Lytix Biopharma

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

Newsletter April 2017

Torbjørn Furuseth
CFO Lytix Biopharma

NASDAQ FIRST NORTH IN STOCKHOLM WILL GIVE THE COMPANY AND ITS TECHNOLOGY THE ATTENTION IT DESERVES

Torbjørn Furuseth joined Lytix Biopharma as CFO February 1st, 2017. His main focus will be to prepare Lytix Biopharma for an IPO at Nasdaq First North this year.

- Lytix has come to the stage where we need access to more capital to maintain the speed in our drug development. Listing Lytix on Nasdaq First North in Stockholm will give the company and its technology the attention it deserves, Torbjørn Furuseth says.

Several Norwegian investors have followed and supported Lytix Biopharma for many years, but when the company now decided to go public we chose to go to Sweden.

- There is a larger cluster with investors, analysts and companies in the pharma and biotech sector in Sweden, so we consider it the best place for Lytix, Torbjørn Furuseth comments.

Torbjørn has an untraditional background for a CFO, but is a great fit for Lytix and our needs, CEO Håkan Wickholm comments.

Dr. Furuseth is a Medical Doctor by training, but has 10 years of experience from pharma development and management consulting. He worked in McKinsey & Co for six years consulting clients in pharma and health care. He later joined the Aker companies Trygg Pharma and Aker BioMarine, where he held responsibilities for commercial development and innovation, respectively.

Lytix Biopharma has closed the pre-IPO financing round, and is now conducting a repair share issue.

- We were able to reach the target of raising 60 MNOK, and the repair share issue was fully subscribed and brought in 20,8 MNOK more. The proceeds for these share issues will fund the rest of the Phase I study and one new trial that we are planning.

The IPO is planned for Q4 of 2017 so much of the data from the ongoing trial will be available before the IPO.

- It is important to have a broad set of data for the IPO, however, it is also good to have some more news following on after the IPO.

The appetite for biotech and pharma investments is fairly strong at the moment, and Lytix is well positioned in the immuno-oncology space, which is the highest growth segment, Torbjørn Furuseth concludes.

The importance of good planning for initiation of a clinical trial

The pharmaceutical industry is one of the most regulated industries. Prior to market approval by the respective regulatory agencies (FDA; US, EMA; Europe), all new drugs must demonstrate safety and efficacy. The aim of clinical trials (Phase I-III) is to test whether a particular drug have any side effects, demonstrate how well it works, and if it can prove to be better than other treatments on the market.

Wenche Marie Olsen
Chief Operating Officer
in Lytix Biopharma

Wenche Marie Olsen, Chief Operating Officer of Lytix Biopharma, emphasizes the importance of understanding the process and requirements from the National Competent Authorities (NCA) in order to obtain the approval to run a clinical trial.

- Initiation of a clinical trial is a strictly regulated process that takes time and needs good planning, Olsen says. Prior to starting a clinical trial, the company needs to obtain an authorisation from the NCA in the country/countries where the trial is to be conducted.

In general, the regulatory procedure for starting a clinical trial in EU first involves registration of the clinical trial in the European clinical trial database EudraCT (European Union Drug Regulating Authorities Clinical Trials). Thereafter, the company must prepare a set of clinical and quality regulatory documents, which together constitute an application for a clinical trial for a new medicinal product, a so-called Clinical Trial Authorization (CTA) application.

Documents to be included in the CTA application are e.g. the study protocol, which describes all aspects of the study and how to conduct the study at each clinical site, the Investigator's Brochure (IB), which describes the results of all relevant animal tests and clinical studies done so far with the drug to be tested, and the Investigational Medicinal Product Dossier (IMPD), which describes all chemical and manufacturing related details of the drug, Olsen explains.

In addition, she points out, the responsible investigator at each lead site in each country needs to receive a positive opinion by a Research Ethics Committee (REC), which is an independent body consisting of healthcare professionals and non-medical members, whose responsibility is to give an independent review of the study to protect the rights, safety, dignity and well-being of the subjects involved in a clinical trial.

The company will receive a response from the NCA within 30-35 days after the application package has been registered as valid. A validation usually takes from a few days to 2 weeks after the submission of the CTA application. Often the NCA has requests or question for additional information during the assessment – the most common questions are related to toxicology, the study drug, or dose and/or inclusion/exclusion criteria. A final assessment should be sent to the company within 60 days after receiving a valid application. The feedback time from the REC depends on their meeting frequency – though in average this committee will give their opinion within 6-8 weeks after submission.

If the trial has to be amended, i.e. significant adjustments of the study protocol, changes to the stability and quality of the study drug, or any changes that may affect the safety of the patients; the regulatory processes involving both NCAs and RECs in all countries have to be restarted. The timelines for approvals of an amended study protocol are almost the same as mentioned above, except for the NCA that has to respond within 35 days rather than 60.

