Lytix Biopharma

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

Newsletter April 2016

New CEO Håkan Wickholm:

-Lytix Biopharma intensifies business development

With Håkan Wickholm taking over as CEO for Unni Hjelmaas as of March 1, 2016, Lytix Biopharma has commenced a new phase in the company's history. *– Business development is more important now than ever, in addition to maintaining a strong focus on clinical research. We are at a stage right now where collaborating with other institutions is essential,* Håkan Wickholm says.

The process of developing new drugs is changing. Collaboration with other companies/institutions at a very early stage in drug development is becomming more and more important. This applies in particular to small biotech companies. Håkan Wickholm notes that this requires business or commercial considerations at an earlier stage than previously; - *We are in a very competitive industry which is characterized by high risk / high reward, and we are dependent on collaborations with others, for example in developing combination studies. The promising data that Lytix Biopharma has generated so far has the potential to provide great opportunities, as long as the clinical trials confirm the positive preliminary results.*

Key combination studies

An important part of the immune system is its ability to tell the difference between normal cells in the body and those it sees as «foreign». This allows the immune system to attack the dangerous cells while leaving normal cells alone. But cancer is insidious; it builds up a resistance to the body's own immune system. When the immune system slows down, it does not attack the cancer cells. Current available immunotherapies removes this resistance but not all patients respond. Therefore, the general paradigm today is to combine products with different mode of actions to further enhance the patient immune response.

–That is why it is so important to conduct combination studies. We are exploring how Lytix Biopharma's drug candidate LTX-315 can work together with so-called «checkpoint inhibitors» in order to augment the efficacy and make more patients respond to the therapies, Håkan Wickholm explains.

The global market

The global market for cancer drugs is predicted to grow from 11 billion dollars in 2011 to 35 billion in 2022 (Citibank, 2013). According to this prognosis, the increase will be in large part derived from development within immunotherapy.

-There is a paradigm shift in cancer treatment, which is due to the recent knowledge about immunotherapy; drugs that enhance the body's own immune system. Many believe that this class of medications will be the most important drugs in future cancer treatment, Håkan Wickholm says.

Lytix Biopharma's strategy is to develop its drug candidates to end clinical Phase II, and collaborate with partners for late stage development and commercialization.

-The market is intensely competitive. We are therefore continuously working to build awareness of LTX-315 and relationships to the major pharmaceutical companies and to keep them informed about our results, Håkan Wickholm concludes.

–A pivotal change to the LTX-315 trial history

Lytix Biopharma's LTX-315 trials are about to enter a new and exciting phase. Starting in June, LTX-315 will be evaluated in an intensive schedule in combination with 2 different immune therapies in addition to LTX-315 monotherapy. *-This is a pivotal point in the LTX-315 development plan,* Andrew Saunders, M.D., Chief Medical Officer at Lytix Biopharma says.

The new trials will determine the safety and effect of using LTX-315 as part of a combination therapy to treat advanced skin and breast cancer.

-The monotherapy trial has demonstrated a safety profile that has informed the optimal treatment schedule for further LTX-315 development. We plan novel and scientifically compelling combinations with other immune therapies that are synergistic with LTX-315. In targeting different pathways with complementary immunotherapies, we believe incremental clinical benefit may be observed in patients with advanced disease, Saunders says.

The findings of the monotherapy trial of LTX-315 have created a solid basis and rationale to begin testing the drug as part of a combination immunotherapy treatment.

New combination trials added

This spring, the LTX-315 trials will be amended to include three separate "study arms", each of which to be conducted in parallel. The first arm, LTX-315 monotherapy, will continue, but will administer LTX-315 more frequently and to several sites of disease simultaneously compared to the current monotherapy phase 1 study.

Arm B will include patients with advanced stage, malignant melanoma type skin cancer. The study will include 9-12 patients who have already received treatment with an anti-CTLA-4 agent, ipilimumab. Multiple lesions will be injected with a combination of LTX-315 and the immunotherapy drug ipilimumab, which is produced by Bristol Meyers Squibb under the brand name Yervoy.

Dr. Andrew Saunders
Chief Medical Officer in Lytix Biopharma

-There is very strong scientific pre-clinical evidence showing a strong synergistic effect between ipilimumab and LTX-315. The goal of the study is to determine the treatment's safety profile, optimal dosage and anti-tumor effect, Saunders explains.

The third arm, Arm C, will start in June and include 9-12 patients with advanced stage breast cancer. Patients will be treated with LTX-315 in combination with an anti-PD1 agent, pembrolizumab, produced by Merck.

-Although not yet approved in breast cancer, pre-clinical data of pembrolizumab indicate synergy when combined with LTX-315, making it an exciting combination to evaluate. As in the skin cancer trial, the study will examine patient safety, optimal dosage as well as anti-tumor effect, Saunders clarifies.- *Moving LTX-315's development strategy to include combination therapy evaluation is a major change, and I strongly believe that if LTX-315 is to have a place in treatment of advanced disease it will be as part of combination therapy- including with other immunotherapy agent. We expect to have initial combination data by the end of Q1 2017, and at that point we will evaluate moving to phase II trials.*

Monotherapy studies to continue

LTX-315 monotherapy will continue in parallel to the new combinations being evaluated. Recent key changes to the LTX-315 monotherapy treatment plan since the autumn in addition to evaluating increasing LTX-315 dosages up to 7mg have included increasing the frequency of administration and injecting several tumour lesions concurrently on each planned LTX-315 treatment day. Critically no new safety concerns have emerged with these changes and it is feasible to inject several sites of disease concurrently.

