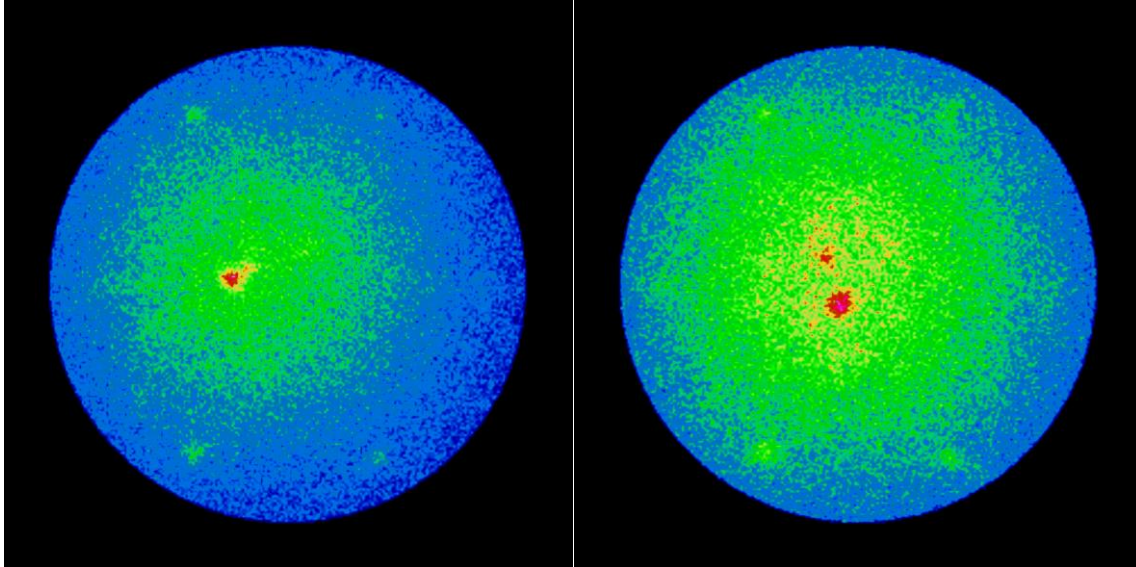


**1 hour**

**24 hours**



Two images from the successful in-vivo test of gamma camera imaging of Radspherin® distribution in the peritoneal cavity of rats

## **QUARTERLY REPORT**

### **Third quarter 2018**

## QUARTERLY REPORT – 3rd QUARTER 2018

### Highlights

- **Successful imaging of Radspherin® in pre-clinical study**
- **Radspherin® clinical formulation for phase 1 selected**
- **Oncoinvent hires two new key team members**

### Operational Review

Work towards moving Radspherin® into clinical trials in Q1 of 2019 continued during the third quarter of 2018. A key priority for the company was the preparation for the planned inspection of the Radspherin® production facilities by the Norwegian Medicines Agency in early Q4. The company also focused efforts on completing work necessary to send in a clinical trial application (CTA) during Q4.

#### **Successful imaging of Radspherin® in pre-clinical study**

The company performed imaging studies in rats using gamma cameras and SPECT CT scanners to test the feasibility of using these imaging modalities to measure the distribution of Radspherin® in human peritoneal (abdominal) cavities during the phase 1 clinical trials. Radspherin® particles were imaged by gamma cameras from 1 up to 96 hours after injection. Results from the imaging studies indicate the feasibility of using gamma camera images to confirm the distribution of Radspherin® in the abdominal cavity after administration in patients. Further imaging studies are being carried out to confirm this finding.

#### **Radspherin® clinical formulation for phase 1 selected**

Oncoinvent has selected a formulation for the Radspherin® drug product candidate that will be used during the upcoming phase 1 clinical trials based on the results of formulation development studies carried out in 2018 and completed in Q3 of 2018. GMP productions of the Radspherin® clinical drug product formulation will be carried out during Q4.

#### **Oncoinvent hires two new key team members**

The company is pleased to announce that Hans Matthias Hild and Helén Johansen Blanco have joined the Oncoinvent team during the 3<sup>rd</sup> quarter of 2018.

Dr. Hans Matthias Hild, Ph.D., has been hired as Head of Production and will be responsible for ensuring the supply of Radspherin® drug product during the clinical trials. Dr. Hild has over fifteen years of experience with international pharmaceutical companies including Avecia Biotechnology and GE Healthcare. He has successfully led large scale-up and technology transfer projects and has a strong, hands-on background in manufacturing science, GMP/Quality Assurance and production of radiopharmaceuticals.

Dr. Hild holds a Ph.D. in Biochemical Engineering from the Imperial College of Science, Technology and Medicine, London, England.

