Lytix Biopharma

Newsletter September 2017

Edwin Klumper
CEO Lytix Biopharma

TURNING SCIENCE INTO BUSINESS IS THE KEY TO VALUE CREATION...

Edwin Klumper joined Lytix Biopharma as CEO in September 2017. However, he knows Lytix quite well as he in 2012 acted as an interim CMO leading the management team to reset its oncology strategy.

The unique power of the lead compound LTX-315 in 'turning cold tumors hot' was recognized early and ahead of the curve in the immuno-oncology field those days. To further strengthen the science substantiating this unique feature, international collaborations with world leading experts were established, and this indeed proved to confirm these claims over recent years.

Edwin Klumper's main focus will be to take Lytix Biopharma to the next level while going public this year.

– *Lytix has come off its academic stage as a regional biotech spin-off in recent years and needs to keep raising its level in becoming a globally recognized immuno-oncology Biotech Company. With Lytix firmly based on a truly unique scientific platform, it is my role to lead the company in continuously strengthening our business on all levels, and ensure we focus on driving our drug development, hire the best people addressing the immune therapy challenges ahead, and the leadership team are agile and decisive in reacting to the latest developments and opportunities,* Edwin Klumper says.

With my 25 years of industry experience, being an advisor for nearly 100 oncology drug development programs, combining my scientific and business background, it is my personal ambition to lead the Lytix team in capitalizing on our science. Turning science into business is the key to value creation and bringing new cancer treatments closer to a reality for so many patients. I am thrilled to have the opportunity to be reunited with the Lytix team and for us to play together in the most promising and exciting field of immuno-oncology today, Edwin Klumper concludes.

Translational Research report

The majority of cancer patients do not respond to immunotherapy due to a lack of a T cell-inflamed tumor microenvironment (cold tumors). LTX-315 has shown strong ability to enhance the number of tumor-infiltrating T cells both in preclinical models and also recently in patients.

During the last two months we have published two papers in internationally peer reviewed journals, describing LTX-315´s ability to increase the number of T cells in the tumor microenvironment. In one of the papers we report LTX-315's ability to induce regression of both treated tumors and non-treated tumors (abscopal effects). In collaboration with HalioDx (Marseille, France) it has been documented that LTX-315 treatment induces upregulation of a number of genes involved in turning non-T cell-inflamed tumors (cold) into T cell-inflamed tumors (hot) in patients. With its promising ability to heat up cold tumors, LTX-315 has the potential to enhance the proportion of patients responding to immune therapy including immune checkpoint inhibitors.

As a part of the company´s pipeline we have identified several potential oncolytic second generation molecules. Several of these molecules have shown very promising effects in deep-seated cancer models such as liver cancer. The company will in the near future decide how to move forward with these molecules.

Lytix Biopharma is very happy to announce that Robert D. Schreiber, Ph.D, has joined our scientific advisory board. Schreiber is a Distinguished Professor at Washington University School of Medicine in St. Louis. Schreiber's is an internationally recognized capacity in the field of immune-oncology and his research has led to a generalized appreciation of the profound effect of immunity on developing tumors and has contributed critical conceptual and practical support to the fields of tumor immunology and cancer immunotherapy. Recently, Schreiber pioneered the use of genomics approaches to define the antigenic targets of cancer immunoediting and the mechanisms that underlie the process. The latter work supports ongoing efforts to develop individualized cancer immunotherapies.

Robert Schreiber has authored more than 300 peer-reviewed and invited publications and has received many honors including the William B. Coley Award for Distinguished Research in Basic and Tumor Immunology from the Cancer Research Institute, The Charles Rodolphe Brupbacher Prize for Cancer Research, and The Lloyd J. Old Prize in Cancer Immunology awarded jointly by the American Association for Cancer Research and The Cancer Research Institute. Schreiber is a Fellow of the American Association for the Advancement of Science, a member of the American Academy of Arts and Sciences and a member of the U.S. National Academy of Sciences.

