

Lytix Biopharma AS

Addressing the major challenge in cancer therapy with Oncolytic Molecules

First quarter 2022 presentation

May 12, 2022





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Today's presenters



platform. Over the last years Rekdal has been inst

Øystein Rekdal / CEO and co-founder

 Over the last years Rekdal has been instrumental in the development of intra-tumoral therapy of LTX-315 from preclinical to clinical 'proof of concept'-studies.

Dr. Rekdal's post-doctoral research forms the basis of Lytix Biopharma's oncolytic molecule

• He previously served Lytix in various roles including CSO, and Head of R&D.



Graeme Currie / CDO

- Has 30 years of drug development experience in pharmaceutical, medium and small biotechnology companies.
- Most recently Chief Development Officer of Tolerion Inc.
- Has held senior leadership roles at both public and privately held biotech organizations.
- Dr. Currie has been integrally involved in the development of 8 approved new drugs.
- Dr. Currie holds a Ph.D. from Aston University in the UK.

Gjest Breistein / CFO

- Mr. Breistein has eight years of experience from PwC as an auditor and consultant working with public and private companies across multiple industry sectors.
- Prior to joining Lytix Biopharma, he was in PwC's capital markets group advising clients in capital market transactions, financing and listing processes.

Lytix Biopharma in brief

Lytix is a biotech company headquartered in Oslo, Norway.

The company was listed at Euronext Growth in June 2021.

Lytix has developed a unique and proprietary technology platform for *in situ* vaccination.

Lytix aims to accelerate progression of this unique platform, building a pipeline of oncolytic molecules for intratumoral injection.

The lead asset is in a clinical Phase II at MD Anderson Cancer Center.

A second clinical Phase II trial commenced in April 2022, performed by our commercial partner Verrica Pharmaceuticals.





Why is it so difficult to cure cancer ?



New mutations occur during cancer evolution ______ leading to different cancer cells in a tumor

Tumor

heterogeneity



Each tumor is unique





Tumor heterogeneity is the major challenge in current cancer immunotherapy





Source: GlobalData High-Prescriber Survey (Dec. 2020)



Failing to kill all cancer cells often leads to recurrence of even "harder to treat" tumors



Oncolytic molecules kill all cancer cells

- Able to kill all types of cancer cells including chemotherapyresistant cells
- Effective exposure of tumor antigens (mutations) from all killed cells
- Results in a broad T cell response towards the tumor

A cancer cell before treatment



A cancer cell after treatment





Oncolytic molecules address tumor heterogeneity



TREATED TUMOR

Exposure of mutations (tumor antigens) from all dead cancer cells

LYMPH NODE

Generating T cells that recognize the different mutations (tumor antigens)

BLOOD VESSELS

T cells enter the blood stream searching for cancer cells

NON-TREATED TUMOR

T cells infiltrate and eradicate distant cancer cells





Highlights of the first quarter 2022

- First patient in Verrica Pharmaceutical's study with LTX-315 screened in March and dosed on April 4th
 - Triggered a milestone payment of 1m USD to Lytix
- ATLAS-IT-05 Expanding site network to highly recognized sites with expertise within intratumoral immunotherapy in Europe
- ATLAS-IT-04 Abstract approved for presentation of the clinical results at ASCO in June
- LTX-401 for intratumoral treatment of liver cancer
 - At pre-clinical stage and will be made ready for clinical studies in liver cancer patients within 2022
- In March, CEO Øystein Rekdal held a plenary presentation at the Next Generation Immuno-Oncology Congress in London
 - Topic: Addressing tumor heterogeneity with oncolytic molecules

Clinical/operational update



Lytix`license partner Verrica Pharmaceuticals Inc shows progress with their Phase II study

- First patient in Verrica's Phase II study was screened in March and dosed on April 4th evaluating LTX-315 for the treatment of Basal Cell Carcinoma (BCC, skin cancer)
- Approximately 66 patients with Basal Cell Carcinoma will be enrolled in the study
- Estimated completion date: February 28, 2023 (clinicaltrials.gov)
- In the US alone, there are approximately 3-4 million patients diagnosed with basal cell carcinomas each year and there is a high need for new therapeutics