Helén Johansen Blanco has been hired as Head of Clinical Operations and will be responsible for the Radspherin® clinical trials. Ms. Blanco has eighteen years of international clinical trial experience ranging from phase 1 to phase 3 registration studies and has worked for major pharmaceutical companies including Astra Zeneca, Mylan, and Celgene as well as the internationally recognized clinical research organisation Covance. Ms. Blanco holds an M.Sc. from NTH in Trondheim.

## **Financial review**

### Profit and loss statement

Income in the 3rd quarter of 2018 was NOK 1,285,859 as grants for the research activities from the Norwegian Research Council (NRC) were recognized. The income figure includes support from the NRC BIA program totaling NOK 1,000,000 for the 3rd quarter.

Total operating expenses increased to NOK 12,657,060 in the 3rd quarter of 2018 from NOK 5,363,751 in the same quarter in 2017. Other operating expenses increased to NOK 8,565,369 in the 3rd quarter of 2018 compared to NOK 2,542,437 in the same quarter of 2017, mainly due to expenses associated with the manufacturing operations in the laboratory facility in Nydalen and costs related to preparation of the start-up of Oncoinvent's first clinical trial. Depreciations as included in other operational expenses amounted to NOK 1,008,741 in the 3rd quarter.

A broad range and high level of expertise is required for the in-house production of Radspherin® at the facility in Nydalen and for the management of clinical trials. To secure the quality and quantity of Radspherin, and the approvals required for the first clinical trial to commence in 2019, payroll and related expenses increased to NOK 4,091,691 in the 3rd quarter of 2018 compared to NOK 2,821,314 in the same quarter of 2017.

Key figures Amounts in NOK	3rd quarter		9 months		Full year
	2018	2017	2018	2017	2017
Total revenues and other income	1 285 859	359 667	4 113 333	1 613 706	5 680 898
Payroll and related expenses	-4 091 691	-2 821 314	-10 276 717	-6 281 827	-10 332 347
Other operating expenses	-8 565 369	-2 542 437	-20 495 615	-6 656 791	-12 580 460
Total operating expenses	-12 657 060	-5 363 751	-30 772 332	-12 938 618	-22 912 807
Finance cost and other income	11 961	2 754	21 720	-3 313	1 310 338
<b>Net operating profit (loss) for the period</b>	<b>-11 359 240</b>	<b>-5 001 330</b>	<b>-26 637 279</b>	<b>-11 328 225</b>	<b>-15 921 571</b>
Net proceeds from equity issue	0	0	25 000	210 283 494	210 283 494
Cash and cash equivalents, end of period	159 571 983	200 929 116	159 571 983	200 929 116	189 833 725
Outstanding shares, beginning of period	13 187 181	13 184 681	13 184 681	7 751 000	7 751 000
Outstanding shares, end of period	13 187 181	13 184 681	13 187 181	13 184 681	13 184 681

### Statement of financial position

In February 2017, Oncoinvent received net proceeds from the private placement at the amount of NOK 210,283,494. On September 30, 2018, Oncoinvent had total assets of NOK 187,250,390, with cash and cash equivalents of NOK 159,571,983. Shareholders equity was NOK 184,051,157.

Oslo, 24. October 2018

The Board of Directors

Oncoinvent AS

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### **Company news and updates**

Oncoinvent will on a quarterly basis present the company's development, including financial updates, through a newsletter.

Press releases will be issued whenever Oncoinvent reaches important milestones or significant events take place at the company.

October 2018

Quarterly report Q3-2018

## Additional Information

### Glossary of Terms

**computed tomography (CT):** An imaging technique that uses a combination of X-rays and a computer to create pictures of a body's organs, bones, and other tissues. It shows more detail than a regular X-ray.

**gamma camera:** A gamma camera ( $\gamma$ -camera), also called a scintillation camera or Anger camera, is a device used to image gamma radiation emitting radioisotopes, a technique known as scintigraphy. The applications of scintigraphy include early drug development and nuclear medical imaging to view and analyse images of the human body or the distribution of medically injected, inhaled, or ingested radionuclides emitting gamma rays.

**good manufacturing practices (GMP):** are the practices required in order to conform to the guidelines recommended by government agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products. These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

**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.

**single photon emission computed tomography (SPECT):** SPECT images are obtained following an injection which contains a small amount of radioactivity. This is used to determine how an area of the body is functioning. During the SPECT procedure a special camera rotates in a 360 degree arc allowing for reconstruction of three dimensional images.

**SPECT CT:** A SPECT CT scan is made up of 2 separate components, a SPECT scan and a CT scan. The images from each scan are fused together. The fused images can provide more accurate information about the anatomy and function of the area being scanned. For example, in areas such as the spine or feet, it can be difficult to determine from the Nuclear Medicine imaging alone whether the abnormality lies in the bone or the adjacent joints. The fusion of SPECT with CT images provides added confidence in identifying and localizing the problem.