

# Lytix Biopharma AS

*Building the Phase II evidence base*

*First half and second quarter 2023 presentation*

August 31, 2023

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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.



## 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*
- *Promising results from Verrica's ongoing Phase II study in skin cancer*

## Innovative pipeline that overcomes major challenges in cancer therapy

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

## Our solution:

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

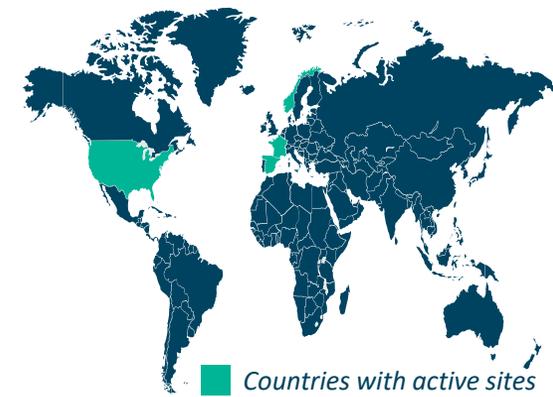
## Scientifically and commercially validated

- *Exceptional scientific advisory board*
- *Asset deal generating revenue in place*

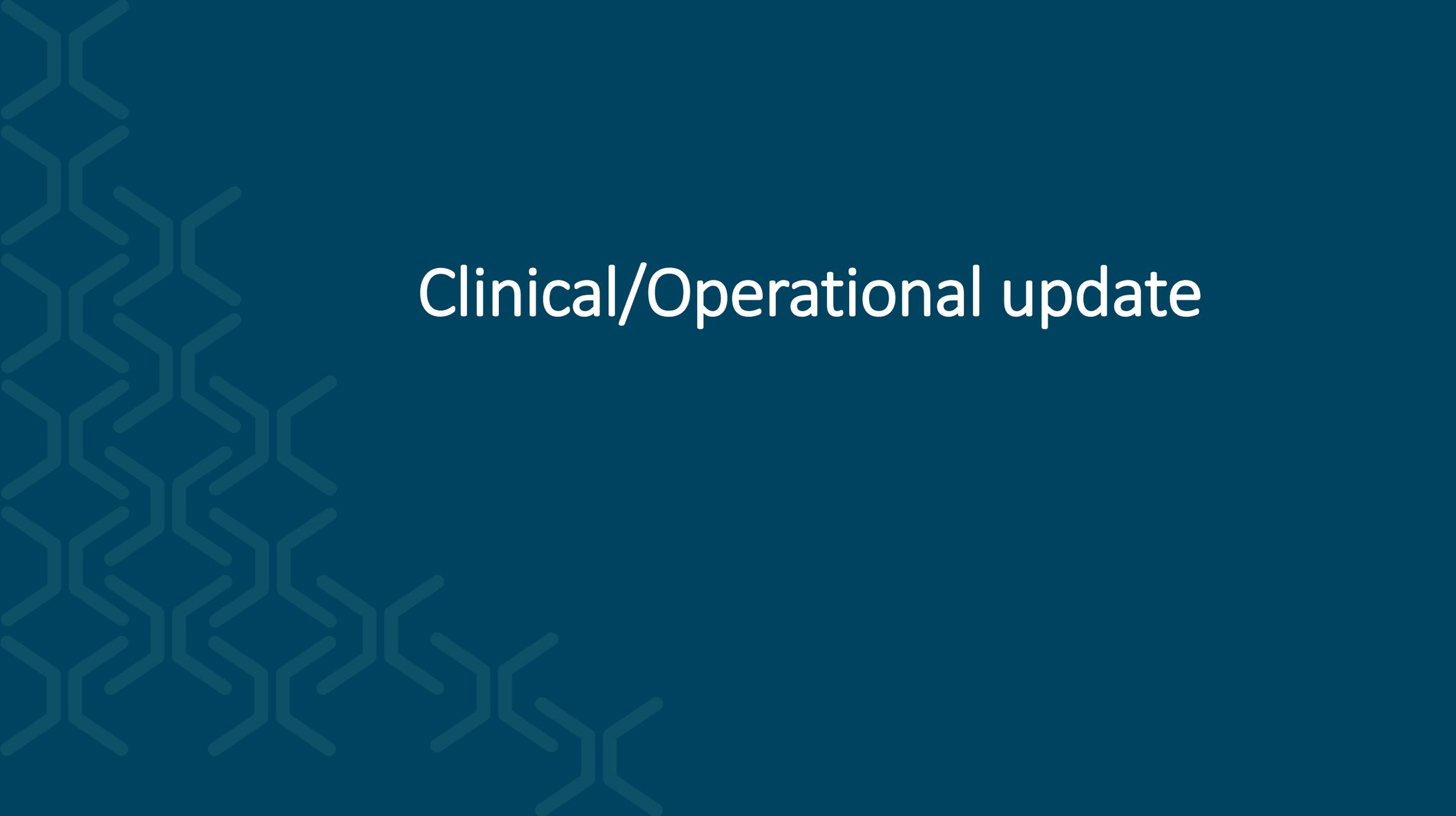


# Highlights for the second quarter

## - and post-period events



- Verrica Pharmaceuticals' Phase II study evaluating LTX-315 for the treatment of basal cell carcinoma (BCC)
  - Complete clearance observed in four lesions, 95% clearance in one lesion and 30% clearance in one lesion.
  - Based on the stronger than expected activity observed in patients receiving LTX-315, Verrica has decided to accelerate the clinical development of LTX-315 and to complete the entire Phase II study in H1 2024.