Phase II study with our lead cancer drug candidate LTX-315 (ATLAS-IT-05)

- A Phase II combination study evaluating LTX-315 and pembrolizumab in patients with solid tumors
- The study protocol has been amended to narrow its focus to patients with advanced melanoma
- Objective for the study
 - Document whether LTX-315 in combination with pembrolizumab is effective in inducing responses in melanoma patients who have failed prior anti-PD-1/PD-L1 immune checkpoint therapy
- Current status
 - Two sites have initiated recruitment, and enrollment is ongoing and to be completed by the end of 2022
 - A larger network of clinical sites with short activation time managed by OncoBay is added
 - Process to open sites in Europe started









Expanding the global reach

Site network

- US sites have been impacted by Covid-19
- To quickly expand our access to patients in the US we added Oncobay in February 2022
- To mitigate recruitment challenges, the study is expanding to Europe
- Added operational expertise
 - Jackie Earabino recruited as Head of Clinical Operations



LTX-315 in combination with adoptive T-cell therapy in a Phase II study for patients with sarcoma

Adoptive T cell therapy

- A method to isolate and expand the patient's own T cell before they are given back to the patient to combat the tumor
- Soft tissue sarcoma
 - Often cold tumors with low number of T cells
- LTX-315 increases the number of T cells in treated tumors





LTX-315 in combination with adoptive T-cell therapy in a Phase II study for patients with sarcoma

Objectives

- Does LTX-315 induce T-cell infiltration in sarcoma patients?
- Are the T cells generated specific for the patient's tumor cells?
- Is there any correlation between T cells generated by LTX-315 and clinical benefit?
- Status
 - Treatment completed (n=6)
 - Data analysis ongoing
 - Abstract approved, results will be presented at ASCO in June





LTX-401 - Activities are on track with the aim to be Phase I ready end of 2022



LTX-401 is a small oncolytic molecule that has demonstrated outstanding results in experimental liver cancer models

DISRUPTS MITOCHONDRIA OF CANCER CELLS



Disintegration of mitochondria result in release of potent danger signals

EFFECT IN EXPERIMENTAL HEPATOCELLULAR CARCINOMA



LTX-401 treatment cured 50% of the animals with only 2 injections

COMMENTARY

Hepatocellular carcinoma and liver cancer metastases are two big cancer segments with high unmet medical need and significant market potential

High incidence with poor standard treatments -6th most common cancers worldwide High severity and low survival rate -2nd most deadly cancer worldwide

Total diagnosed incident population for HCC is expected to reach 343,761 patients by 2029 in the eight major markets (8MM) - US, France, Germany, Italy, Spain, UK, Japan, and China.

HCC market (8MM) expected to grow from \$1.0B in 2019 to 5.3B in 2029.

LTX-401 has shown favorable safety data -LTX-401 is well tolerated in animals -Maximum tolerated dose established

LTX-401 Is in late pre-clinical program and the preparation for a First in Human clinical trial at the end of 2022 is ongoing

3 MNOK grant received from RFF (Regionalt Forskningsfond)



Key company objectives for 2022

- Expand the clinical impact field for LTX-315 and complete enrollment in the ATLAS-IT-05 Phase II trial by the end of 2022
- Provide API to and support our commercial partner Verrica Pharmaceuticals in their Phase II trial in BCC
- Analyze and present data from the ATLAS-IT-04 at ASCO in June
- Complete the required pre-clinical program for a Clinical Trial Application for LTX-401 in Europe
- Increase presence and attention in the international investment community
- Identify additional opportunities to expand our innovative pipeline of molecules