- Hence, it takes time to plan, prepare and obtain approvals from the authorities and ethical committees to start a clinical study. When a company conducts a clinical trial in several countries, it takes longer time to obtain approvals due to involvement of independent NCAs and RECs in each country. However, all NCAs assess the same documents for the clinical trial, according to the same principles, in order to secure that the trial is safe, evaluable and address all clinically relevant questions, Olsen emphasizes.

STATUS CLINICAL SITES ACTIVATION

The current LTX-315 clinical trial is ongoing in four out of the five countries where CTA applications have been submitted – Norway, Belgium, United Kingdom and Italy. In total nine clinical sites in these countries are activated and may recruit patients. The approval in France is pending.

STATUS PATIENT ACCRUAL

The enrolment of three patients to the first cohort in the triple negative breast cancer arm, LTX-315 in combination with pembrolizumab (anti-PD1), is completed. The second cohort in this study arm opened for enrolment of patients in April. The two other arms in the trial are recruiting patients that will receive either LTX-315 alone (all cancer types) or LTX-315 in combination with ipilimumab (anti-CTLA4) (malignant melanoma). In the combination arm with ipilimumab, one patient is enrolled so far. In the LTX-315 monotherapy arm, two patients are in screening – i.e. under evaluation to see if they are eligible for the study.

Håkan Wickholm
CEO in
Lytix Biopharma

Letter from the CEO

Time flies, they say. Well, I could not agree more, suddenly we are in April and a lot has happened since the last newsletter.

As indicated in the previous letter we launched a private placement /pre-IPO financing round in December last year. The plan is that the company will go public at the end of this year and be listed at the Nasdaq Stockholm exchange. In order to prepare for the IPO the pre-IPO was directed towards the largest Norwegian shareholders (>1%) as well as Swedish life science investors. The pre-IPO was successful and we reached the target of 60 MNOK. Among the new investors, we are pleased to see the Norwegian Cancer Society (Kreftforeningen) with an investment of 6 MNOK. At the moment, we are also finishing a repair issue directed towards those not invited in the pre-IPO.

OTHER IMPORTANT DEVELOPMENTS:

Patient enrolment in the combination arms; advanced melanoma and TNBC (Triple Negative Breast Cancer) in combination with checkpoint inhibitors, has been initiated. In fact, the first cohort of three patients in the TNBC arm is completed and we have already patients in line for the second cohort which is now open.

The enrolment in the melanoma arm has been slightly slower than planned due to delay of regulatory approvals, despite all documents being submitted timely to regulatory agencies. Some processes are outside of our control and this impacted especially a couple of dedicated melanoma trial sites.

The team did a great job last year putting together a grant application to the Norwegian Research Council (User-driven Research-based Innovation), and in January we got the reward:- a NOK 16 million grant over 4 years to support the investigation of LTX-315's ability to make "cold tumors hot" and a Phase II trial in Triple Negative Breast cancer (TNBC). We are very pleased that the Research Council share our view of LTX-315's potential and support our work to give patients better treatments.

We have also strengthened the Lytix team; Torbjorn Furuseth has joined us as new Chief Financial Officer and Vibeke Sundvold Gjerstad as Immunologist, Oncology.

Attending International Scientific or Investor/Partnering conferences is important to increase awareness of the company and LTX-315. In early March, by invitation, we got the opportunity to participate at a dedicated Cancer Immunotherapy meeting in Boston. The meeting focused on combination treatments, and we met and discussed with experts from both academia and industry. LTX-315 attracted a lot of interest from the audience and further discussions will follow.

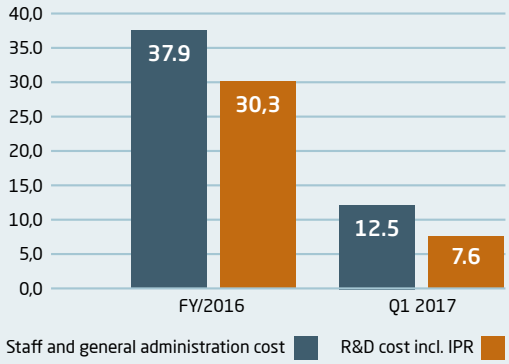
This spring, our focus is delivery of the Phase I combination program and to prepare for the IPO.

PRELIMINARY FINANCIALS 2016 (MNOK)

	FY/2016	Q1 2017
Income - public grants, other revenue	**13.2**	**0.1**
Staff and general administrative costs	-37,9	-12,5
R&D Costs incl. IPR	-30,3	-7,6
Total Operational Cost	**-68,2**	**-20,1**
EBIT	**-55,0**	**-20,0**
Net Financials	0,7	-0,3
Earnings before tax	**-54,3**	**-20,3**
Cash end of period	**18,0**	**55,9**

Staff costs include all employed R&D personnel. Costs for IPR are included in the R&D cost. Earned tax refund ("Skattefunn") is not included. All figures are for the parent company, preliminary and not audited.

