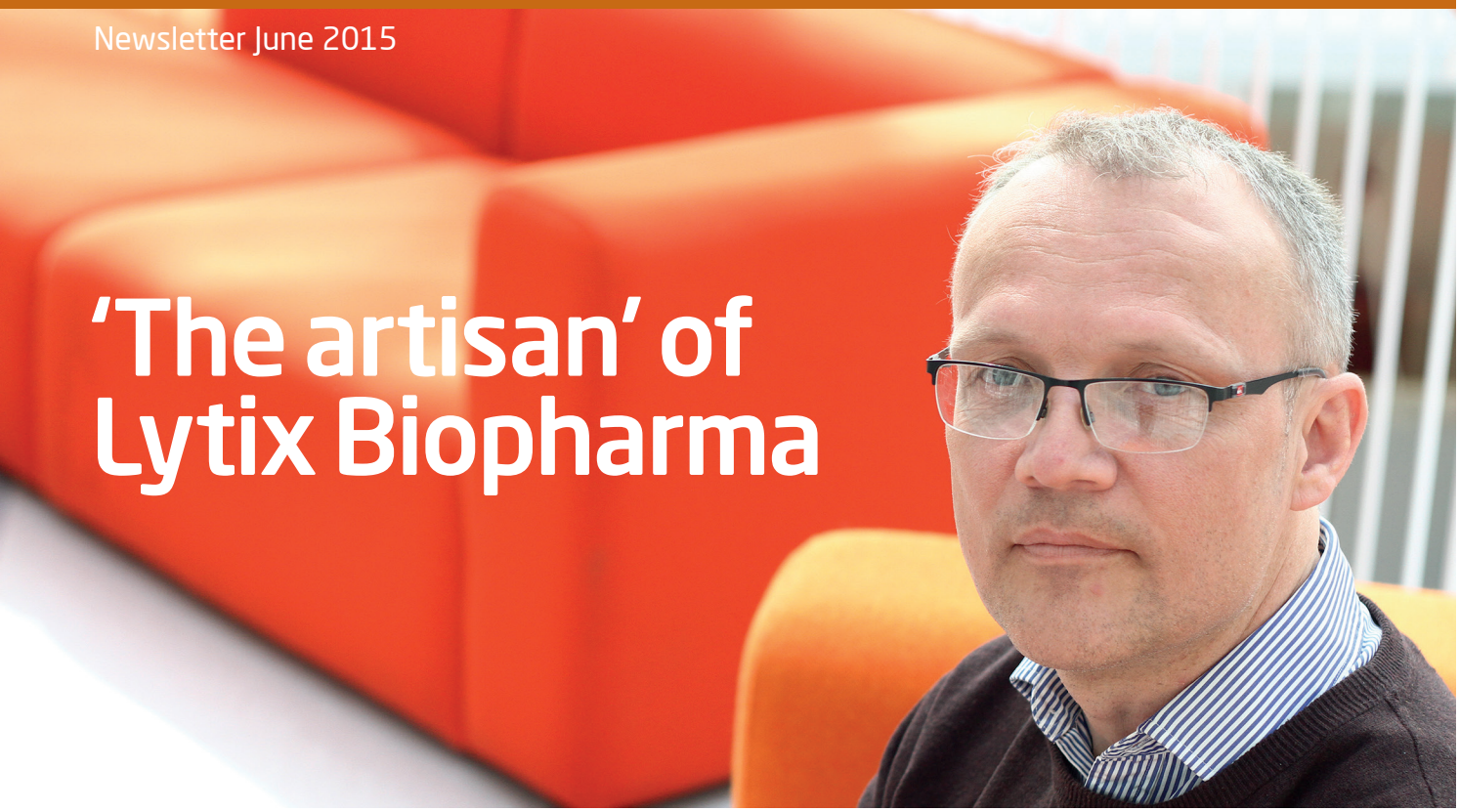
Lytix Biopharma

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

Newsletter June 2015

'The artisan' of Lytix Biopharma



Bjarte Mortensen, Toxicologist (PhD). Manager for Preclinical Toxicology & Safety in Lytix Biopharma

"It's an art - preparing and implementing tests of new drugs on animals and people. You can't expect to be successful unless you really prepare in advance for all the different phases of clinical trials," says Bjarte Mortensen, Lytix Biopharma's toxicologist.

Bjarte Mortensen, who has a PhD in toxicology, is responsible for toxicology in Lytix Biopharma, including the safety studies before drugs are tested on human beings. The authorities regulate drug discovery, setting rules both for how drug candidates can be tested on animals, and what has to be in order before drug candidates can be tested on people.

In addition to the internal evaluations that drug companies commit themselves to, there are strict guidelines from The World Health Organization (WHO) and Norwegian authorities.

