

# Lytix Biopharma AS

*Addressing the major challenge in cancer therapy*

Fourth quarter 2022 presentation

February 16, 2022



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# Presenting team



## 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.



## 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.



## 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.



## Ole Peter Nordby / Head of IR & Communication Manager

- Mr. Nordby has 30 years of financial market experience, mainly with life science investments in the Nordic region.
- He has held positions as senior portfolio manager, analyst, investment director and CFO at Vesta Fondsforvaltning, Handelsbanken Markets, Norgesinvestor and Sigma Fondsforvaltning respectively
- Most recently he served as CFO at Oncoinvent

# Scientifically and commercially validated

## Unique non-viral oncolytic platform with broad pipeline opportunities

- *Lead candidate; one completed and two ongoing Phase II studies*
- *Second generation molecule: Phase I study in 2023*

## Innovative pipeline that addresses major challenges in cancer therapy

- *Tumor heterogeneity*
- *Cold tumors*
- *Resistance*

## Our solution:

- *By facilitating T-cell priming, oncolytic molecules can increase the number of patients responding to immune checkpoint inhibitors*

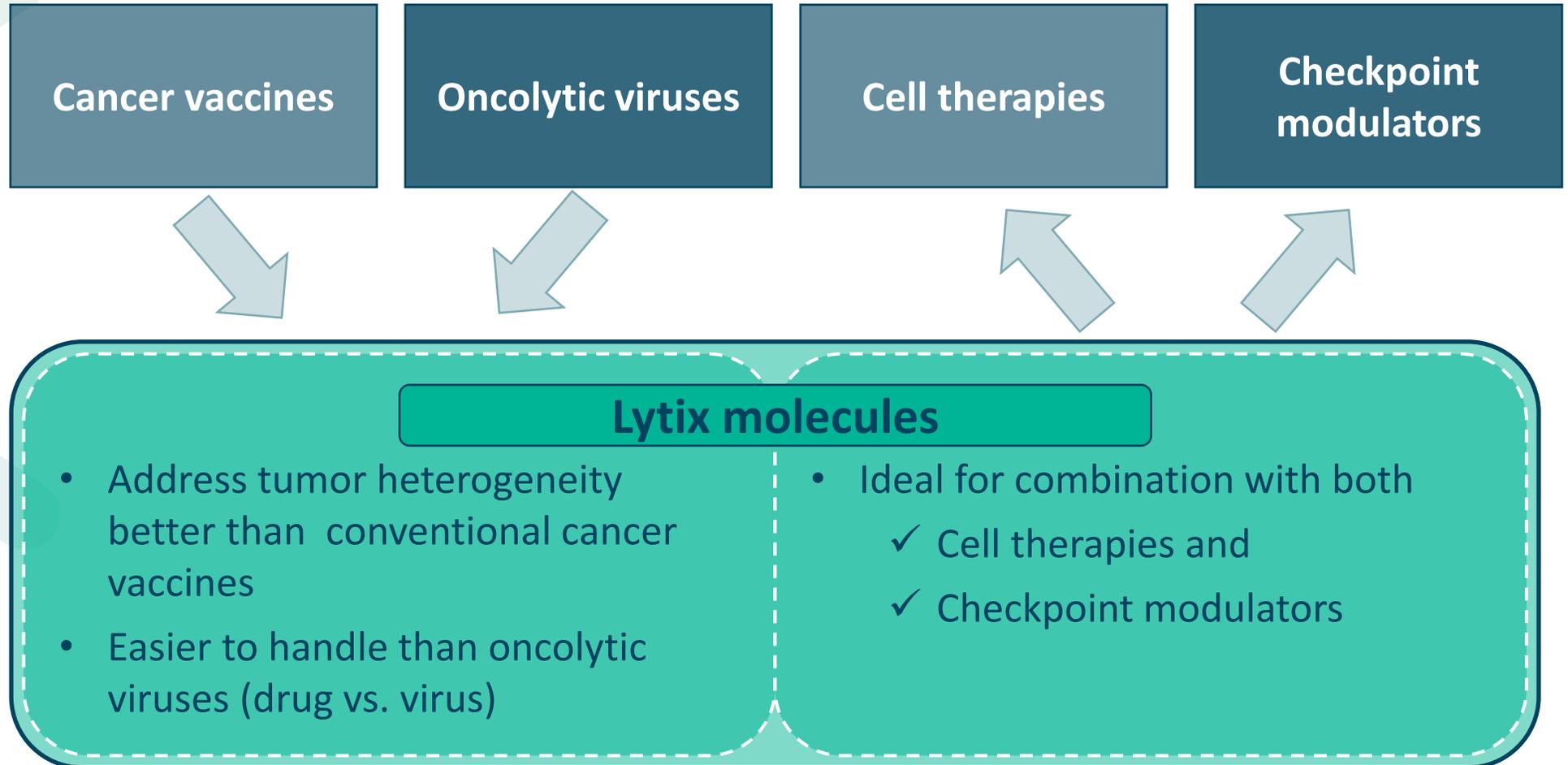
## Scientifically and commercially validated

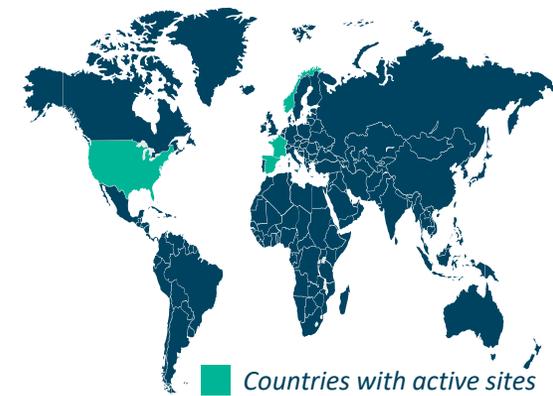
- *Strong scientific advisory board*
- *Commercial deal in place*