Robert D. Schreiber, Ph.D
Member of Scientific Advisory Board in Lytix Biopharma

CLINICAL UPDATE

15 patients have been enrolled in the current ongoing 3 arm trial (LTX-315 monotherapy, combination with Ipilimumab and combination with Pembrolizumab). No clinically significant LTX-315 related adverse events or dose-limiting toxicities have occurred, and no atypical immune checkpoint related adverse events have been observed. Patients are receiving LTX-315 injections in multiple tumour lesions on 6 injection days over a 3 week period.

Preliminary evidence of anti-tumour efficacy has been observed, including durable (> 6 months and ongoing) stable disease in a malignant melanoma patient who received Ipilimumab (2 infusions) + LTX-315 and who was refractory to 1st line pembrolizumab. In addition; significant CD8+ T-cell infiltration has been documented in injected tumour lesions after 3 weeks of LTX-315 treatment compared to baseline biopsies. The study will complete patient accrual to all study arms by Q4 2017.

Håkan Wickholm
Previous
acting CEO in
Lytix Biopharma

Statement from previous acting CEO

The company's focus before the summer was on advancing the clinical Phase I program. Patient enrolment in the combination arms (LTX-315 and checkpoint inhibitors in advanced melanoma and Triple Negative Breast Cancer (TNBC)), picked up after a somewhat slow start. The TNBC arm recruitment is going very well and the third and last dose cohort is opened. The recruitment in the advanced melanoma arm has been slower due to the delay in regulatory approvals of the protocols and the fact that there are more treatment alternatives available for these patients. However, all approvals are now in place, patient accrual is moving at a satisfying pace and we are in line to complete the study during the autumn with full data read-out early 2018. The primary objective with this Phase I study is to ensure that the combination of LTX-315 and checkpoint inhibitors is safe for patients and so far there are no indications of any major safety issues.

Presenting pre-clinical or clinical data at large international conferences is an important activity in making the company and its research projects known to both academic institutions and industrial companies. In addition to presenting important pre-clinical data at AACR (American Association of Cancer Research) in Washington, Lytix presented for the first time a poster with clinical data at ASCO (the American Society of Clinical Oncology). The poster data was on 28 patients treated with LTX-315 in monotherapy, showing promising anti-tumor and immune responses, and it included a recently performed analysis by HalioDX (a leading immune oncology diagnostic company). The HalioDX's state-of-the-art Immune gene expression technology Immunosign® was applied to a set of pre and post LTX-315 treatment biopsies. This Immunosign® analysis of LTX-315 treated tumors showed clear effect on key genes involved in the immune-mediated tumor regression in patients. This strongly supports LTX-315's potential to be an ideal combination partner by converting "cold tumors to hot" and thereby these tumors are more responsive to treatment with checkpoint inhibitors. It was encouraging that the presentation gained such a lot of attention and the team had fruitful discussions with both academic and industrial visitors.

OUTLOOK

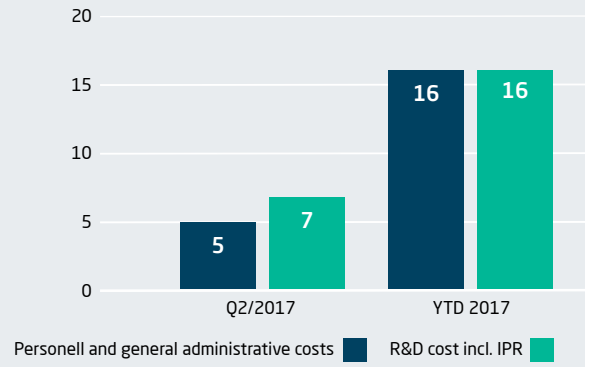
Lytix has several important work streams during the second half of this year; Completing the clinical Phase I trial is of course a key activity and another one, which is already initiated, is to prepare the company for a public listing in Q4 this year.

PRELIMINARY FINANCIALS 2017 (MNOK)

	01.04-30.06	YTD
Income - public grants, other revenue	**4.5**	**4.7**
Personell and general administrative costs	-5.0	-16.4
R&D Costs incl. IPR	-7.0	-15.6
Total Operational Cost	**-12.0**	**-32.0**
EBIT	**-7.5**	**-27.3**
Net Financials	-0.2	-0.5
Earnings before tax	**-7.7**	**-27.8**
Cash end of period	**37.9**	**37.9**

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 YTD 2017 AND Q2 2017 (MNOK)



INCOME

In 2017, the Research Council of Norway has awarded Lytix Biopharma a new 16 MNOK grant. In addition the Company has on-going public grants from "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. The grants 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

The cost level for the second quarter of 2017 has been somewhat lower than expected. The lower costs are mainly related to a longer regulatory process to get approvals in all five countries where the clinical trials are running, and hence patient recruitment started later. The company's continued investment in R&D and IPR portfolio is fully expensed. The demerger of non-cancer related business was finalised in early may 2017.

