



Picture 1. Containers with various amounts Radspherin®

Picture 2. Gamma camera images of the containers with Radspherin®

**Gamma camera images of Radspherin® phantoms demonstrate the possibility of imaging a dose of Radspherin®**

## **QUARTERLY REPORT**

### **Third quarter 2017**

## QUARTERLY REPORT – 3<sup>ND</sup> QUARTER 2017

### Highlights

- Imaging of Radspherin® successful
- Application for medical device classification submitted to TÜV
- Heads of Clinical Operations and Quality Control hired

### Operational Review

#### Radspherin® development program

In the third quarter of 2017 the company performed multiple preclinical studies with Radspherin®. One of the most significant studies carried out was a gamma camera imaging experiment with varying concentrations and volumes of Radspherin® to determine whether gamma radiation imaging could be used to measure distribution of Radspherin® in animal models. The results were positive, and the company is now planning biodistribution studies in rodent and large animal species using this imaging technique. Should the method prove useful in pre-clinical studies, the same imaging technique may potentially be used in clinical studies as well, to evaluate the distribution of Radspherin® in the peritoneal cavity.

Oncoinvent has submitted a classification review application to Technischer Überwachungsverein (TÜV SUD) in Germany for Radspherin®. TÜV is one of Europe's largest notified bodies that are responsible for providing CE approvals for medical devices. The company anticipates receiving an evaluation from TÜV SUD during the 4<sup>th</sup> quarter as to whether Radspherin® should be considered a class IIB or class III medical device. The results of the evaluation will have an impact on how Radspherin® is developed moving forward.

#### Collaboration with CPDC initiated

Oncoinvent initiated the collaboration with the Centre for Probe Development and Commercialization (CPDC) in Canada with a site visit and audit of CPDC's operations in the 3<sup>rd</sup> quarter. CPDC is currently assisting Oncoinvent with design and process aspects of Oncoinvent's pilot plant for Radspherin® production and will be responsible for scaling up of the Radspherin® production process to a commercial scale upon the successful completion of clinical trials with Radspherin®.

#### Clinical and quality management teams strengthened

Hedda Wold joined Oncoinvent as Head of Clinical Operations September 1. Hedda has over eighteen years clinical research experience from both Pfizer and Lytix Biopharma. Hedda reports to CMO Øyvind Bruland and is currently working together with Dr. Bruland on the clinical trial protocol design for Radspherin®.

Gro Hjellum joined Oncoinvent as Head of Quality Control September 1. Gro has over twenty-five years' experience within pharmaceutical R&D and has worked for companies such as Nycomed Imaging/Amersham Health/GE Healthcare as well as Algeta and Bayer Healthcare. Gro has a Master of Science in Radiochemistry and has extensive experience in the characterization and quantification of radioisotopes, radiotherapeutics, as well as microparticles.

## Gullhaugveien 7 - Construction of Oncoinvent's production and research facility

Construction of the new production and lab facility is nearing completion, and the company is planning on moving all its laboratory equipment from Kjelsåsveien 168B to the new laboratories in Gullhaugveien 7 at the end of October.

## **Financial review**

### Profit and loss statement

Income in the 2nd quarter of 2017 was NOK 359 667 as grants for the research activities from the Norwegian Research Council were recognized.

Total operating expenses were increased to NOK 5 363 752 in the 3rd quarter of 2017 from NOK 1 787 689 in the same quarter in 2016, reflecting the substantial shift in activity level and the intensified effort put into the construction of the pilot plant for Radspherin® production. Other operating expenses increased to NOK 2 542 437 in the 3rd quarter of 2017 compared to NOK 884 459 in the same quarter of 2016.

The required transformation of Oncoinvent into a full-scale development organisation with units assigned to production, quality control, regulatory affairs and pre-clinical as well as clinical trials implies a concomitant increase in the cost base. Payroll and related expenses was NOK 2 821 314 in the 3rd quarter of 2017 compared to NOK 903 230 in the same quarter of 2016.