# Lytix Molecules

- a new class of immuno-oncology therapies





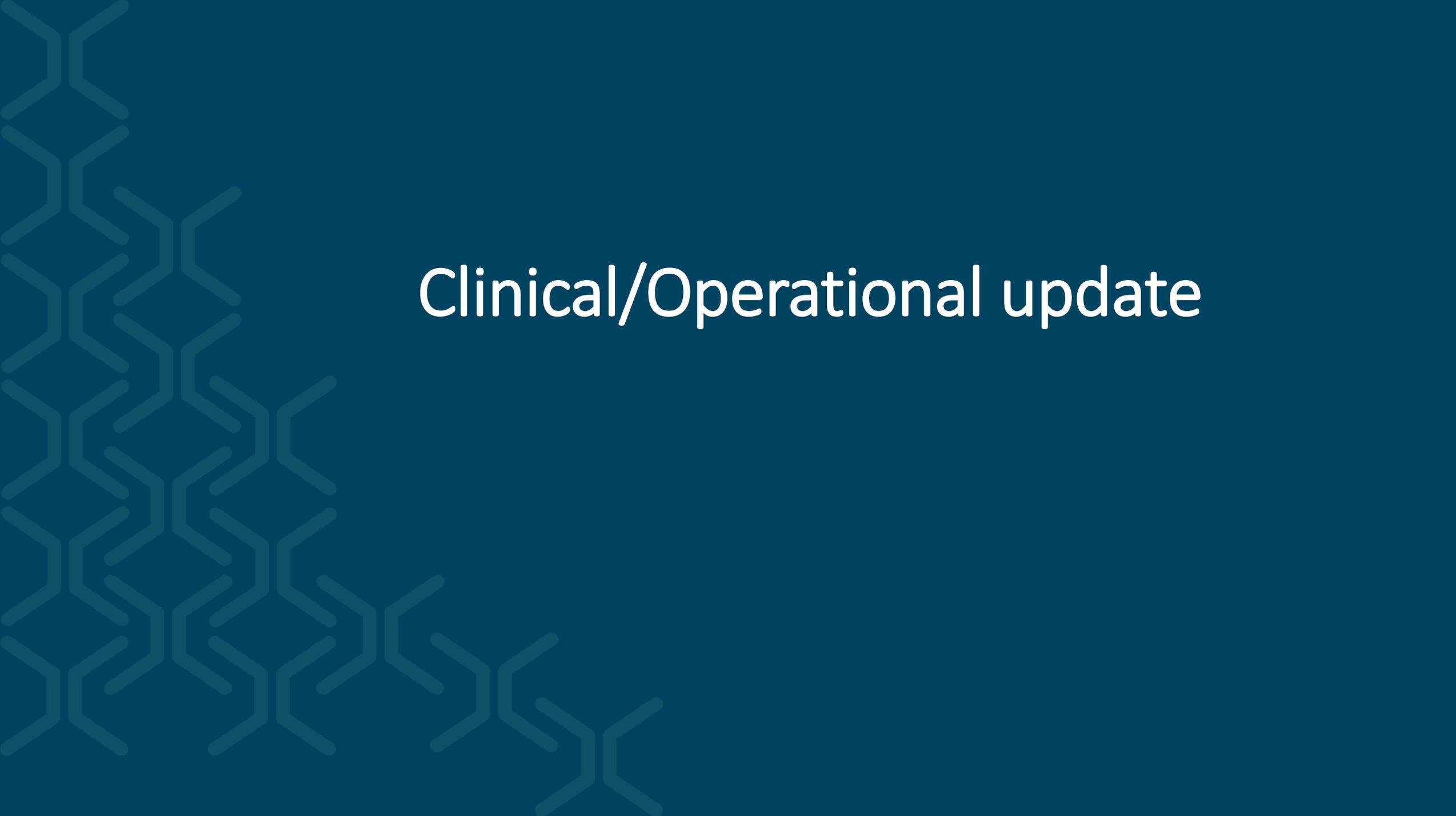
## Highlights for the fourth quarter

- Following approval of the clinical trial application (CTA) for ATLAS-IT-05 in Europe in Q3 2022, the Phase II study has expanded from the US to an additional three European countries; Norway, France and Spain
- Regulatory submission enabling activities required to start a Phase I study with LTX-401 is progressing as planned
- Compelling data describing how LTX-315 in addition to killing cancer cells also activates critical immune cells was presented at the Society for Immunotherapy of Cancer (SITC)
- ATLAS-IT-04 Clinical Study Report was completed
  - LTX-315 in combination with Adoptive Cell Therapy (ACT) in heavily pre-treated sarcoma patients with a progressive disease was able to stabilize the disease for up to 26 weeks

## Post-period events:

- Verrica Pharmaceuticals has completed treatment in part 1 of three parts of their ongoing Phase II study evaluating LTX-315 in basal cell carcinoma
  - Part 1 has enrolled 10 patients and demonstrated a favorable safety and tolerability profile with no reported serious adverse events
  - Patients receiving the higher range of dosing experienced a consistent response of clinical tumor necrosis
- CEO Øystein Rekdal presented Lytix at the investment banking company Redeye's Fight Cancer webinar in Stockholm

