



特許証
(CERTIFICATE OF PATENT)

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(PATENT NUMBER)

発明の名称
(TITLE OF THE INVENTION)

放射線療法用粒子と懸濁液

特許権者
(PATENTEE)

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QUARTERLY REPORT
3rd QUARTER 2019

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2019)



Highlights

- Radspherin[®] patent issues in Japan
- Oncoinvent's 1st Industrial PhD graduate
- Targeting to have Radspherin[®] CTA ready by end of 2019.

Operational review

Radspherin[®] patent issues in Japan

Oncoinvent received notice that the final procedural processes have been completed and the patent covering lead product candidate Radspherin[®] has formally issued in Japan. This patent protection of Radspherin[®] will remain in effect until July 2036. The company now has patent protection for Radspherin[®] in the all major pharmaceutical markets including Japan, USA, and Europe.

Oncoinvent's 1st Industrial PhD graduate



Dr. Sara Westrøm has joined the Oncoinvent R&D team as Senior Research Scientist

Sara Westrøm defended her PhD thesis "Evaluation of Carrier Compounds for Systemic and Intracavitary α -Radionuclide Therapy of Cancer" on the 5th of September at the Radium Hospital. Sara's research has resulted in four publications and she is also co-inventor on Oncoinvent's Radspherin[®] patent. The company congratulates Dr. Westrøm on this major accomplishment and welcomes her to the R&D team.

Based on the success Oncoinvent has experienced with Sara and the two industrial PhD programs that are still ongoing, the company has decided to engage a new industrial PhD student that will work in Belgium together with the researchers at the University Hospital of Leuven (UZ Leuven) and KU Leuven. The focus of the industrial Ph.D. project will be the preclinical evaluation of the effects

of Radspherin[®] in an immune competent ovarian cancer mouse model. The project is designed to extensively characterize Radspherin[®] effects and look for optimal combinations with other therapies (such as standard chemotherapy and immunotherapy). Furthermore, the project will include participation in the first evaluation of Radspherin[®] in ovarian cancer patients.

Targeting to have Radspherin[®] CTA ready by end of 2019.

During the 3rd quarter the company has made significant progress in the development of Radspherin[®]. The company maintains its guidance with regards to submitting a new clinical trial application (CTA) to Norwegian, Belgian, Swedish, and German authorities during Q4 in 2019 in order to initiate the planned clinical trials in peritoneal carcinomatosis in ovarian and colorectal cancer patients.

Financial review

Oncoinvent had an EBITDA of minus NOK 8.7 mill. in the 3rd quarter of 2019, compared to minus NOK 4.7 in the 3rd quarter of 2018. The company reported an EBITDA of minus NOK 29.6 mill. YTD compared to NOK 24.0 in 2018. Total operating expenses during the quarter was NOK 10.4 an increase from NOK 7.0 the same period in 2018.

The operating expenses was significantly below expectations due to a strict expense policy as well as the planned clinical studies starting later as previously communicated. The company has had higher operating expenses within the R&D area as several preclinical studies have been carried out during the quarter with regard to formulation issues previously communicated. This shows the flexibility of the organization being able to adjust both the focus as well as operation once needed.

The company had NOK 125.6 mill. in cash and cash equivalents at the end of the quarter and expect to have sufficient funds to complete and present the phase I safety data as previously guided.

KEY FIGURES AMOUNTS IN NOK	3rd QUARTER		YTD		FULL YEAR
	2019	2018	2019	2018	2018
TOTAL REVENUES AND OTHER INCOME	1 617 603	2 369 061	3 187 333	4 122 633	10 458 850
Payroll and related expenses	5 994 221	2 637 726	16 691 176	10 276 717	15 617 140
Other operating expenses	4 367 638	4 410 389	16 133 211	17 806 543	25 592 754
TOTAL OPERATING EXPENSES	10 361 859	7 048 115	32 824 387	28 083 261	41 209 894
EBITDA	- 8 744 256	- 4 679 054	- 29 637 054	- 23 960 628	- 30 751 044
Depreciation and amortization	1 091 642	1 008 741	3 269 164	2 887 731	3 987 007
EBIT	- 9 835 898	- 5 687 795	- 32 906 218	- 26 848 359	- 34 738 051
Finance cost and other income	52 327	5 969	68 536	21 720	1 686 127
NET PROFIT(LOSS) FOR THE PERIOD	- 9 888 225	- 4 673 085	- 32 974 754	- 26 826 639	- 33 051 924
Net Proceeds from equity issue	-	25 000	125 000	25 000	25 000
Cash and cash equivalents, end of period	125 562 444	159 571 983	125 562 444	159 571 983	153 553 317
Total number of shares, beginning of period	13 190 411	13 187 181	13 187 181	13 184 681	13 184 681
Total number of shares, end of period	13 190 411	13 187 181	13 190 411	13 187 181	13 187 181

Oslo, 23. October 2019

The Board of Directors
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Glossary

GMP	Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture.
Intraperitoneal	Intraperitoneal injection or IP injection is the injection of a substance into the peritoneum (body 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 abdominal organs and surrounds the abdominal 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 contains the intestines, the stomach, and the liver. It is bound by thin membranes.
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 either 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.
Radiotherapeutics	The treatment of disease, especially cancer, by means of alpha or beta particles emitted from an implanted or ingested radioisotope, or by means of a beam of high-energy radiation.