-Anti-tumour effects of LTX-315 include local tumour control, complete or partial shrinkage of injected tumours in approximately 30% of patients, stabilization of overall tumour burden as assessed by CT scan in approximately 60% of patients and evidence of significant immune cell infiltration in biopsies in 50% of injected tumour lesions, Saunders reveal.

Kjetil Vangsnes, CFO in Lytix Biopharma

Operational highlights 2015

- The clinical program progressed with the current mono study across several indication areas. This study is expected to be completed in 2016. Furthermore, the company prepared for the start-up of combination studies with ICI's within malignant melanoma and breast cancer.
- The infection project (LTX-109) with Diabetic Foot Ulcer was terminated because of a substantially changed outlook in cost and time frame and in order to focus the company's resources on the LTX-315 cancer immunotherapy project. Lytix Biopharma's subsidiary Lytix Amicoat AS (Amicoat AS from January 2016) commenced its activities towards industrial applications for LTX-109 within the antimicrobial sector and has showed good progress.
- In June 2015, Gert Munthe was elected Chairman, and the company strengthened its board of directors with three new members. Together with a high-level, global Scientific Advisory Board, the company has an excellent position to drive product development based on its patented technologies.

Financial highlights 2015

- In January 2015, Lytix Biopharma AS successfully raised 50 mNOK from existing and new shareholders
- In February 2015, the company secured full IP rights for its lead candidate LTX-315 through a non-cash transaction valued at 5.5 mNOK, making the company independent of IP in-licensing
- In December 2015, Lytix Biopharma AS successfully raised 78.5 mNOK from existing and new shareholders. Payment was received in January 2016.

New developments

Lytix Biopharma has amended its protocol to include two (instead of one, as communicated in the November Newsletter) new combination treatment arms in the same study. These arms will address malignant melanoma and breast cancer, respectively, with LTX-315 in combination with immune checkpoint inhibitors in the studies. This will provide for more efficient logistics, as well as cost savings. The plan for the combination trials is to include the first patients in June 2016.

Cash situation and future financing

Lytix Biopharma's cash position as of the end of the first quarter was 66.6 mNOK, which is forecasted to last through 2016. During this year, the company expects to spend around 100 mNOK, and further expects to receive public grants in the order of 10 mNOK.

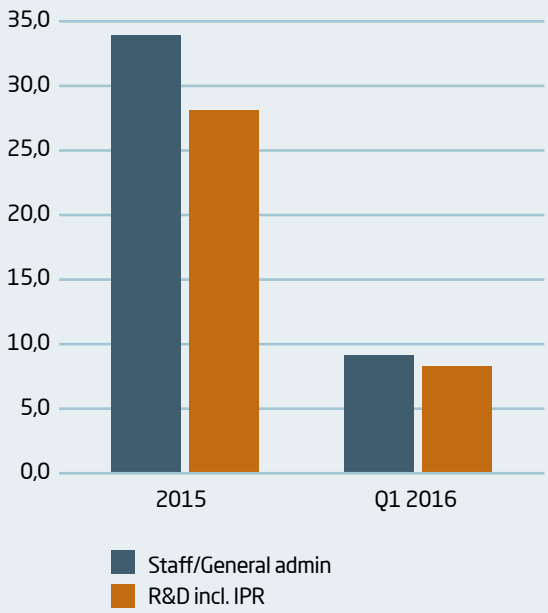
There is a continuous focus on cash out, as well as new financing opportunities. Alternatives for future financing include share issues to present shareholders, venture capital, pre-IPO and IPO.

FINANCIALS 2015 AND Q1/2016 (MNOK)

	2015	Q1 2016
Income - public grants, other revenue	**9.7**	**1.3**
Staff and general administration costs	-34.0	-9.4
R&D costs	-28,1	-8.1
Total Operational Cost	**-62.1**	**-17.5**
EBIT	**-52.4**	**-16.2**

Staff costs include all employed R&D personnel. IPR costs are included in the R&D costs. Earned tax refund («Skattefunn») is not included for Q1 2016 and will be booked as a reduction in operational cost by year-end. All figures are preliminary and not audited.

COST DISTRIBUTION 2015 AND Q1 2016 (MNOK)



INCOME

In 2015, Lytix Biopharma has had on-going public grants from Innovation Norway, The Research Council of Norway and Eurostars. The grants have been booked as the payments have been received. Lytix Biopharma considers the financial support from public sources as very valuable, and for our shareholders, these grants are essential to relieve risk on the equity capital. Lytix Biopharma's management works continuously with opportunities for part financing of our comprehensive R&D program with public funding.