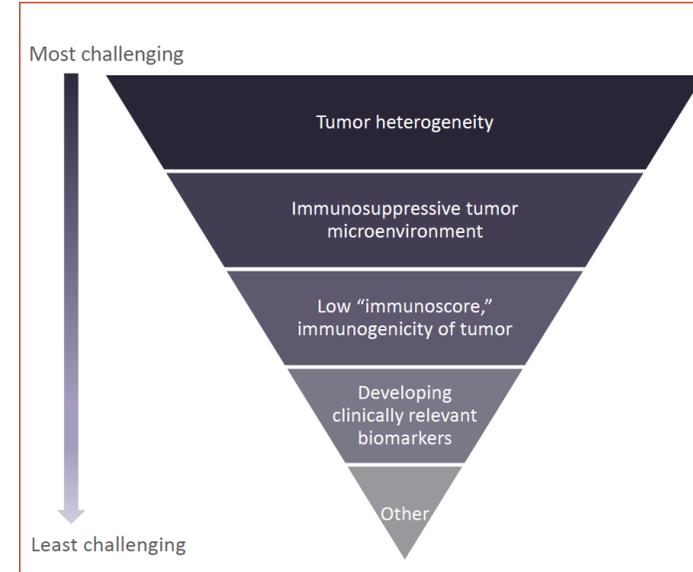
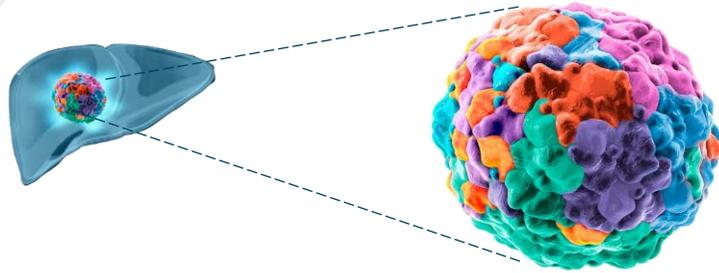




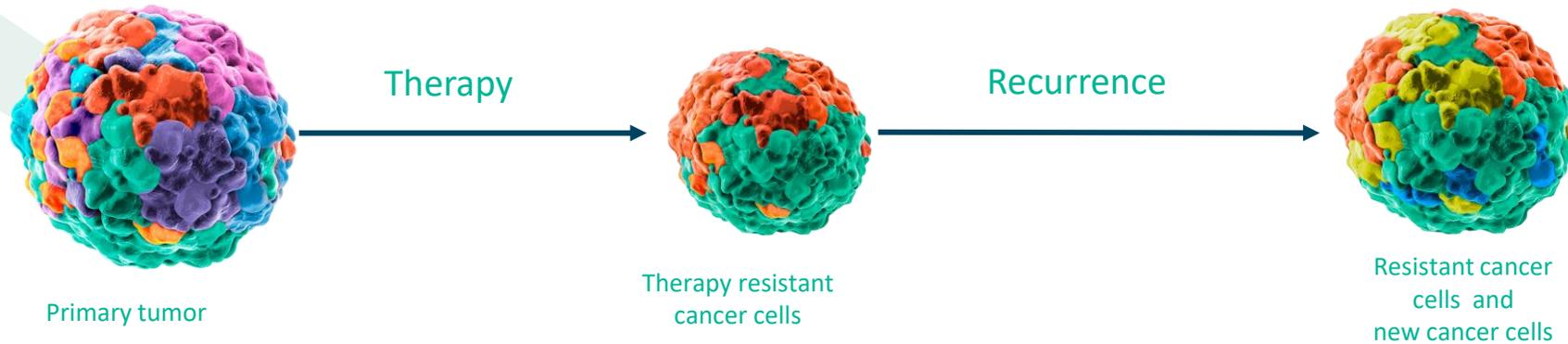
# Clinical/Operational update

# The challenge

- *the heterogeneity of cancer*



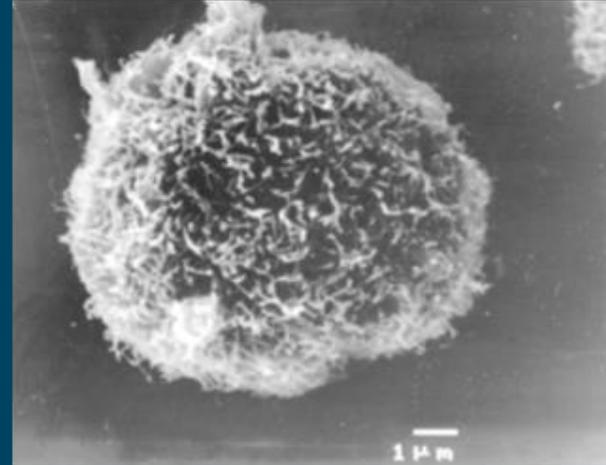
Failing to kill all cancer cells often leads to recurrence of even "harder to treat" tumors



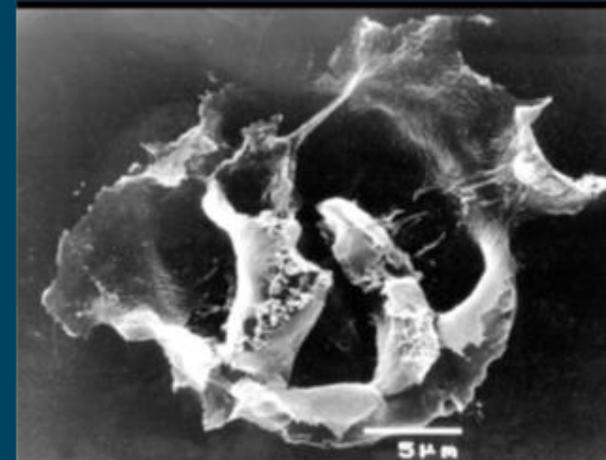
# Our Solution with oncolytic molecules

- Able to kill all types of cancer cells including chemotherapy-resistant 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

