the intestines, the stomach, and the liver. It is covered by thin membranes (peritoneum).
Radspherin®	Oncoinvent's lead product candidate currently being developed to treat peritoneal carcinomatosis
Radioisotope	A radioisotope (radioactive nuclide, radionuclide, or radioactive isotope) is an atom that has excess nuclear energy, making it unstable. This excess energy can be emitted from the nucleus as gamma radiation, or create and emit from the nucleus a new particle (alpha particle or beta particle), or transfer this excess energy to one of its electrons, causing that electron to be ejected as a conversion electron. During those processes, the radionuclide is said to undergo radioactive decay and emit ionizing radiation.
Radiotherapy	The treatment of disease, especially cancer, by means of ionizing radiation.