COST AND INVESTMENT

Clinical costs were lower in 2015 than budgeted, which relate to changes in the clinical program and slower patient recruitment.

For Q1/2016, programs and costs develop according to plan.

CASH

Cash was 66.6 mNOK by the end of Q1/2016, and in combination with incoming public grants, the company has sufficient cash until end 2016.

The company has no interest-bearing debt.

Highly promising antimicrobial arm of Lytix Biopharma

Amicoat AS (formerly Lytix Amicoat AS) is currently a 100% subsidiary of Lytix Biopharma and seeks to commercialize Lytix Biopharma's LTX-109 technology in non-pharmaceutical applications, including in the medical device and marine sectors.

"Amicoat's antimicrobial solution is arguably the most promising novel antimicrobial technology in the market" says newly appointed CEO Steven Wang. Specific advantages include a rapid effect, low resistance development, broad spectrum of activity, and a benign environmental impact.

Currently, Amicoat is in dialogue with several medical device companies to establish commercial collaborations to license the LTX-109 technology for specific applications. The principle is to coat a surface or material with the peptide, which will significantly reduce bacterial colonization and the risk of infection. "Bacteria are ubiquitous and the market scope where Amicoat can add value is theoretically unlimited. In the future, Amicoat will seek opportunities to expand into more product applications spanning diverse industries", Wang concludes.

For more information:
steven.wang@amicoat.com

amicoat
Antimicrobial coating technology

A major milestone for Pharmasum Therapeutics AS

Pharmasum Therapeutics has achieved a major milestone in its path toward developing a treatment for Alzheimer's disease. The company achieved "Proof of Principle" designation for its research, a full quarter ahead of schedule.

"Our scientists in Norway and the U.K. are studying human nerve cells and the proteins that are linked to Alzheimer's disease. When tested in the laboratory, our drug candidates show strong inhibition of the 'Tau phosphorylation', one of the major Alzheimer's disease mechanisms. This is a strong indication that our drugs are going to be effective in directly inhibiting the disease," company CEO, Anders Fugelli explains.

The next step is to progress our lead drug candidate towards toxicology and phase 1 clinical studies, something which requires further funding. *"Our focus now is on "lead optimization" - developing a drug that can be taken in tablet form,"* Fugelli says.

Pharmasum Therapeutics has received substantial grants from the Norwegian Research Council and Innovation Norway. *"Business-wise, our cost level and cash position are in line with, or better than, forecasted. We will be raising private equity in 2016 as we progress into drug development,"* Fugelli states.

For more information:
afugelli@pharmasum.com

Pharmasum Therapeutics

LATEST NEWS

FROM LYTIX BIOPHARMA

- Lytix Biopharma was represented by Øystein Rekdal (CSO), Andrew Saunders (CMO) and Baldur Sveinbjørnsson (Senior Scientist) at American Association of Cancer Research (AACR) in New Orleans, USA, April 2016. Lytix presented 4 posters of research results at the meeting.
- Håkan Wickholm, CEO, attended a biotech partnering conference, BIO-Europe Spring, in Stockholm in April, where he met with other industry representatives.
- In March Lytix Biopharma had several publications in highly regarded peer-reviewed scientific journals related to LTX-315 research.
- We were deeply saddened to learn of the death of Holbrook Kohrt M.D., PhD on February 24th last. Holbrook was a highly valued member of the Scientific Advisory Board at Lytix Biopharma. Holbrook made a significant contribution to the field of tumour immunology. It was our privilege to work with Holbrook and his passing is a great loss to the scientific and clinical community.
- Lytix Biopharma attended for the first time the JP Morgan / Biotech Showcase meetings in San Francisco, January 2016. These two meetings run in parallel and make this event to the world's largest gathering of pharma and biotech companies, academic life science institutions and investors. Lytix Biopharma was represented by Håkan Wickholm (CEO), Øystein Rekdal (CSO) and Andrew Saunders (CMO), and they met with various industry representatives.
- Lytix Biopharma's preclinical activity moved into Oslo Cancer Cluster Incubator (OCCI) in August 2015. OCCI was in November 2015 announced in The European Biotech News Website as the coolest Bio-incubator in Northern Countries and top 6 in Europe.
- Norwegian cancer research is a new industry with huge potential - both financially and for patients. Lytix Biopharma was one of ten companies featured in a newspaper article regarding this new industry.
- The Health minister, Bent Høie, visited Oslo Cancer Cluster Incubator to gain insight into cancer research. As part of the visit, he killed live human melanoma cells with two cancer products in the lab - one of them was Lytix Biopharma's drug candidate LTX-315.
- Lytix Biopharma has received a "Notice of Allowance" from the US Patent Office regarding its LTX-315 patent application. From December 14, Lytix Biopharma's first-in class oncolytic peptide immunotherapy LTX-315 is patent protected in the US.

CONTACT DETAILS LYTIX BIOPHARMA

Main office:
Box 6447, N-9294 Tromsø

Oslo office:
Gaustadalleen 21, N-0349 Oslo

Phone number +47 77 67 55 00

post@lytixbiopharma.com
lytixbiopharma.com