Lytix Biopharma

.....improving nature's own defense mechanisms

Newsletter November 2015

## Lytix Biopharma announces

# Gert W. Munthe as new Chairman of the Board

Gert W. Munthe is Lytix Biopharma's new Chairman of the Board, after being elected by the General Assembly (GA) on June 11th 2015.

*"Lytix Biopharma is one of the most exciting companies in the Life Science sector today. I look forward to contributing to the successful development of the company,"* says Gert Munthe.

Munthe has been a member of the Lytix Biopharma board since GA 2014, and a shareholder for several years, and now he looks forward to an even more active role in Lytix Biopharma.

Munthe is the founder and Managing Partner of Herkules, a leading Nordic private equity player. He has more than 20 years' experience as a senior executive from both Norwegian and international business, as well as extensive life science experience. While at Nycomed (Imaging) 1989-1993 he was responsible for the blockbuster drug Omnipaque sold gobally through own subsidiaries as well as various licensing collaborations. Munthe was chairman at Pronova 2004 – 2013. Pronova's main product Omacor/Lovaza reached blockbuster status through global distribution agreements in this period.

*"Lytix Biopharma has a unique patented technology within the most exiting area in modern cancer treatment; immunotherapy of cancer",* says Gert Munthe.

Knut Eidissen, who has been of instrumental importance to Lytix Biopharma for several years decided to step down from the chair position. He remains in the Board together with John Sigurd Svendsen and Kari Grønås. The General Assembly has also elected three new highly experienced professionals to join the board.

*"Our new Board of Directors consists of professionals with extensive international drug development and commercialization experience. They will add tremendous value to our plans and we look forward to collaborating with them,"* says Unni Hjelmaas, CEO of Lytix Biopharma.

## THE THREE NEW BOARD MEMBERS

**Morten Jurs**

Jurs has broad executive experience from the pharmaceutical sector as well as non-executive experience from several board positions from both public and private companies. He is CEO in Stamina Group AS (a leading Scandinavian Health and Lifestyle company) and is former CEO and CFO in Pronova BioPharma ASA.

**Debasish F. Roychowdhury**

Roychowdhury is an oncologist with a background in R&D, regulatory affairs and commercial operations. He is President of Nirvan Consultants and serves in senior advisory roles for biotechnology companies. He is the acting CMO for Ra Pharmaceuticals and former CMO at Seragon Pharmaceuticals. He is also former Senior Vice President and Head of the Global Oncology Division at Sanofi, and former Vice President and head of Clinical Development at GlaxoSmithKline. Roychowdhury has also directed the Oncology global regulatory group at Eli Lilly and Company.

**Lena Torlegård**

She is an advisor on corporate communication, mainly dealing with financial, corporate and crisis communication. She has worked with a number of Life Science companies, among others Sobi, Karo Bio, Orexo and Medivir. She is currently a member of the Board of Directors for Nanologica - drug delivery and analytical chromatography.

# Expanding the LTX-315 trial

After presenting promising results from the ongoing LTX-315 trial, Lytix Biopharma will include more patients and increase both the dose and number of tumour lesions injected.

**Dr. Andrew Saunders** Chief Medical Officer in Lytix Biopharma

Lytix Biopharma presented preliminary LTX-315 monotherapy results at the European Cancer Congress in Vienna on the 26th of September. The results of the ongoing trial indicate promising emerging anti-tumour activity.

*"Our results show clear evidence of local tumour control, and increased immune cell infiltration in tumours injected with LTX-315. As for the effect on tumours not being directly injected, 6 of 8 patients for whom we have data had stable disease. This means either less than a 50 percent decrease or less than a 25 percent increase in tumour size, and reflects a tumour control effect. Our results compare favourably with Phase I data of other intra-tumoural immunotherapy agents,"* says Dr. Andrew Saunders, Chief Medical Officer at Lytix Biopharma.

Data was presented from 15 patients in five cohorts, with LTX-315 administered in doses ranging from 2 to 6 milligrams. Results indicate that Lytix Biopharma can safely increase the dose to seven milligrams.