"My work as a toxicologist is to make sure we are testing responsibly, so that we can ensure that our drugs are safe within the doses and the use they are meant for, and that they have the desired effects," says Mortensen.

Strong protection both for animals and human test subjects

As part of the development process, new drugs are tested both in test tubes and on animals.

"Before we can test drugs on people, we test them on animals, to make sure they are safe to use, but the animals are protected as well. There are clear rules and ethical guidelines for how to test drugs on animals," says Mortensen.

Before drugs are tested on human test subjects, the drug company must be able to document that the drugs will not affect genetic material or reproduction. The drugs cannot have unwanted effects on vital organs like the heart and kidneys. They must also be safe to use for extended periods of time and not result in side effects.

The work is not over

Both LTX-109 and LTX-315 have been subject to tests in tubes and in animals. Bjarte Mortensen has worked for Lytix Biopharma for almost nine years, taking part in the whole journey - from small-scale experiments to complete testing on patients.

«In the last five to six years we have really picked up speed by recruiting talented colleagues. We have transitioned from being research-based with just a few employees to being able to implement full-scale clinical trials with patients in several countries. It's been fun," says Mortensen.

But the work of a toxicologist isn't over until the drug is approved. Mortensen says there is still a way to go before Lytix Biopharma has drugs ready for sale.

"Getting 'Proof of Concept' on our cancer medicine was an important milestone - the first clear indication that our drug candidate has a real effect on patients. We are working continuously to find ways of accelerating the process towards approval," says Mortensen.

WHAT IS TOXICOLOGY

Toxicology studies hazardous effects of chemicals and other agents on living organisms. Toxicology involves disciplines such as biology, chemistry and medicine (physiology, pharmacology) and is important during drug development.

Lytix Biopharma has achieved an important milestone in the development of the cancer immunotherapy treatment LTX-315. Evidence of anti-tumour effects in the Phase I study has provided Proof of Concept for LTX-315.

Lytix Biopharma's potential backed by international research

In April, Lytix Biopharma took part in the annual meeting of the American Association for Cancer Research (AACR) held in Philadelphia. During the conference, which was dominated by immunotherapy topics, several important findings were presented. Notably, two of the studies presented are of great significance to the ongoing development of LTX-315. These studies, published in the New England Journal of Medicine, provide clinical evidence that treating cancer with immunotherapy has a greater effect when provided through combination therapy.

– This shows that it is rational to combine LTX-315 with existing immunotherapy treatments, says Andrew Saunders, Chief Medical Officer at Lytix Biopharma.

According to Dr. Saunders, LTX-315's position in advanced tumours will be as part of combination therapy. The first clinical test results from the Phase I monotherapy study will be presented at the European Cancer Congress in Vienna in September this year.

– We predict one of the significant advantages of combining systemic immunotherapy treatment is increased cancer killing efficiency, but the level of undesirable side effects has turned out to be an issue. Combining a locally acting agent such as LTX-315 with systemic cancer immunotherapy could augment efficacy without adding toxicity compared to existing cancer treatment in the field of cancer immunotherapy, Dr. Saunders explains.

So far, LTX-315 has been given as a single agent to patients and has not yet been combined with other treatments. Evidence from preclinical trials show complete tumour regression in both LTX-315 injected and non-injected tumours. Preclinical data also show synergy when LTX-315 is combined with other cancer immunotherapies-immune checkpoint inhibitors. The next steps will be to increase the dose of LTX-315 and inject several tumour lesions simultaneously and take this optimized treatment schedule into combination with approved cancer immunotherapies.

Another key development reported with the latest clinical trials is that they provide clear evidence that the use of cancer immunotherapy will be extended beyond melanoma and lung cancer.

– Our goals are ambitious. If successful LTX-315 may become part of standard of care treatment in several tumour types such as breast cancer, soft tissue sarcoma and head&neck cancer when added to immune checkpoint inhibitors.

Dr. Andrew Saunders
Chief Medical Officer in Lytix Biopharma.

OBSERVER AT HUG (GENEVA)

As mentioned in previous communications Lytix Biopharma has been awarded funding from the Eurostars programme to conduct a LTX-109 study in infected diabetic foot ulcers. Project manager for LTX-109, Hedda Wold, plans to include the first patient in the study during the summer.

Hedda Wold – Project manager for LTX-109.

Diabetic foot ulcer is a complex and complicated indication, and to get the best possible knowledge and understanding of the disease and practical handling of it, Wold wanted to "shadow" and observe treatment of patients at the University Hospital in Geneva (Hospitale Universite de Geneve, HUG), one of the competence centers in Europe within this area.

HUG participates in a pilot study with another topical antibiotic treatment, and the center is under supervision of one of the world's leading experts on infected diabetic foot ulcers, Professor Benjamin Lipsky. Lipsky has also been one of the main responsibles in the development of the current guidelines for classification and treatment of infected diabetic foot ulcers, and he is an advisor for Lytix Biopharma.