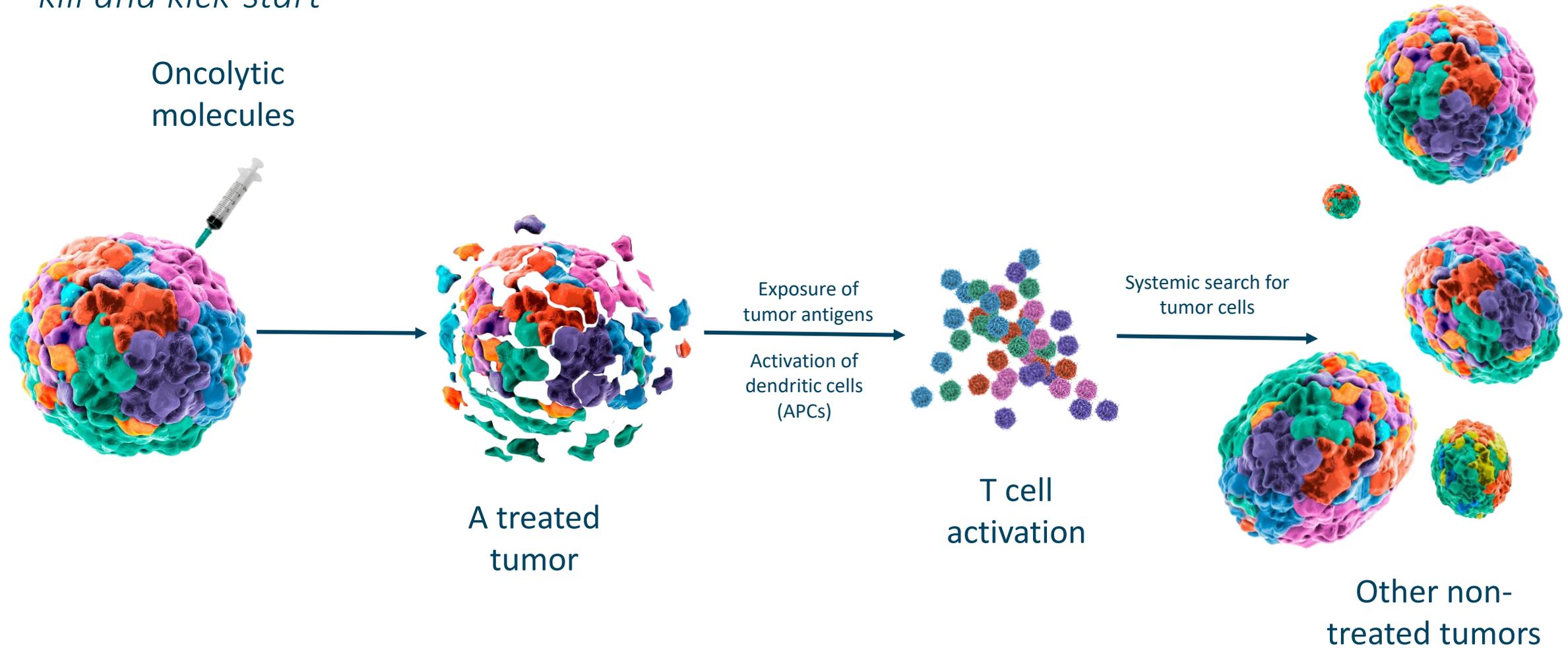


A cancer cell after treatment



# Our solution

- *kill and kick-start*

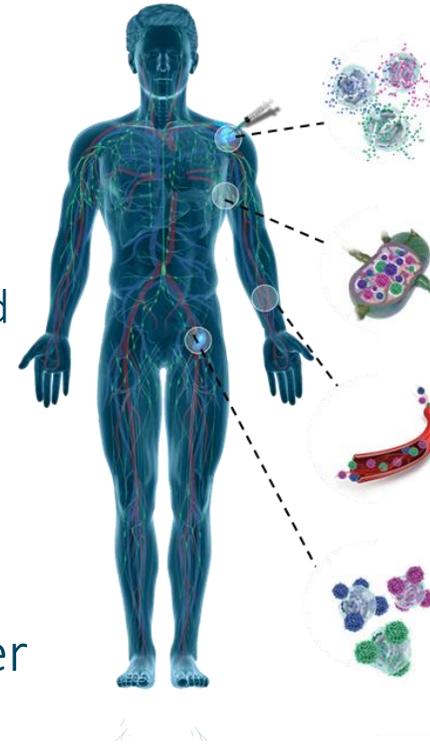


Activation of a broad repertoire of T cells that can recognize the diversity of tumor cells

## ATLAS-IT-05

- *expanding into new European sites*

- The clinical trial application approved under EU`s clinical trial regulation
  - 6 sites are opened in Norway, Spain and France
  - The sites are recognized for intratumoral immunotherapy expertise, and studies will be led by clinical teams with recognized expertise in melanoma
- Secure patient enrollment and recruitment completion
- The primary objective is to document whether LTX-315 can induce responses in checkpoint inhibitor resistant malignant melanoma patients in combination with pembrolizumab