*"There are no dose-limiting toxicities to-date. This means that there are no serious side effects that limit our ability to continue to increase the dose,"* says Dr. Saunders.

The dose-escalation Phase I trial will be followed by Phase I/II dose-escalation of LTX-315 in combination with other agents including immune checkpoint inhibitors.

**Parallell doses and new combinations**

Until now, Lytix Biopharma's researchers have been injecting tumor lesions one by one, so that one lesion is treated for 6 weeks before starting treatment in another lesion. Lytix have now started multiple concurrent injections, so that a patient might be injected in more than one tumour lesion on the same day.

*"This allows for increased LTX-315 exposure and will invoke a stronger systemic immune response. The first patient treated with this schedule tolerated multi-lesion injection without any significant side effects"*, says Dr. Saunders.

The Phase I/II combination trials of LTX-315 will be in different tumour types and will include malignant melanoma and breast cancer. They will also explore LTX-315 in combination with different types of treatments.

**Hoping to perform trials in the US**

Lytix Biopharma will also be recruiting patients from new participating countries in addition to Norway, Belgium, France and U.K., including Italy and the U.S.

*"We are increasing the number of recruiting sites to access more patients, in particular those who have multiple lesions accessible for injection. We have also filed a U.S. Investigational New Drug application in order to be able to perform trials in the United States. U.S. trial participation will facilitate FDA regulatory agency approval, so this is an important milestone,"* says Dr. Saunders.

Lytix Biopharma intend to complete the Phase I program at the end of the first quarter of 2016. Combination trials will start in the first or second quarter of 2016.

## PRESENTING THE NEW SCIENTIFIC ADVISORY BOARD

**The new scientific advisory board met for the first time 21st October 2015.**

*"I am happy to announce that Lytix Biopharma have created a scientific and clinical advisory board with world renowned members. Their participation in the board reflects their belief in the science and potential of LTX-315. The advisory board will provide us with invaluable expertise and direction to execute the LTX-315 development programme optimally,"* says Dr.Saunders.

- Prof. Robert Andtbacka, surgical oncologist, Salt Lake City, U.S.A.
- Prof. Sandra Demaria, Prof. of radiation oncology and pathology, Weill Cornell Medical College, New York, U.S.A.
- Prof. Kevin Harrington, Head of biological cancer therapies, Royal Marsden / Institute for Cancer Research, London, UK
- Prof. Holbrook Kohrt, hematologist, Prof. of Medicine, Stanford University, U.S.A.
- Prof. Guido Kroemer, tumor cell biologist, Research director INSERM, Institute Gustave Roussy, Paris
- Prof. Aurelien Marabelle, Director of clinical immunology unit, Institute Gustave Roussy, Paris, France
- Prof. Laurence Zitvogel, immune oncologist, Research director INSERM, Institute Gustave Roussy, Paris, France

Read more about the SAB members on www.lytixbiopharma.com

**Kjetil Vangsnes,** new CFO in Lytix Biopharma

# New developments

As part of the ongoing Phase I monotherapy dose escalation trial, Lytix Biopharma has amended the protocol to include treatment of several accessible tumors in the same patient with only 5 minutes apart. Until now we have treated tumors in the same patient sequentially. The aim is to increase exposure to LTX-315 in order to assess safety, increase efficacy and to develop a dosing schedule for the planned combination trials. The first planned combination trial is in malignant melanoma, and the plan is to include the first patient March/April 2016.

**LTX-109**

Lytix Biopharma has decided not to proceed with the planned clinical LTX-109 programme in mildly infected diabetic foot ulcers. The decision is based on recent information indicating that the study will take considerably longer time and incur significantly higher costs than estimated. The company will evaluate alternative routes for LTX-109.

**Scientific Advisory Board**

Lytix Biopharma is delighted to announce that some of the world's leading experts in cancer immunotherapy have accepted to join our newly formed Scientific and Clinical Advisory Board to guide Lytix Biopharma on the optimal development of our lead candidate, the oncolytic peptide immune-therapy, LTX-315.