- ATLAS-IT-05
  - All 20 patients have been recruited to the study.
  - Interim results from the study will be presented at the European Society for Medical Oncology (ESMO) Congress in October 2023.
- Neoadjuvant study in earlier stage melanoma patients
  - Lytix has decided to support an investigator led Phase II study at Oslo University Hospital, Radiumhospitalet.
  - The study is expected to commence in H1 2024 and will enroll 27 melanoma patients.
- LTX-401
  - Decision to refocusing resources and generating additional clinical efficacy data with LTX-315 and postpone the start of the planned Phase I safety study with LTX-401.

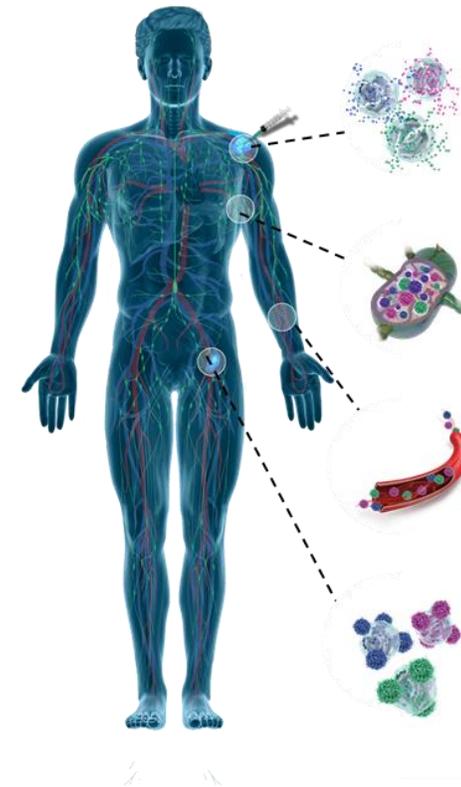


# Clinical/Operational update

# ATLAS-IT-05

- All 20 patients recruited

- On August 28<sup>th</sup>, 2023, Lytix announced that all 20 patients have been recruited to the study
- An abstract with interim results from the study has been approved for presentation at European Society for Medical Oncology (ESMO) Congress 2023, 20-24 October
- If interim analysis shows encouraging efficacy, an expansion of the study will be considered



