

# Lytix Biopharma AS

*New encouraging clinical data*

Second quarter 2022 presentation

August 25, 2022



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# Today's presenters



## Øystein Rekdal / CEO and co-founder

- Dr. Rekdal's post-doctoral research forms the basis of Lytix Biopharma's oncolytic molecule platform.
- 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.
- 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 clinical stage 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 cancer treatment
- Lytix aims to accelerate progression of this unique platform, building a pipeline of oncolytic molecules for intratumoral injection
- Lytix has completed on phase II study and two phase II studies are ongoing with our lead drug candidate

## Highlights of the second quarter 2022

- In April, Verrica Pharmaceuticals dosed the first patient in their Phase II study evaluating LTX-315 in basal cell carcinoma, triggering a milestone payment to Lytix of USD 1 million.
- The results from the ATLAS-IT-04 study presented at ASCO in June demonstrated proof-of-concept by showing that the combination of LTX-315 and Adoptive Cell Therapy (ACT) stabilized the disease in patients with progressive metastatic sarcoma.
- Regulatory process is ongoing to expand the site network for the ATLAS-IT-05 study to highly recognized sites with intratumoral immunotherapy expertise in three European countries.
- Preclinical studies with LTX-401 is finalized and show a favorable safety profile. Preparations for a Phase I clinical study are ongoing and progressing according to plan.
- Jacqueline Earabino joined Lytix as Head of Clinical Operations to strengthen Lytix' clinical team.



# Clinical/operational update

## Lytix` license partner Verrica shows progress with their Phase II study in basal cell carcinoma

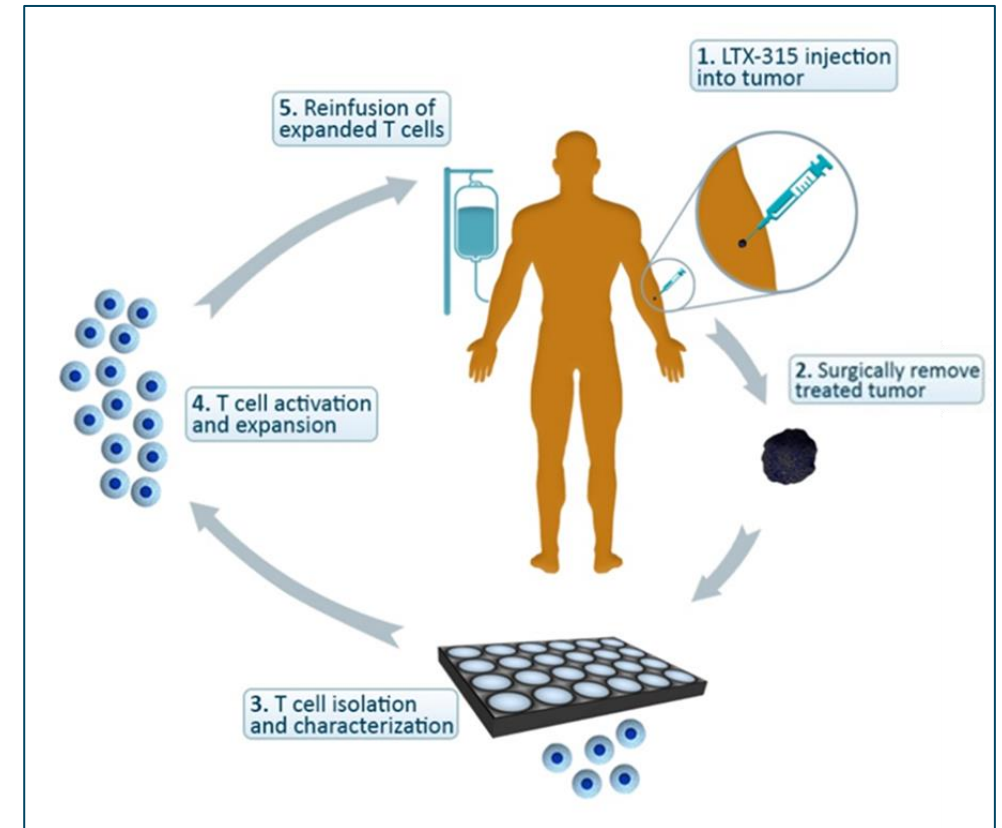
- ⊗ First patient in Verrica`s Phase II study was dosed on April 4<sup>th</sup>
- ⊗ This triggered a milestone payment of USD 1 million to Lytix
- ⊗ Approximately 66 patients with Basal Cell Carcinoma will be enrolled in the study
- ⊗ In the US alone, there are approximately 3-4 million patients diagnosed with basal cell carcinomas each year
- ⊗ Basal cell carcinoma as the most common skin cancer opens up for a large commercial potential for LTX-315