**New CFO**

In September, Lytix Biopharma appointed Kjetil Vangsnes as new CFO. Vangsnes has served as CFO in several companies within industry (including healthcare), oil services and maritime shipping. His first task will be to work with the upcoming financing round that the company is preparing. On this occasion, Vangsnes stated *"I really look forward to working together with the rest of the Lytix Biopharma team in realizing the further development of LTX-315 on the road to commercialization within the exciting cancer immunotherapy space."*

**Financing and cash situation**

Lytix Biopharma's cash position as of the end of the third quarter was approx. 20 mNOK, which is forecasted to last into the first quarter of 2016. For its base case, the company expects to spend around 60 mNOK during next year. At the same time, the company expects to receive public grants in the order of 10 mNOK for 2016.

In line with what was communicated in the June newsletter, Lytix Biopharma is therefore planning a share issue by the end of this year. Preparations are ongoing, and pre-marketing meetings with some potential new shareholders have taken place in Norway and abroad. The company is planning a 'road show' with its present and potential new shareholders in Norway, and a shareholders' meeting is planned in the second half of November. Further information regarding terms and conditions of the share issue, as well as time schedule, will be available at that time.

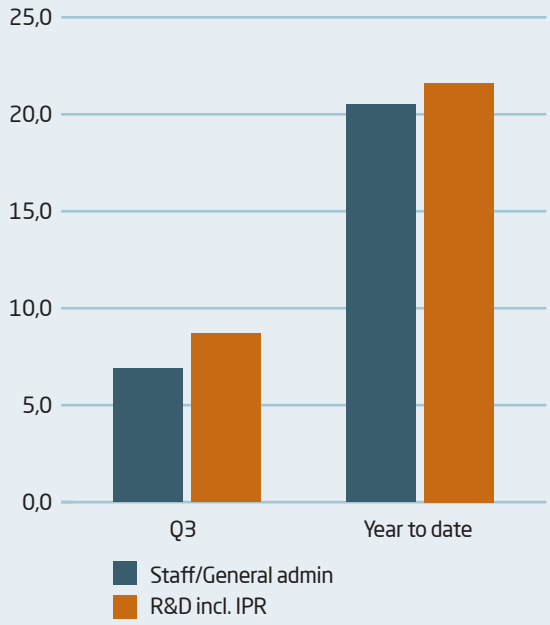
Based on the cash situation described above, and in line with previous share issues, the company is targeting an increase in equity of 60-90 mNOK in this financing round.

## PRELIMINARY FINANCIALS Q3 2015 mNOK

| | Q3/2015 | Yr-To-Date |
|---|---|---|
| **Income - public grants, other revenue** | **1.9** | **4.0** |
| Staff and general administration costs | -6.9 | -20.5 |
| R&D costs | -8.7 | -21.6 |
| **Total Operational Cost** | **-15.6** | **-42.1** |
| **EBIT** | **-13.7** | **-38.1** |

Staff costs include all employed R&D personnel. IPR costs are included in the R&D costs. Earned tax refund («Skattefunn») is not included and will be booked as a reduction in operational cost. All figures are preliminary and not audited.

## COST DISTRIBUTION Q3 AND YTD mNOK




## INCOME

In 2015, Lytix has on-going public grants from Innovation Norway, The Research Council of Norway and Eurostars. The grants are booked when the payments are received. In an industry characterized by long-lasting R&D programs with significant implied risk, the financial support from public sources is very valuable. For our shareholders, these grants are essential to relieve risk on the equity capital. Lytix' management works continuously with opportunities for part financing of our comprehensive R&D program with public funding.

## COST AND INVESTMENTS

The cost level in Q3 has been lower in the oncology area than planned. This relates to changes in the clinical program and lower recruitment pace for patient inclusion. In other areas, the cost level has been around the expected level. Investments in R&D and IPR portfolio are fully expensed.

## EQUITY AND CASH

The last share issue took place in December last year with gross proceeds of 50 mNOK.