Financials



Key figures – profit and loss

_ Amounts in NOK thousands	Unaudited Q1 2022	<i>Unaudited</i> Q1 2021	FY 2021
Total operating income	1,509	21,561	25,821
Total operating expenses	(16,182)	(22,012)	(73,844)
Loss from operations	(14,673)	(452)	(48,017)
Loss for the period	(15,231)	(356)	(48,049)

- The decrease in operating income is explained by the milestone payment of NOK 19.3 million received from Verrica in Q1 2021. Operating income for Q1 2022 consist of public grants.
- The decrease in total operating expenses is mainly explained by the extraordinary and nonrepetitive bonus following the IND approval in Q1 2021.
- Excluding salaries, operating expenses increased from NOK 8.2m to NOK 12.5m due to higher R&D activity in 2022.



Key figures – balance sheet

	Unaudited	Unaudited	
Amounts in NOK thousands	31.03.2022	31.03.2021	31.12.2021
Assets			
Property, plant and equipment	35	-	-
Trade and other receivables	7,242	6,190	5,680
Cash and cash equivalents	180,666	22,582	197,282
Total assets	187,942	28,772	202,962
Shareholder's equity and liabilities			
Total equity	174,807	20,701	189,624
Total liabilities	13,135	8,071	13,338
Total equity and liabilities	187,942	28,772	202,962

In March 2022, PBM LYT Holdings, LLC, an affiliate of PBM Capital Group, LLC exercised their warrants giving rights to 1,329,306 new shares. The share capital increase was registered on April 20, 2022.

Company presentation







Tumor heterogeneity is the major challenge in current cancer immunotherapy





Source: GlobalData High-Prescriber Survey (Dec. 2020)



T cells may be the only solution to combat tumor heterogeneity

Each T cell can only fight one type of cancer cells

Each person has a repertoire of $10x^{10}$ different T cells

T cells need to see tumor antigens to be activated





Oncolytic molecules address the major challenges with tumor heterogeneity by generating a broad T cell response





The oncolytic peptide LTX-315 generates a high number of different T cells in mouse melanoma



Effective exposure of tumor antigens leads to activation of a broad T cell response

One type of T cell





LTX-315 is effective in "hard to treat" cancer models



No effect of chemotherapy or immune checkpoint inhibitors in the BRAF mutated melanoma model



LTX-315 also generates new high number of novel T cells in a breast cancer patient



T cell clones before treatment

126 different T cells increased significantly in numbers after treatment



Broad T cell response induced in cancer patients with different types of cancer



T cell clones before treatment

Proof of Principle – T cells generated by LTX-315 are able to attack and reduce size of non-treated tumors



Proof of Principle – T cells generated by LTX-315 are able to attack and reduce size of non-treated tumors





Spicer, Clin. Cancer Res., 2021

Oncolytic molecules are ideal for being combined with immune checkpoint inhibitors



Oncolytic molecules generate T cells that recognize different cancer cells



Immune checkpoint inhibitors keeps the brakes off and make the T cells work more efficiently



Case study: Proof of Principle - LTX-315 + checkpoint inhibitor showed effects not obtained with same checkpoint inhibitor alone in breast cancer patient



The checkpoint inhibitor pembrolizumab alone

- No effect in liver metastasis
- 5 % overall response rate (ORR)

LTX-315 + pembrolizumab

- Significant effects in liver metastasis
- 12,5% overall response rates



Large commercial opportunities for T cell activators in metastatic cancer

Global Immune Checkpoint Inhibitors Market

Market forecast to grow at CAGR of 16.8%





Oncolytic molecules have a potential to enhance the number of patients responding to immune checkpoint inhibitors









Pipeline









Verrica Pharmaceuticals has started their Phase II study in the most common form of skin cancer

- Approximately 3-4 million patients diagnosed with basal cell carcinoma in US each year and high unmet need for new treatment options
- First patient in Verrica Pharmaceutical's study treated
- Regulatory milestones based on development goals and sales milestones at >100 mill. USD
- Royalty rates from the low double-digits to the mid-teens based on net sales USD
- The collaboration will be highlighted in a Capital Markets Day June 1st





Nobel laureate Jim Allison, who discovered the first immune checkpoint inhibitor, is a member of our scientific advisory board

"The ability of an activated immune response to generate a **diverse** T-cell repertoire that adapts to **heterogeneous** and genetically unstable tumors (...) make it **absolutely essential** to expand our efforts to find rational **combinations** to unleash antitumor immune responses for the benefit of cancer patients."