**Oncolytic molecules**  
generate T cells that recognize different cancer cells

+

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

# Verrica Pharmaceuticals

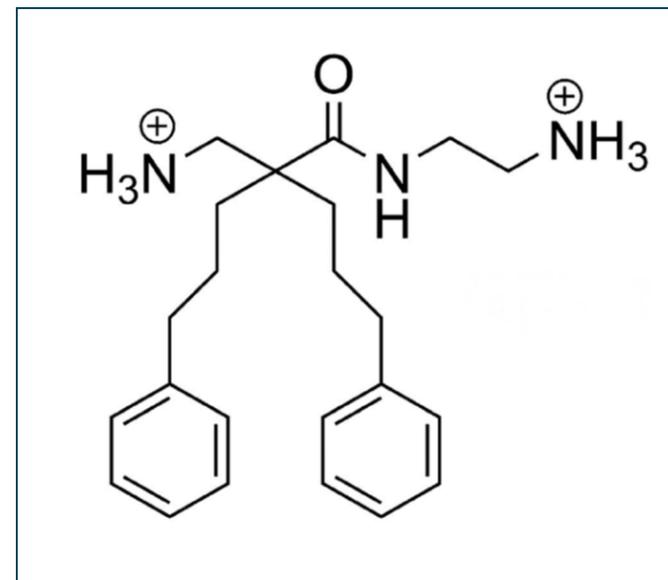
- *Phase II study in basal cell carcinoma (BCC) in good progress*

- ⊗ Verrica has completed treatment in part 1 of three parts of their ongoing Phase II study evaluating LTX-315 in basal cell carcinoma (BCC)
- ⊗ Part 2 of the Phase II trial is expected to begin in the second quarter of 2023 and will further explore dosing regimens allowing identification of the recommended dose for part 3 of the study
- ⊗ Part 3 is expected to start in the second half of 2023
- ⊗ Current treatment(s) for BCC and squamous cell carcinoma (SCC) are invasive, painful, disfiguring, and may require destruction of healthy tissue
  - LTX-315 may represent a non-surgical alternative for patients suffering from skin cancer
- ⊗ BCC is the most common skin cancer representing large commercial potential for LTX-315
- ⊗ Approximately 3-4 million patients are diagnosed with BCC each year in the US

# Our second-generation oncolytic molecule, LTX-401

- *Moving into the clinic*

- ⊗ Activities progressing as planned to submit a Clinical Trial Application in 2023 to start a Phase I study
- ⊗ Liver cancers represent big cancer segments with a high unmet medical need and low effect with checkpoint inhibitors
- ⊗ LTX-401 may solve the high unmet medical need in deep-seated tumors such as hepatocellular carcinoma and cancer types that spread to the liver
- ⊗ Pre-clinical results have documented very promising anticancer efficacy in liver cancer model and a favorable safety profile
- ⊗ LTX-401 has a potential for being used for additional types of deep-seated cancer



# Pipeline

Product candidate	Description	Indication	Discovery	Preclinical	Phase I	Phase II	Phase III	
LTX-315	ATLAS-IT-05 Pembrolizumab (Keytruda®)	Melanoma patients progressed on checkpoint inhibitors	→					
	Phase II by Verrica Pharmaceuticals (monotherapy)	Basal cell carcinoma	→					
	ATLAS-IT-04 Adoptive Cell Therapy	Advanced soft tissue sarcoma	→ <i>COMPLETED</i>					
LTX-401	Monotherapy	Liver cancer	→					
LTX-122	Adoptive Cell Therapy	Dog lymphoma	→					
Undisclosed	Undisclosed	Not applicable	→					
<b>A unique technology platform</b>	<b>Inspired by nature</b> Based on the scientific 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 figures

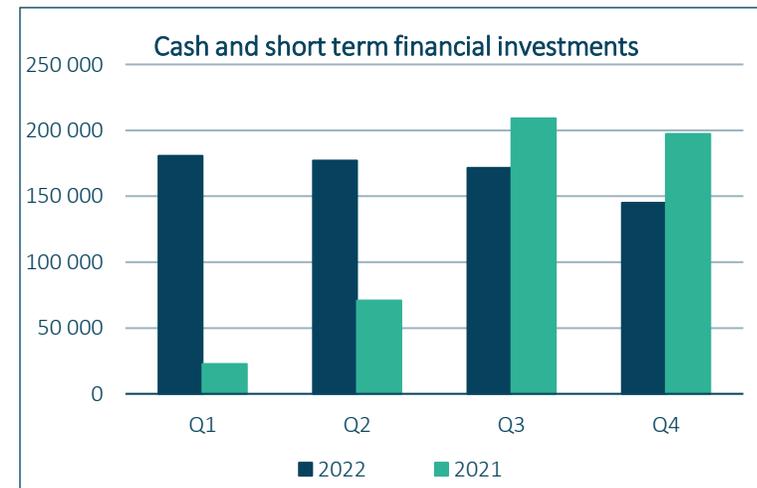
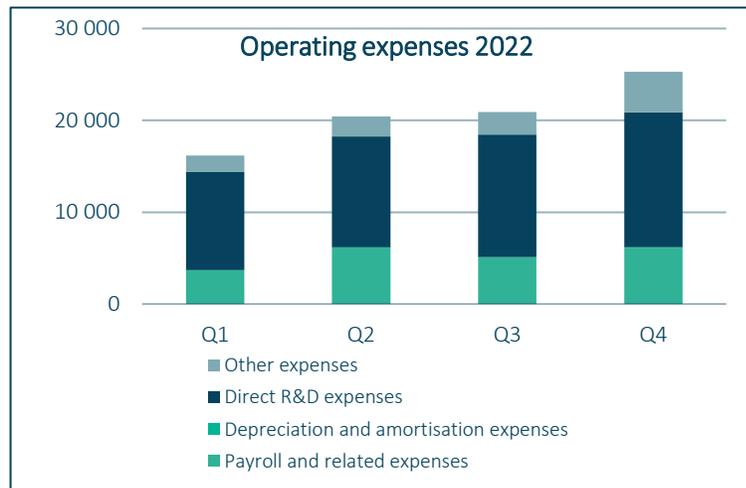
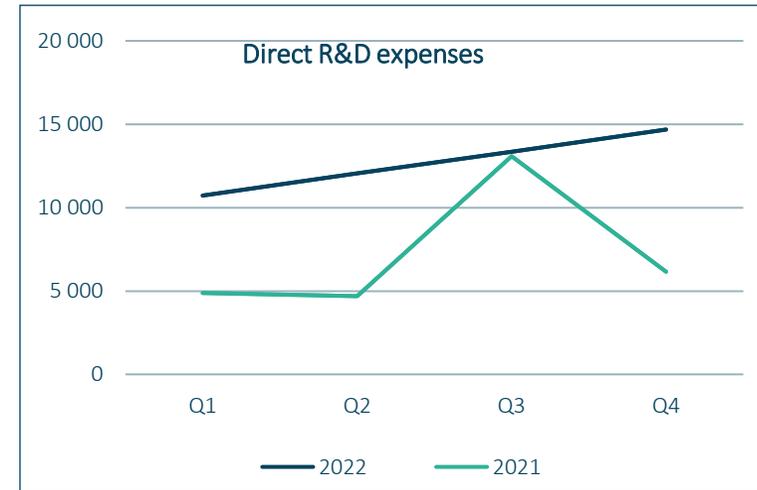
## Key figures – profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q4 2022	<i>Unaudited</i> Q4 2021	<i>Unaudited</i> H2 2022	<i>Unaudited</i> H2 2021	<i>Unaudited</i> 2022	<i>Unaudited</i> FY 2021
Total operating income	1,615	719	4,587	2,626	17,273	25,827
Total operating expenses	(25,453)	(17,087)	(46,368)	(37,790)	(82,968)	(73,844)
<b>Loss from operations</b>	<b>(23,837)</b>	<b>(16,368)</b>	<b>(41,781)</b>	<b>(35,164)</b>	<b>(65,695)</b>	<b>(48,017)</b>
<b>Loss for the period</b>	<b>(29,195)</b>	<b>(16,395)</b>	<b>(40,343)</b>	<b>(35,301)</b>	<b>(56,006)</b>	<b>(48,049)</b>