COST DISTRIBUTION 2016 AND Q1 2017 (MNOK)



INCOME

Lytix Biopharma had in 2016 on-going public grants from The Research Council of Norway and "Skattefunn" (Tax refund). The grants are booked at the time for received payment. In an industry characterized by long-lasting R&D programs with significant implied risk, the financial support from public sources has been very valuable. For our shareholders the grants are essential to relieve risk on the equity capital. Lytix Biopharma's management is continuously working with public funding opportunities for part financing of our comprehensive R&D program.

This year, the Research Council of Norway has awarded Lytix Biopharma a new 16 MNOK grant, which will contribute significantly to the financing of our R&D program for the period 2017-2020. Other income is relatively small and related to consultancy to other companies.

COST AND INVESTMENT

During 2016, the cost level has been significantly lower than planned due to a halt in the ongoing clinical mono-study in the second half of the year and the consequent delay of the planned combination studies. In other areas, the cost level has been as planned. The company's continued investment in R&D and IPR portfolio is fully expensed. The company financed the 100% owned subsidiary Amicoat AS through 2016 with 5 MNOK in equity and a 4 MNOK loan. Amicoat was de-merged with effect from 01.01.2017; the formal process to be finalized in April this year.

EQUITY AND CASH

The last equity issue with gross proceeds at 60 MNOK was approved by the Extraordinary General Meeting in February this year. A repair issue is ongoing and will be finalized in April. The board has prepared a strategy in order to finance the extensive R&D program for the forthcoming years. Cash by the end of Q1/2017 was 56 MNOK.

The company has no interest-bearing debt.

Lytix Biopharma is developing second generation oncolytic molecules for deep seated tumors

CSO Øystein Rekdal and the scientific team

In addition to LTX-315, Lytix Biopharma has a small portfolio of second-generation oncolytic molecules for use as local treatment of primary and secondary liver malignancies, explains CSO Øystein Rekdal.

He and the scientific team are currently verifying data from a lead series aiming to enter into a preclinical and clinical development program. The selection of a lead candidate is planned for Q3 2017.

The molecules are currently assessed in a battery of anticancer activity and toxicology studies. Preliminary data show that these second-generation molecules may, based on their properties, enable local immunotherapy of visceral lesions. Initially we will focus on hepatocellular carcinoma and liver metastases of colorectal cancer with the selected lead candidate, but other deep-seated cancer indications may also be evaluated, says Øystein.

Lytix Biopharma is collaborating with a multidisciplinary team of leading, national and international experts working on the cutting edge of cancer biology and immunotherapy. Upon successful completion of the initial toxicological, in vitro and in vivo anticancer studies and the subsequent selection of a lead candidate, a formal preclinical assessment will be initiated. The aim is to start clinical Phase I studies in late 2018.

LATEST NEWS

FROM LYTIX BIOPHARMA

- Lytix Biopharma raised 60 MNOK in the Pre-IPO
- Fully subscribed repair share issue
- The Norwegian Cancer Society invested 6 MNOK in Lytix Biopharma
- Lytix Biopharma presented 4 posters at AACR in Washington in April
- Øystein Rekdal (CSO) and Andrew Saunders (CMO) presented Lytix Biopharma at ICI Boston (a dedicated Cancer Immunotherapy meeting) in March
- Lytix Biopharma featured in Mergermarket article in March
- Lytix Biopharma presented at the 10th Annual European Life Sciences CEO Forum & Exhibition in Zurich in March
- Lytix Biopharma supports research at Weill Cornell Medicine, New York
- Lytix Biopharma was granted 16 MNOK from The Research Council of Norway - BIA, Brukerstyrt Innovasjonsarena
- Lytix Biopharma was present at J.P. Morgan 35th Annual Healthcare Conference in San Francisco in January
- Håkan Wickholm presented Lytix Biopharma at Redeye Life Science Seminar in November 2016

SPIN-OUT OF AMICOAT AS AND PHARMA HOLDINGS AS

In a parallel process to the share issue, Lytix Biopharma's non-cancer assets were spun out with effect from January 1st 2017, and Lytix Biopharma AS now emerges as a dedicated cancer medicine company only.

After the spin-out, shares in Lytix Biopharma AS hold no rights to Amicoat AS and Pharma Holdings AS. However, the 'old shareholders' will receive shares in these companies corresponding to their proportion of equity in Lytix before the pre-IPO .

Amicoat AS works with antimicrobial coating technology, presently focusing on medical devices, such as special wound care bandages, based on LTX-109. The pharma patents relating to the pharmaceutical use of LTX-109 now rest with Pharma Holdings AS.

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