## ATLAS-IT-04:

# Rational for combining LTX-315 with Adoptive Cell Therapy

- ACT therapy
  - T cells are isolated and multiplied before being transferred back to the cancer patient
- ACT therapy has shown promising effects in melanoma
- In sarcoma and many other tumor types ACT will not be effective as a stand-alone therapy due to low number of T cells
- LTX-315 has demonstrated ability to generate T cells in several different cancer types including sarcoma





## ATLAS-IT-04: LTX-315 combined with Adoptive Cell Therapy

- LTX-315 in combination with ACT stabilized the disease in patients with progressive metastatic soft tissue sarcoma for up to 26 weeks (N=6)
- LTX-315 generated T cells that were able to recognize tumor-specific antigens enabling the immune system to attack the cancer cells
- The encouraging results were presented at the world`s largest clinical oncology conference (ASCO) in June
- Combination of LTX-315 and ACT has a commercial potential for sarcoma and other tumors with low number of infiltrating T-cells
- Lytix will initiate discussions with potential partners with commercial interest in ACT

## ATLAS-IT-05:

# Phase II study with our lead cancer drug candidate LTX-315

- ⊗ A Phase II combination study evaluating LTX-315 and pembrolizumab in patients with solid tumors
- ⊗ Objective for the study
  - Document whether LTX-315 in combination with pembrolizumab is effective in inducing responses in patients who have failed prior anti-PD-1/PD-L1 immune checkpoint therapy
- ⊗ The study protocol has been amended to focus on advanced melanoma only
  - Will strengthen the significance of clinical efficacy

## ATLAS-IT-05: Factors to drive enrollment






- Current status
  - Sites in the US are open and recruitment ongoing
- COVID-19 continues to impact site resources
  - To mitigate recruitment challenges, the study is expanding to sites in Europe
  - The regulatory application in Europe was submitted in Q2 2022 and sites in Europe will open in Q3/Q4 2022
  - Study will be led by melanoma experts at each new site
  - The study will complete enrollment in early 2023
- Optimized CRO resources
  - Voisin Consulting Life Sciences (VCLS) was engaged for the EU regulatory application process
- Strengthening of the clinical team
  - Jacqueline Earabino joined Lytix as Head of Clinical Operations – more than 20 years of experience in clinical operations

## LTX-401:

# Lytix` second generation oncolytic molecule

- LTX-401 has demonstrated a commercial potential for deep-seated tumors such as hepatocellular carcinoma and other cancer types that spread to the liver. Liver cancers represent big cancer segments with high unmet medical need and significant market potential
- Pre-clinical results have documented promising anticancer efficacy and a favorable safety profile
- During 2022 Lytix will perform activities required in order to submit a Phase I trial application

# Pipeline

Product candidate	Combination partner	Population	Preclinical	Phase I	Phase II	Phase III	Collaborators
LTX-315	ATLAS-IT-05 Pembroluzimab (Keytruda®)	Patients progressed on checkpoint inhibitors	→				
	Verrica Pharmaceuticals Monotherapy	Basal cell carcinoma	→				
	ATLAS-IT-04 Adoptive T-cell therapy	Advanced soft tissue sarcoma	→				
LTX-401	Monotherapy	Liver cancer	→				
LTX-122	Adoptive T-cell therapy	Dog lymphoma	→				
<b>A unique technology platform</b>	<b>Inspired by nature</b> Based on the concepts of naturally occurring host defense peptides, scientifically improved for cancer therapy			<b>In situ vaccination platform</b> Candidate drugs to be directly injected into solid tumors priming the immune system for potent activation			