Oncolytic molecules generate T cells that recognize different cancer cells

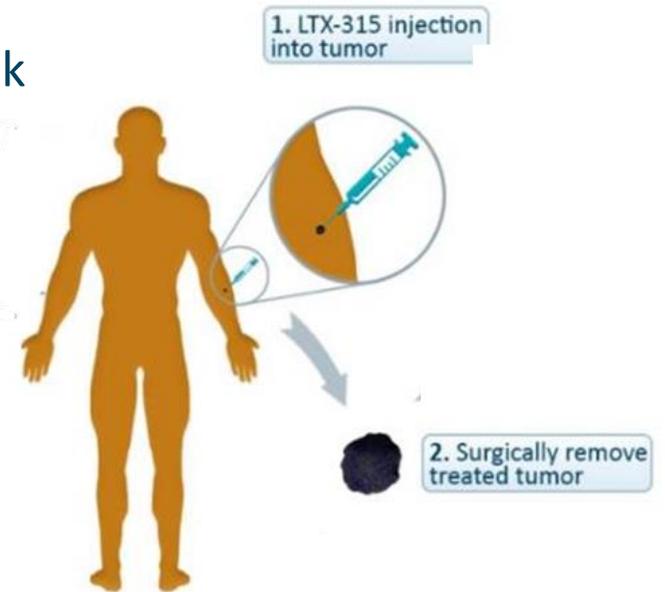
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Immune checkpoint inhibitors keep the brakes off and make the T cells work more efficiently

## ATLAS-IT-06:

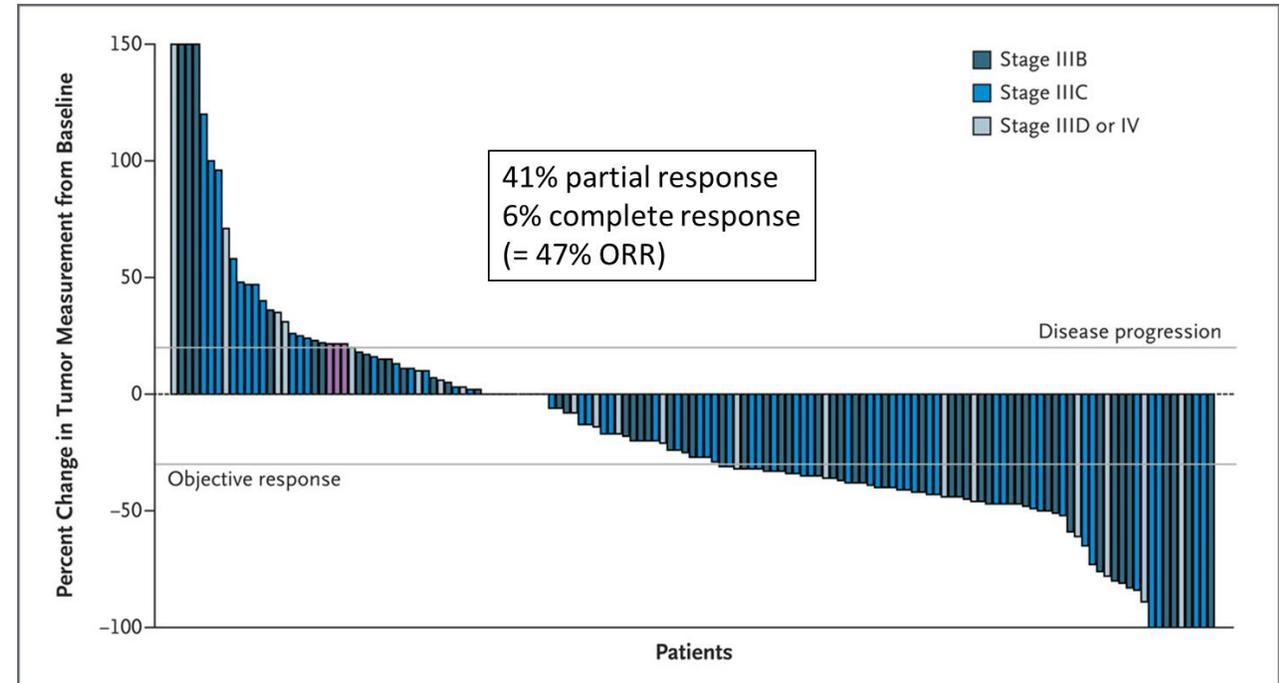
- *NeoLIPA: Neoadjuvant study with LTX-315 in melanoma patients*