- Total operating income for the three months ended 31 December 2022 was NOK 1.6 million and is related to governmental grants, compared to NOK 0.7 million for the same period in 2021
- Total operating expenses for the three months ended 31 December 2022 amounted to NOK 25.5 million compared to NOK 17.1 million for the same period in 2021
  - The major cost drivers for the quarter are the ATLAS-IT-05 trial in the US and EU and the preclinical development of LTX-401. The important expansion of ATLAS-IT-05 to the EU has been driving costs during this period.

# Key figures

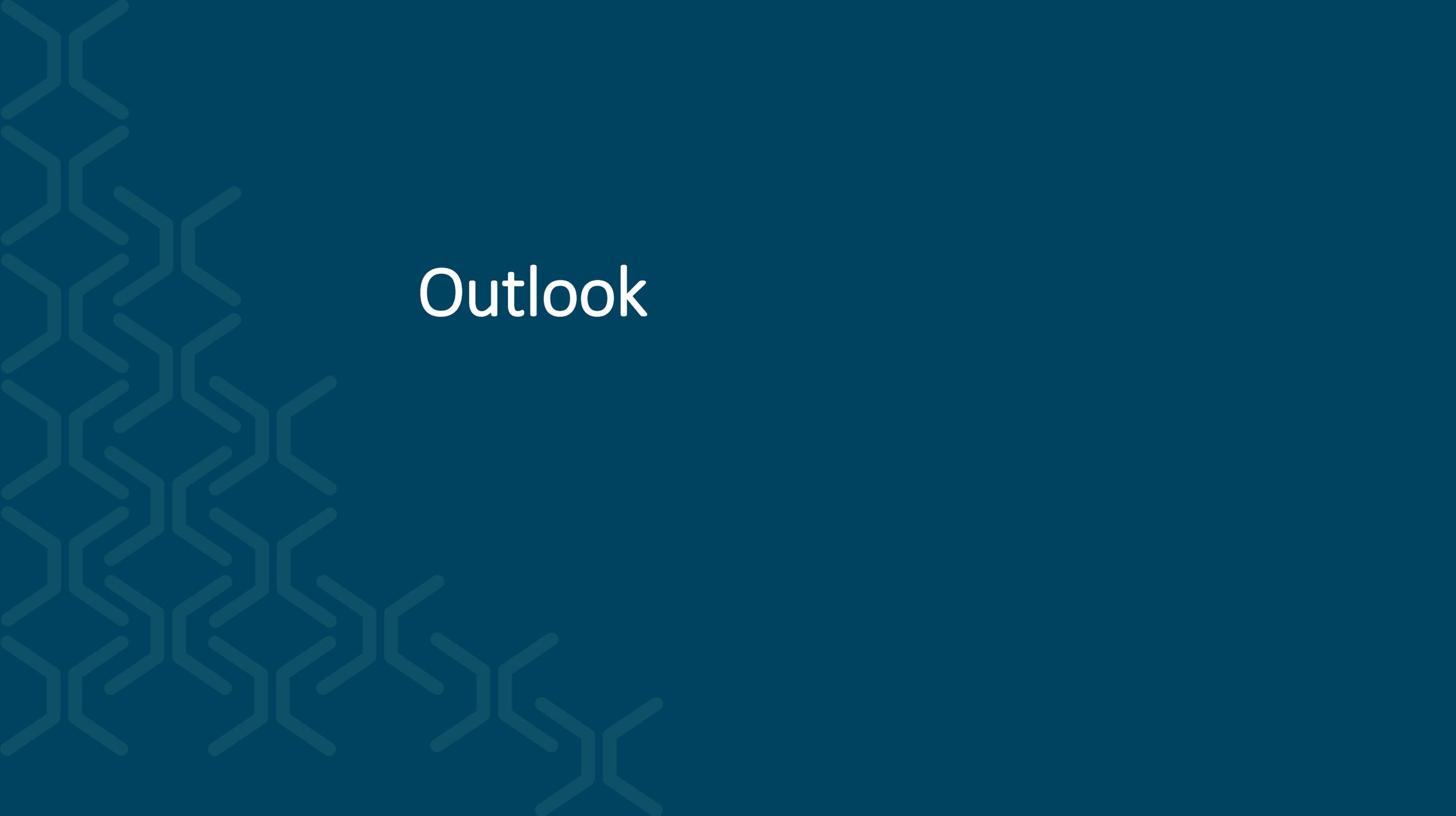
- increased activity



## Key figures – balance sheet

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 31.12.2022	31.12.2021
<b>Assets</b>		
Property, plant and equipment	124	-
Trade and other receivables	6,735	5,680
Short-term financial investments	50,606	-
Cash and cash equivalents	94,552	197,282
<b>Total assets</b>	<b>152,017</b>	<b>202,962</b>
<b>Shareholder's equity and liabilities</b>		
Total equity	135,126	189,624
Total liabilities	16,891	13,338
<b>Total equity and liabilities</b>	<b>152,017</b>	<b>202,962</b>

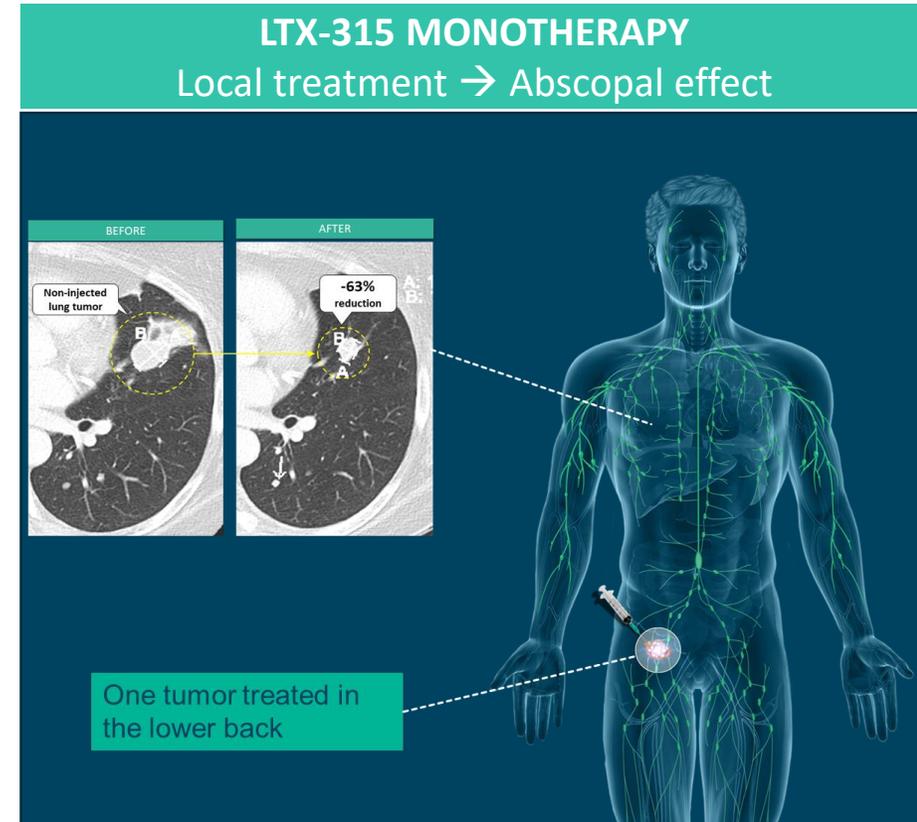
- As of 31.12.2022 Lytix has NOK 145.2 in cash and short-term financial investments compared to NOK 197.3 as of 31.12.2021



# Outlook

## Key objectives moving forward

- Clinical development
  - Expand the clinical impact field for LTX-315 and drive enrollment in the ATLAS-IT-05 Phase II trial towards completion
  - Continue to support Verrica Pharmaceuticals' Phase II trial with LTX-315 in BCC
  - Continue activities required for a Clinical Trial Application for LTX-401 in 2023