The main responsibility of Dr. Uckay and nurse Benjamin Kressman is to find patients for the clinical trial at HUG. The challenge, according to Lipsky, Kressman and Uckay, is making the right clinical assessment of patients' wounds and to assess the degree of infection. Most diabetic foot ulcers are caused by pressure, friction or other reasons for the skin barrier to break. Diabetic patients often have neuropathy (low sensitivity) in the feet, and ulcers are usually painless, which means that it may take some time before it is detected. Diabetic foot ulcers are often difficult to heal if you do not address the cause of why the wound occurred. Persistent wounds will become infected in about 50% of the cases, and then the patient needs antibiotic treatment. Initially infection in a diabetic foot ulcer is be of a mild degree, before it progresses to a moderate and further on severe degree. It is during this last period we want to test whether treatment with LTX-109 directly on the wound may remove the infection. As antibiotic resistance is a growing challenge, it will be a great advantage if patients do not have to be treated with systemic antibiotics, as is the case today.

During Wold's two-day stay at HUG she followed Kressman and Uckay in their daily treatment of patients with different severities of infected diabetic foot ulcers. She saw several examples of how even severe foot ulcers with infection healed after antibiotic treatment and proper wound care. She also saw examples where treatment unfortunately did not succeed, and the result was amputation of toes or a foot.

- We hope to prevent amputations by removal of the infection in foot ulcers treated with LTX-109, says Wold.

Knut Eidissen
Chairman of the Board, Lytix Biopharma

Lytix Biopharma is entering an exciting period

2014 and 2015 have been exciting years for Lytix Biopharma with news about the Proof of Concept (PoC) for LTX-315 in 2015 as the biggest milestone for the company to date.

Lytix Biopharma is actively pursuing commercialization of its potential drug candidates. It is very difficult to influence the timing of entering into different types of agreements, convincing clinical results are important to reach them. Lytix Biopharma must therefore generate additional clinical data to get in position to get commercial partnership for both drug candidates. This will also increase shareholder value.

Impetigo is a common indication for showing PoC, but as commercial indication, it is of limited value because the market is generic. PoC in Impetigo is however a good stepping stone and prerequisite to progress in an indication where there is a high unmet medical need and commercial potential. To increase LTX-109's value, the company therefore decided to conduct a Phase 1/2 study in infected diabetic foot ulcers. This project has qualified for prestigious Eurostars support from EU. Positive results from this study will form the basis for a future partnership or sale of LTX-109. Lytix Biopharma is in continuous dialogue with stakeholders in this area.

For LTX-315, Lytix Biopharma is in continuous dialogue with potential future partners. Cancer immunotherapy is a very attractive and competitive area on the development and collaborating side. It is important, and in Lytix Biopharma's interest, to conduct a Phase 2 study before commercial partnership is entered into. If successful, the value of the project and thus the shareholder value will increase significantly. Before entering into a commercial partnership, Lytix Biopharma is seeking research collaboration with one or more potential future partners. Such collaboration will limit dilution because of cost sharing. LTX-315 is a unique treatment concept in the attractive immunotherapy area due to its differentiated mechanism of action. This implies great opportunities for a potential partner who wants a differentiated product, but it also means we must generate convincing clinical results.

According to plans approved by the board, Lytix Biopharma has sufficient liquidity to operate through 2015. The company now has 248 shareholders.

PREPARATION FOR IPO

- On 11 June the Board will ask the General Assembly for permission to authorize the preparation of IPO to ensure future financing of the company.
- Knut Eidissen notified the Nomination Committee early January that he will withdraw as Chairman of the Board. The Nomination Committee has proposed Gert W. Munthe as new Chairman of the Board with support from the largest shareholders in the company.

PRELIMINARY RESULT 1Q 2015	NOK 1000
Revenue - public grants, miscellaneous	**658**
Costs R&D - cancer area (LTX-315)	3 996
Costs R&D - infection area (LTX-109)	1 431
Costs R&D - READI area (kinase etc)	2 492
Costs R&D - IPR	616
Costs to adm. and business development	4 512
Total operating expenses	**13 047**
Operating profit (EBIT)	**-12 389**

All figures are preliminary and unaudited. Minor changes must be expected. Gained support through Tax Refund (Skattefunn) is not included and will come to the reduction of operating costs.

REVENUE

The company has in 2015 financial support through Innovation Norway, the Norwegian Research Council (NFR) and Eurostars which are recognized immediately taken into account payments from IN/NFR. Public support was not paid in Q1 and thus not recognized. Revenues in Q1 is constituted by consulting revenue.

COST / INVESTMENTS

Costs in Q1 2015 was significantly lower in the cancer area than budgeted; which is due to changes in study plans and lower recruitment rate of patients than expected. In other areas the cost is mainly on budget and according to plans.