EQUITY AND CASH

During the first six months of 2017 the Company has had two equity issues. First a private placement which was followed by a repair issue. In total, the gross proceeds amounted to 80 MNOK. The board has prepared a strategy in order to finance the extensive R&D program for the forthcoming years. Cash by the end of Q2/2017 was 38 MNOK. (This does not include the proceeds from the repair issue, that 20,3 MNOK was received in July 2017.) The company has no interest-bearing debt.

Financing

80 million NOK raised

The company maintains its preparations for an IPO this year.

The Management and the Board of Directors has confirmed their intention to proceed with the preparations towards an Initial Public Offering (IPO) and listing of Lytix Biopharma at Nasdaq First North in Stockholm this year. The Management and the Board of Directors believe a public listing is the logical next step for the Company and is in line with the previously communicated ambitions.

In the Pre-IPO private placement and the repair issue earlier this year Lytix secured a guaranteed amount of 116 MSEK in an IPO.

"This guarantee gives us and new investors comfort for the IPO. However, the ambition is to raise more money to take us through important milestones and value inflection points" the CFO, Torbjørn Furuseth, says.

The Company will use the proceeds from the IPO to continue the development of the lead drug candidate LTX-315, through clinical Phase II trials. We have further documented LTX-315's ability to turn "cold tumours hot" and as such make them able to respond to immune therapy. The immune checkpoint inhibitors is the first wave in immune-oncology with a rapid uptake in the market. However, there is a challenge with too many non-responders, and the need for drugs that can turn cold tumors hot is growing.

As part of the preparations to become a public company, Lytix has strengthened the financial team:

Gjest Breistein joined Lytix Biopharma as Business Controller in August, 2017. In the short run, his main focus will be to help Lytix Biopharma complete a successful IPO.

Breistein is a state authorized public accountant and has a master in applied economics and finance. He has 8 years of experience from PwC where he worked as an auditor and as a consultant in the capital market group - advising clients in their IPO processes and bond transactions.

"Gjest is a very strong professional, and his background and experience are of great value for Lytix Biopharma. We are very excited he joined our team" Furuseth concludes.

LATEST NEWS

FROM LYTIX BIOPHARMA

- Lytix Biopharma completed 1st combination cohort of LTX-315 and pembrolizumab in TNBC in April, and the 2nd combination cohort was completed in July. The third combination cohort is ongoing.
- Immunotherapeutic effects of LTX-315 was published in Future Medicinal Chemistry in April, and abscopal effect (regression of non-injected lesions) in sarcoma model was published in OncoImmunology in August.
- Lytix Biopharma held a company presentation at BioEquity Europe in Paris in May.
- Clinical monotherapy data from the ongoing Phase I trial with LTX-315 was presented at a poster at ASCO in June, and at the same conference a meeting with all investigators in the ongoing trial was arranged.
- Data from HalioDx SAS (an immuno-oncology diagnostic company) show that LTX-315 upregulates key genes involved in the immune-mediated tumour regression in patients.
- Lytix Biopharma renewed its profile in July - this includes a new logo, new colors and a new website.
- Robert D. Schreiber, Ph.D, joined Lytix Biopharma´s Advisory Board in August. Schreiber is "The Andrew M. and Jane M. Bursky Distinguished Professor" in the Department of Pathology and Immunology at Washington University School of Medicine in St. Louis.
- The first cohort of LTX-315 monotherapy was completed in August.
- Gjest Breistein was employed as business controller in Lytix Biopharma from August.
- Edwin Klumper joined the Board of Directors in August and was appointed as CEO in September.
- Lytix Biopharma is sponsoring the CIMT meeting in Mainz in September and is presenting two posters at the conference.

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