- Identify additional opportunities to expand our innovative pipeline of molecules
- Strengthen our position in the immuno-oncology space
  - Commercial collaborations
  - Partnering



*Proof of Principle Achieved*

# Q&A

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# Interim Financial Statements

# Condensed Interim statement of profit or loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q4 2022	<i>Unaudited</i> Q4 2021	<i>Unaudited</i> H2 2022	<i>Unaudited</i> H2 2021	<i>Unaudited</i> FY 2022	<i>Unaudited</i> FY 2021
Revenue	-	-	1,409	-	1,409	17
Other operating income	1,615	719	3,178	2,626	15,864	25,810
<b>Total operating income</b>	<b>1,615</b>	<b>719</b>	<b>4,587</b>	<b>2,626</b>	<b>17,273</b>	<b>25,827</b>
Payroll and related expenses	(6,163)	(8,701)	(11,253)	(14,309)	(21,133)	(31,605)
Depreciation and amortization expenses	(13)	-	(24)	-	(30)	-
Direct R&D expenses	(14,847)	(6,161)	(28,194)	(19,248)	(50,974)	(28,817)
Other expenses	(4,430)	(2,225)	(6,897)	(4,233)	(10,832)	(13,421)
<b>Total operating expenses</b>	<b>(25,453)</b>	<b>(17,087)</b>	<b>(46,368)</b>	<b>(37,790)</b>	<b>(82,968)</b>	<b>(73,844)</b>
<b>Loss from operations</b>	<b>(23,837)</b>	<b>(16,368)</b>	<b>(41,781)</b>	<b>(35,164)</b>	<b>(65,695)</b>	<b>(48,017)</b>
<b>Net financial items</b>	<b>(5,357)</b>	<b>(27)</b>	<b>1,439</b>	<b>(137)</b>	<b>9,689</b>	<b>(32)</b>
<b>Loss before tax</b>	<b>(29,195)</b>	<b>(16,395)</b>	<b>(40,343)</b>	<b>(35,301)</b>	<b>(56,006)</b>	<b>(48,049)</b>
Tax expense	-	-	-	-	-	-
<b>Loss for the period</b>	<b>(29,195)</b>	<b>(16,395)</b>	<b>(40,343)</b>	<b>(35,301)</b>	<b>(56,006)</b>	<b>(48,049)</b>