## Key company objectives for 2022

- ⊗ Expand the clinical impact field for LTX-315 and drive enrollment in the ATLAS-IT-05 Phase II trial towards completion
- ⊗ Support our commercial partner Verrica Pharmaceuticals in their Phase II trial in BCC
- ⊗ Initiate discussion with partners with commercial interest in ACT
- ⊗ Complete the required pre-clinical activities within 2022 for a Clinical Trial Application for LTX-401
- ⊗ Increase presence and attention in the international biotech investment and business community
- ⊗ Identify additional opportunities to expand our innovative pipeline of molecules



# Key figures

## Key figures – profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2022	<i>Unaudited</i> Q2 2021	<i>Unaudited</i> H1 2022	<i>Unaudited</i> H1 2021	FY 2021
Total operating income	10,427	1,640	11,936	23,201	25,827
Total operating expenses	(20,418)	(14,041)	(36,600)	(36,054)	(73,844)
<b>Loss from operations</b>	<b>(9,991)</b>	<b>(12,401)</b>	<b>(24,664)</b>	<b>(12,853)</b>	<b>(48,017)</b>
<b>Loss for the period</b>	<b>(1,183)</b>	<b>(12,392)</b>	<b>(16,414)</b>	<b>(12,748)</b>	<b>(48,049)</b>

- ✘ In April, Lytix received a USD 1 million milestone payment from Verrica Pharmaceuticals following first patient dosed in its Phase II study of LTX-315 for the treatment of basal cell carcinoma.
- ✘ Total operating expenses for the six months ended 30 June 2022 ended at NOK 36.6 million, which is in line with last year's figures of NOK 36.0 million. Compared to the six months ended 30 June 2021, there has been an increase in activities in connection to the ongoing ATLAS-IT-05 trial in the US and the preclinical development of LTX-401. In parallel, personnel expenses and other operating expenses have decreased. Cash position at the end of the period was NOK 177.1 million compared with NOK 71.0 million as of 30 June 2021.



## Key figures – balance sheet

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2022	<i>Unaudited</i> 30.06.2021	31.12.2021
<b>Assets</b>			
Property, plant and equipment	132	-	-
Trade and other receivables	6,893	162,792	5,680
Cash and cash equivalents	177,084	70,950	197,282
<b>Total assets</b>	<b>184,108</b>	<b>233,742</b>	<b>202,962</b>
<b>Shareholder's equity and liabilities</b>			
Total equity	173,967	223,030	189,624
Total liabilities	10,141	10,712	13,338
<b>Total equity and liabilities</b>	<b>184,108</b>	<b>233,742</b>	<b>202,962</b>

- ⊗ 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.