The company's ongoing investments in R & D and IPR portfolio are expensed in full.

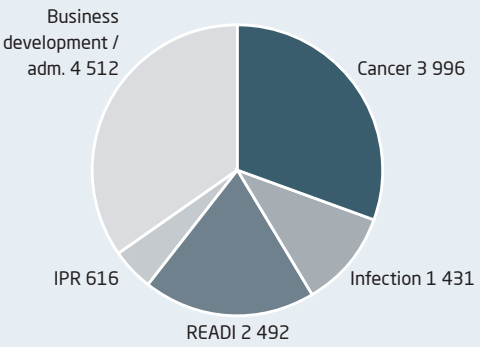
FINANCIAL SITUATION / LIQUIDITY

The company completed a private placement with Arctic Securities as facilitator that was registered in February 2015. The issue gave gross proceeds of 50.0 million NOK.
The Board has initiated efforts to put in place a strategy to finance its extensive R & D program for the next 2-3 years.

Counting the proceeds from the issue, cash balance at year-end as well as public grants secured for disbursement in 2015, the company has given firm plans sufficient cash to operate through the year. The Board aims to further strengthen the company through a capital increase in the second half of 2015. The company has no interest bearing debt.

COST ALLOCATION Q1 2015

MNOK



CEO Unni Hjelmaas in dialog with Prime Minister Erna Solberg and the Labour Party Leader Jonas Gahr Støre.

Lytix Biopharma at the Industry Conference

Lytix Biopharma attended the 'Industry Conference 2015' on May 5th and Unni Hjelmaas was, in addition to the CEO`s of Hydro, Karsten Moholdt and Øglænd Industrier, invited to ask questions to Prime Minister Erna Solberg and the Labour Party Leader Jonas Gahr Støre. The topic of this year's conference was opportunities for the industry in Norway and the outlook in the future low carbon footprint society. A readjustment to new industries as well as focus on knowledge and education are elements of the solution.

Unni Hjelmaas (CEO Lytix Biopharma) introduced the challenges of Norwegian pharma industry before presenting her question

– Norwegian based pharmaceutical industry is global, future oriented and knowledge intensive. We want to, and we can contribute to better health, employment and a positive effect on GDP when successful. We represent a young industry in Norway and need some assistance to evolve. Health&Care21, The Government Declaration and general improvements in public funding tools are positive initiatives, initiated by the present and former government. Public funding alone cannot finance pharmaceutical drug development; it is desirable to attract Norwegian investors and build a competent investor base for our industry. The challenge is a very long, high risk, research-intensive development timeline that requires patient investors. The question is therefore what the Prime Minister and Labour Party Leader can do to help build a competent investor base for this type of long-term investments in Norway.

Solberg advocated that capital taxation prevent those who could take risk from taking it.

– High taxation on small start-up companies is the opposite of what would be the clever thing to do. When punitive taxation' is high, investors turn to safer areas where they can quickly realize their investments. Capital taxation contributes to lower employment in Norway, Erna Solberg stated.

Gahr Støre focused on the purpose of Health&Care21, which is to bring health authorities, academia and industry together to increase commercialization of Norwegian health research.

– If we have to educate the investors, this is what the Government can do to support, Gahr Støre said.

LATEST NEWS

FROM LYTIX BIOPHARMA

- **Unni Hjelmaas presented Lytix Biopharma at "Bioprosp 2015" in Tromsø in February. "Bioprosp" is one of Europe's top conferences in marine bioprospecting.**
- **Lytix Biopharma had partnering meetings at the conference «A partnership for life», which was arranged in the Research Park in Oslo in February. The Association of the Pharmaceutical Industry in Norway, DNB Healthcare, AbbVie, Novartis and Pfizer took the initiative to create an arena where Norwegian biotech meets the global pharmaceutical industry. The objective is increased innovation and increased commercialization of health research in Norway.**
- **Øystein Rekdal and Unni Hjelmaas presented Lytix Biopharma at a mini seminar held by Arctic Securities in March.**
- **Håkan Wickholm and Unni Hjelmaas had partnering meetings at "BIO-Europe Spring" in Paris in March, where the global biotech industry comes to partner.**
- **Unni Hjelmaas presented Lytix Biopharma and had partnering meetings at the partnering conference "The Anglonordic Life Science Conference XII", in London in April.**
- **Lytix Biopharma had well visited shareholder meetings, in Oslo (April 24th), Harstad (April 27th) and Tromsø (April 28th). The main subject was the announcement of Proof of Concept for LTX-315 – Oncolytic Peptide Immunotherapy for cancer.**
- **Lytix Biopharma received «Scientific Advice» from the European Medicines Agency, with no major input to the protocol from the LTX-109 DFI study.**

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