- Government grants recognized in profit and loss, part of Other operating Income, for Q2 2022 was reported at NOK 805 thousand which was NOK 750 thousand lower than actual. The correct amount is NOK 1,555 thousand. The figures in this report are correct, but the YTD figures will therefore not be reconcilable with the H1 report without adjusting for this error.

# Condensed Interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 31.03.2022	<i>Unaudited</i> 30.06.2021	<i>Unaudited</i> 30.09.2022	<i>Unaudited</i> <b>31.12.2022</b>	31.12.2021
<b>Assets</b>					
<b>Non-current assets</b>					
Property, plant and equipment	35	132	137	<b>124</b>	-
Other receivables	-	-	-	-	-
<b>Total non-current assets</b>	<b>35</b>	<b>132</b>	<b>137</b>	<b>124</b>	<b>-</b>
<b>Current assets</b>					
Trade and other receivables	7,242	7,643	5,656	<b>6,735</b>	5,680
Short-term financial investments	-	-	49,909	<b>50,606</b>	-
Cash and cash equivalents	180,666	177,084	121,671	<b>94,552</b>	197,282
<b>Total current assets</b>	<b>187,907</b>	<b>184,727</b>	<b>177,237</b>	<b>151,893</b>	<b>202,962</b>
<b>Total assets</b>	<b>187,942</b>	<b>184,858</b>	<b>177,374</b>	<b>152,017</b>	<b>202,962</b>
<b>Shareholder's equity and liabilities</b>					
<b>Issued capital and reserves</b>					
Share capital	3,874	4,007	4,007	<b>4,007</b>	3,874
Share premium reserve	170,933	170,710	159,876	<b>131,119</b>	185,750
<b>Total equity</b>	<b>174,807</b>	<b>174,717</b>	<b>163,883</b>	<b>135,126</b>	<b>189,624</b>
<b>Liabilities</b>					
<b>Current liabilities</b>					
Trade payables	3,920	2,557	6,426	<b>6,997</b>	1,476
Other current liabilities	9,216	7,585	7,065	<b>9,894</b>	11,862
<b>Total current liabilities</b>	<b>13,135</b>	<b>10,141</b>	<b>13,491</b>	<b>16,891</b>	<b>13,338</b>
<b>Total liabilities</b>	<b>13,135</b>	<b>10,141</b>	<b>13,491</b>	<b>16,891</b>	<b>13,338</b>
<b>Total equity and liabilities</b>	<b>187,942</b>	<b>184,858</b>	<b>177,374</b>	<b>152,017</b>	<b>202,962</b>

# Condensed Interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q4 2022	<i>Unaudited</i> Q4 2021	<i>Unaudited</i> H2 2022	<i>Unaudited</i> H2 2021	<i>Unaudited</i> FY 2022	<i>Unaudited</i> FY 2021
<b>Cash flows from operating activities</b>						
Loss for the period	(29,195)	(16,395)	(40,343)	(35,301)	(56,006)	(48,049)
<b>Adjustments for:</b>						
Depreciation of property, plant and equipment	13	-	24	-	30	-
Share-based payment expense	438	709	751	1,894	1,376	4,055
Increase/decrease in trade and other receivables	(1,079)	(723)	908	157,112	(1,055)	(1,513)
Increase/decrease in trade and other payables	3,400	4,514	6,750	2,626	3,553	610
<b>Cash generated from operations</b>	<b>(26,422)</b>	<b>(11,896)</b>	<b>(31,909)</b>	<b>126,332</b>	<b>(52,102)</b>	<b>(44,896)</b>
Income tax paid	-	-	-	-	-	-
<b>Net cash flows from operations</b>	<b>(26,422)</b>	<b>(11,896)</b>	<b>(31,909)</b>	<b>126,332</b>	<b>(52,102)</b>	<b>(44,896)</b>
<b>Investing activities</b>						
Investments in tangible assets	-	-	(17)	-	(154)	-
Increase/decrease in other investments	(697)	-	(50,606)	-	(50,606)	-
<b>Net cash from/(used in) investing activities</b>	<b>(697)</b>	<b>-</b>	<b>(50,623)</b>	<b>-</b>	<b>(50,761)</b>	<b>-</b>
<b>Financing activities</b>						
Proceeds from share issue	-	-	-	-	133	213,728
<b>Net cash from/(used in) financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>133</b>	<b>213,728</b>
Net increase/(decrease) in cash and cash equivalents	(27,120)	(11,896)	(82,532)	126,332	(102,730)	168,832
Cash and cash equivalents at the beginning of the period	121,671	209,177	177,084	70,950	197,282	28,450
<b>Cash and cash equivalents at the end of the period</b>	<b>94,552</b>	<b>197,282</b>	<b>94,552</b>	<b>197,282</b>	<b>94,552</b>	<b>197,282</b>