Jim Allison

- 2018 Recipient of the Nobel price for the discovery of the first immune checkpoint inhibitor
- 2019 Member of Lytix Advisory Board



Science behind Lytix'technology documented by world leading cancer research institutions



 50+ peer reviewed scientific publications, demonstrating the potential of oncolytic molecules



Lytix investor - the US healthcare specialist PBM Capital invest in game changing technologies

We **partner** with brilliant minds daring to advance science into **revolutionary** therapy.

Summary



Why we will succeed



Interim Financial Statements



Interim statement of profit or loss

	Unaudited	Unaudited	
Amounts in NOK thousands	Q1 2022	Q1 2021	FY 2021
Revenue	-	17	17
Other operating income	1,509	21,544	25,810
Total operating income	1,509	21,561	25,827
Payroll and related expenses	(3,700)	(13,834)	(31,605)
Depreciation and amortization expenses	-	-	-
Direct R&D expenses	(10,725)	(4,878)	(28,817)
Other expenses	(1,757)	(3,301)	(13,421)
Total operating expenses	(16,182)	(22,012)	(73,844)
Loss from operations	(14,673)	(452)	(48,017)
Net financial items	(557)	(96)	(32)
Loss before tax	(15,231)	(356)	(48,049)
Tax expense	-	-	-
Loss for the period	(15,231)	(356)	(48,049)



Interim statement of financial position

Amounts in NOK thousands	Unaudited 31.03.2022	Unaudited 31.03.2021	31.12.2021
Assets			
Non-current assets	25		
Total new surrent essets	35	-	-
lotal hon-current assets		-	-
Current assets			
Trade and other receivables	7,242	6,190	5,680
Cash and cash equivalents	180,666	22,582	197,282
Total current assets	187,907	28,772	202,962
Total assets	187,942	28,722	202,962
Shareholder's equity and liabilities			
Issued capital and reserves			
Share capital	3,874	2,623	3,874
Share premium reserve	170,933	18,078	185,750
Total equity	174,807	20,701	189,624
Liabilities			
Current liabilities			
Trade payables	3,920	1,600	1,476
Other current liabilities	9,216	6,471	11,862
Total current liabilities	13,135	8,017	13,338
Total liabilities	13,135	8,017	13,338
Total equity and liabilities	187,942	28,722	202,962



Interim statement of cash flows

Amounts in NOK thousands	Unaudited 01 2022	Unaudited	FY 2021
	Q1 2022	Q1 2021	112021
Cash flows from operating activities			
Loss for the period	(15,231)	(356)	(48,049)
Adjustments for:			
Depreciation of property, plant and equipment	-	-	-
Share-based payment expense	281	1,168	4,055
Increased/decreased in trade and other receivables	(1,561)	(2,022)	(1,513)
Increased/decreased in trade and other payables	(203)	(4,657)	610
Cash generated from operations	(16,714)	(5,867)	(44,896)
Income tax paid	-	-	-
Net cash flows from operations	(16,714)	(5,867)	(44,896)
Investing activities			
Investments in tangible assets	(35)	-	-
Net cash from/(used in) investing activities	(35)	-	-
Financing activities			
Proceeds from share issue, not yet registered	133	-	213,728
Net cash from/(used in) financing activities	133	-	213,728
Net increase in cash and cash equivalents	(16,616)	(5,867)	168,832
Cash and cash equivalents at the beginning of the period	197,282	28,450	28,450
Cash and cash equivalents at the end of the period	180,666	22,582	197,282



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