The board has prepared a strategy in order to finance the extensive R&D program for the forthcoming years. Cash was approx. 20 mNOK by the end of Q3, and in combination with incoming public grants, the company has sufficient cash until early 2016. The company has no interest-bearing debt.


Prime Minister Erna Solberg and Jonas Einarsson, CEO at Radiumhospitalets Forskningsstiftelse, officially opened OCCI

# Lytix Biopharma becoming part of Oslo Cancer Cluster Innovation Park

**Lytix Biopharma are establishing research activities at Oslo Cancer Cluster Innovation Park (OCCI). This is an opportunity for closer cooperation with the immune oncology community.**

Lytix Biopharma's research department are gradually moving into new facilities at Oslo Cancer Cluster Innovation Park (OCCI). The company will have their own research lab at this new center for cancer research. They will also have access to shared lab facilities, with advanced equipment for immune oncology research.

OCCI houses around 20 companies related to cancer research and drug development. The Norwegian Radium Hospital and the Institute of Cancer Research are the closest neighbors. For Lytix Biopharma, the move is an exciting opportunity for closer cooperation with a broad cancer research community.

*"We have successfully been collaborating with research groups at different universities and hospitals, including the Norwegian Radium Hospital and Rikshospitalet at OUS. By establishing our own research group at the OCCI we hope to strengthen these existing collaborations. In addition we hope to make new connections with other research groups – both within immune oncology and cancer research more generally. Closer integration between pre-clinical research and clinical trials will be especially important going forward",* says Øystein Rekdal, Lytix Biopharma's Chief Scientific Officer.

Norway's Prime Minister Erna Solberg officially opened OCCI on August 24th 2015. By integrating research and innovation, OCCI will become one of Europe's leading centers for private and public research collaboration, for the benefit of future cancer patients. Rekdal believes there will be significant advantages to being part of this cluster of cancer research.

*"Creating a cluster of private companies innovating in the cancer field, so close to public research institutions, means Oslo will stand out internationally. I hope the companies located at OCCI can make each other stronger, by attracting investors and collaborators to this new center for innovative cancer research."* says Rekdal.

Lytix Biopharma will maintain research activities in Tromsø and close cooperation with academic communities in northern Norway. The Tromsø department of Lytix Biopharma will focus on medicinal chemistry, while the research activities within tumour biology and immune oncology research will be located in Oslo.

# LATEST NEWS

## FROM LYTIX BIOPHARMA

- Andrew Saunders (CMO), Øystein Rekdal (CSO), Wenche Marie Olsen (COO) and Berit Nicolaisen (Project Manager, Oncology) represented Lytix Biopharma at ASCO in Chicago May 29-June 2
- Unni Hjelmaas (CEO) and Håkan Wickholm (CBO) represented Lytix Biopharma at "BIO International Convention 2015" in Philadelphia June 15-18
- Senior Scientist Baldur Sveinbjørnsson represented Lytix Biopharma and presented a poster at a Melanoma Conference in Reykjavik June 24-26
- Lytix Biopharma's research department moved into OCCI (Oslo Cancer Cluster Incubator) in August
- John Sigurd Svendsen (Co-founder and Head of Exploratory Research) presented Lytix Biopharma at a 'political seminar on knowledge-based reorganization to new growth and value creation' in Tromsø in September.
- Unni Hjelmaas (CEO) participated in the opening session on Nordic Life Science Days (NLSD) in Stockholm September 9th, the largest partnering conference for pharmaceutical companies in Scandinavia. Håkan Wickholm (CBO) was also present at the conference.
- Lytix Biopharma published scientific articles on LTX-315 mode of action in Oncotarget in September and in October
- Lytix Biopharma presented initial results from LTX-315 Phase I study at ECC2015 – both through a poster and a presentation
- Håkan Wickholm presented Lytix Biopharma at the 15th annual Biotech in Europe forum for global partnering & investment in Basel, September 29-30
- Lytix Biopharma was represented by Andrew Saunders (CMO) and Øystein Rekdal (CSO) at The Immunoncology Meeting in New York in September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