Activated costs for investments, mainly associated with the new laboratory facility at Gullhaugveien 7 amounted to NOK 12 276 796 through the 9 first month of 2017

<b>Key figures</b>	<b>3rd quarter</b>		<b>9 month</b>		<b>Full year</b>
	<b>2017</b>	<b>2016</b>	<b>2017</b>	<b>2016</b>	<b>2016</b>
<i>Amounts in NOK</i>					
Total revenues and other income	359 667	471 598	1 613 706	911 931	2 579 559
Payroll and related expenses	2 821 314	903 230	6 281 827	2 019 497	3 541 977
Other operating expenses	2 542 437	884 459	6 656 791	2 076 116	3 967 857
Total operating expenses	5 363 752	1 787 689	12 938 618	4 095 613	7 509 834
Financial cost and other income	2 754	-7 083	-3 313	-5 339	60 943
<b>Net operating profit (loss) for the period</b>	<b>-5 001 331</b>	<b>-1 323 175</b>	<b>-11 328 225</b>	<b>-3 189 021</b>	<b>-4 869 332</b>
Net proceeds from equity issue	0	3 440 000	210 283 494	18 440 000	18 440 000
Cash and cash equivalents, end of period	200 929 116	17 008 939	200 929 116	17 008 939	14 864 562
Outstanding shares, beginning of period	13 184 681	7 407 000	7 751 000	5 907 000	0
Outstanding shares, end of period	13 184 681	7 751 000	13 184 681	7 751 000	7 751 000
Employees, end of period	14	5	14	5	6

## Statement of financial position

In February, Oncoinvent received net proceeds from the private placement at the amount of NOK 210 283 494. On September 30, 2017, Oncoinvent had total assets of NOK 215 004 217, with cash and cash equivalents of NOK 200 929 116. Shareholders equity was NOK 215 256 783.

## Major shareholders

Shareholder	# shares	%
SCIENCONS AS	3 185 000	24,2
GEVERAN TRADING CO LTD	1 100 000	8,3
BLAAHAUGEN AS	692 500	5,3
LARSEN ROY HARTVIG	678 000	5,1
RADIUMHOSPITALET	670 880	5,1
MUST INVEST AS	517 000	3,9
CANICA AS	493 300	3,7
SYNTAX A.S	440 000	3,3
BENTAX AS	400 000	3,0
LARSEN TROND	310 000	2,4
Other shareholders	4 698 001	35,6
<b>Total number of shares</b>	<b>13 184 681</b>	<b>100</b>

Oslo, 16 October 2017

The Board of Directors

Oncoinvent AS

## **IR Contact**

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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 takes place at the company.

October 2017

Quarterly report Q3-2017

## Additional Information

### Glossary of Terms

**biodistribution:** The distribution (static and dynamic) of compounds within a biological system or within an organism.

**class IIB & class III medical devices:** Depending on its intended purpose, a medical device may be classified as Class I (including Is & Im), Class IIa, IIb and III, with Class III covering the highest risk products. The higher the classification the greater the level of assessment required.

Classification of a medical device will depend upon a series of factors, including:

- how long the device is intended to be in continuous use
- whether or not the device is invasive or surgically invasive,
- whether the device is implantable or active
- whether or not the device contains a substance, which in its own right is considered to be a medicinal substance and has action ancillary to that of the device.

**gamma camera:** A gamma camera is a device used to carry out functional imaging scans of the brain, thyroid, lungs, liver, gallbladder, kidneys and skeleton. Gamma cameras image the gamma radiation from a tracer radioactive isotope introduced into the patient's body.

**microparticles:** Microparticles are particles between 0.1 and 100 micrometers in size. Commercially available microparticles are available 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.

**phantom:** An imaging phantom, or simply phantom, is a specially designed object that is scanned or imaged in the field of medical imaging to evaluate, analyze, and tune the performance of various imaging devices. A phantom is more readily available and provides more consistent results than the use of a living subject or cadaver, and likewise avoids subjecting a living subject to direct risk. Phantoms were originally employed for use in 2D x-ray based imaging techniques such as radiography or fluoroscopy, though more recently phantoms with desired imaging characteristics have been developed for 3D techniques such as MRI, CT, Ultrasound, PET, and other imaging methods or modalities.

**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 injected or ingested radioisotope, or by means of a beam of high-energy radiation.

#### **About Oncoinvent**

Oncoinvent AS is a privately held Norwegian company based in Oslo, Norway. The company is committed to developing new innovative products to provide better treatment options to cancer patients.

The company's founders started Oncoinvent in 2010 with a view to designing better cancer treatments by applying known physical and chemical principles of selected materials in new ways to maximize their medical benefit while minimizing potential safety concerns. This approach has allowed the company to develop a rich development pipeline and to explore multiple technological avenues before selecting a lead product candidate for preclinical testing. The company is currently in late stage preclinical testing with its lead product candidate Radspherin®.