# Summary

# Why we will succeed



## UNIQUE APPROACH

Lytix's molecules represent the missing piece

Ideal combination partners for checkpoint inhibitors and adoptive T-cell therapy



## SCIENCE

Science confirmed by top notch US and European cancer research institutions

Nobel Laureate advisory board member



## VALIDATION

Commercial deal within skin cancer

US health specialist fund as cornerstone investor



## EXECUTION

Management Board

Completed Phase II study in sarcoma patients

Ongoing Phase II study in melanoma patients



# Interim Financial Statements

# Interim statement of profit or loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2022	<i>Unaudited</i> Q2 2021	<i>Unaudited</i> H1 2022	<i>Unaudited</i> H1 2021	FY 2021
Revenue	-	-	-	17	17
Other operating income	10,427	1,640	11,936	23,184	25,810
<b>Total operating income</b>	<b>10,427</b>	<b>1,640</b>	<b>11,936</b>	<b>23,201</b>	<b>25,827</b>
Payroll and related expenses	(6,175)	(3,462)	(9,875)	(17,296)	(31,605)
Depreciation and amortization expenses	(6)	-	(6)	-	-
Direct R&D expenses	(12,055)	(4,692)	(22,780)	(9,569)	(28,817)
Other expenses	(2,182)	(5,887)	(3,939)	(9,188)	(13,421)
<b>Total operating expenses</b>	<b>(20,418)</b>	<b>(14,041)</b>	<b>(36,600)</b>	<b>(36,054)</b>	<b>(73,844)</b>
<b>Loss from operations</b>	<b>(9,991)</b>	<b>(12,401)</b>	<b>(24,664)</b>	<b>(12,853)</b>	<b>(48,017)</b>
<b>Net financial items</b>	<b>8,808</b>	<b>9</b>	<b>8,250</b>	<b>105</b>	<b>(32)</b>
<b>Loss before tax</b>	<b>(1,183)</b>	<b>(12,392)</b>	<b>(16,414)</b>	<b>(12,748)</b>	<b>(48,049)</b>
Tax expense	-	-	-	-	-
<b>Loss for the period</b>	<b>(1,183)</b>	<b>(12,392)</b>	<b>(16,414)</b>	<b>(12,748)</b>	<b>(48,049)</b>

# Interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2022	<i>Unaudited</i> 30.06.2021	31.12.2021
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	132	-	-
<b>Total non-current assets</b>	<b>132</b>	<b>-</b>	<b>-</b>
<b>Current assets</b>			
Trade and other receivables	6,893	162,792	5,680
Cash and cash equivalents	177,084	70,950	197,282
<b>Total current assets</b>	<b>183,977</b>	<b>233,742</b>	<b>202,962</b>
<b>Total assets</b>	<b>184,108</b>	<b>233,742</b>	<b>202,962</b>
<b>Shareholder's equity and liabilities</b>			
<b>Issued capital and reserves</b>			
Share capital	4,007	3,874	3,874
Share premium reserve	169,960	219,156	185,750
<b>Total equity</b>	<b>173,967</b>	<b>223,030</b>	<b>189,624</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade payables	2,557	2,775	1,476
Other current liabilities	7,585	7,937	11,862
<b>Total current liabilities</b>	<b>10,141</b>	<b>10,712</b>	<b>13,338</b>
<b>Total liabilities</b>	<b>10,141</b>	<b>10,712</b>	<b>13,338</b>
<b>Total equity and liabilities</b>	<b>184,108</b>	<b>233,742</b>	<b>202,962</b>

# Interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2022	<i>Unaudited</i> Q2 2021	<i>Unaudited</i> H1 2022	<i>Unaudited</i> H1 2021	FY 2021
<b>Cash flows from operating activities</b>					
Loss for the period	(1,183)	(12,392)	(16,414)	(12,742)	(48,049)
<b>Adjustments for:</b>					
Depreciation of property, plant and equipment	6	-	6	-	-
Share-based payment expense	344	993	624	2,161	4,055
Increased/decreased in trade and other receivables	349	(156,602)	(1,213)	(158,624)	(1,513)
Increased/decreased in trade and other payables	(2,994)	2,641	(3,197)	(2,016)	610
<b>Cash generated from operations</b>	<b>(3,479)</b>	<b>(165,361)</b>	<b>(20,193)</b>	<b>(171,228)</b>	<b>(44,896)</b>
Income tax paid	-	-	-	-	-
<b>Net cash flows from operations</b>	<b>(3,479)</b>	<b>(165,361)</b>	<b>(20,193)</b>	<b>(171,228)</b>	<b>(44,896)</b>
<b>Investing activities</b>					
Investments in tangible assets	(102)	-	(137)	-	-
<b>Net cash from/(used in) investing activities</b>	<b>(102)</b>	<b>-</b>	<b>(137)</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>					
Proceeds from share issue, not yet registered	-	213,728	133	213,728	213,728
<b>Net cash from/(used in) financing activities</b>	<b>-</b>	<b>213,728</b>	<b>133</b>	<b>213,728</b>	<b>213,728</b>
Net increase/(decrease) in cash and cash equivalents	(3,582)	48,368	(20,198)	42,500	168,832
Cash and cash equivalents at the beginning of the period	180,666	22,582	197,282	28,450	28,450
<b>Cash and cash equivalents at the end of the period</b>	<b>177,084</b>	<b>70,950</b>	<b>177,084</b>	<b>70,950</b>	<b>197,282</b>

# Q&A

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