- Neoadjuvant LTX-315 in combination with pembrolizumab in resectable stage III/IV melanoma (NeoLIPA)
- Conducted by principal investigator senior physician PhD Henrik Jespersen at Oslo University Hospital, Radiumhospitalet
- Estimated to commence in 1H 2024
- Rationale for adding LTX-315 to PD-1 inhibition in the neoadjuvant setting:
  - Patients with an earlier stage cancer disease and a more healthy immune system
  - Activation of a broad diversity of T cells before surgery
  - Lowering the risk for progression precluding surgery



# Effect of pembrolizumab alone in a neoadjuvant melanoma study (SWOG 1801 clinical results)

- 9 of 142 patients (6%) had a complete response and 58 (41%) a partial response
- 28 of 132 patients (21%) had a complete pathological response (no viable tumor)
- Potential for combining pembrolizumab with LTX-315 to enhance the number of responders



# Verrica Pharmaceuticals

## - Phase II study in good progress

- Verrica reported promising interim Phase II data with LTX-315 (VP-315) at the 2023 AAD Innovation Meeting
- In the presentation, Dr. Neal Bhatia MD, Director of Clinical Dermatology Therapeutics Clinical Research in San Diego, stated:
  - Subjects received once daily dosing of VP-315 in up to two BCC lesions for up to six treatments over a two-week period.
  - Six lesions were treated with 8 mg of VP-315 and surgically removed at Day 49 (Range 35-70), followed by histological evaluation.
  - Consistent clinical and histological clearance of treated BCC lesions was observed with the 8 mg dose of VP-315 in 4 of 6 subjects. The other 2 subjects showed a partial response (95% and 30% tumor clearance).
  - These early encouraging results from Part 1 support VP-315 as a potential non-surgical therapeutic approach for BCC.
  - Part 2 of the Phase II study is expected to be completed 1H 2024.
- Lytix has a licensing agreement with Verrica, where Lytix is entitled to receive up to USD 111 million in potential milestone payments and tiered royalties based on worldwide annual sales

# Basal cell carcinoma market in the US

- BCC creates significant burden for the patient and healthcare system
  - In the US, skin cancer accounts for \$8.1 billion in total healthcare costs
  - Non-melanoma skin cancer represents 59% of all skin cancers
  - 3-4 million BCC incidences annually
- Treatment modalities for BCC
  - 98% of BCC patients are currently treated with surgery
  - Surgery is painful and may create scarring and hypopigmentation which impacts the patient's appearance and quality of life
  - LTX-315 (VP-315) may represent a better alternative to surgery with less risk of relapse and unsatisfactory cosmetic results
- The global basal cell carcinoma market size was estimated to be valued at **US\$ 6.7 billion** in 2021 and is expected to exhibit a CAGR of 7.9% between 2021 and 2028.

# 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-06 NeoLIPA	Neoadjuvant resectable melanoma patients	→					
	ATLAS-IT-04 Adoptive Cell Therapy	Advanced soft tissue sarcoma	→ <i>COMPLETED</i>					
LTX-401	Monotherapy	Solid tumors (deep-seated lesions)	→					
Undisclosed chemistry		Not applicable	→					
<b>A unique technology platform</b>	<b>Oncolytic molecules 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 are directly injected into solid tumors priming the immune system for potent activation overcoming tumor heterogeneity				



# Key figures

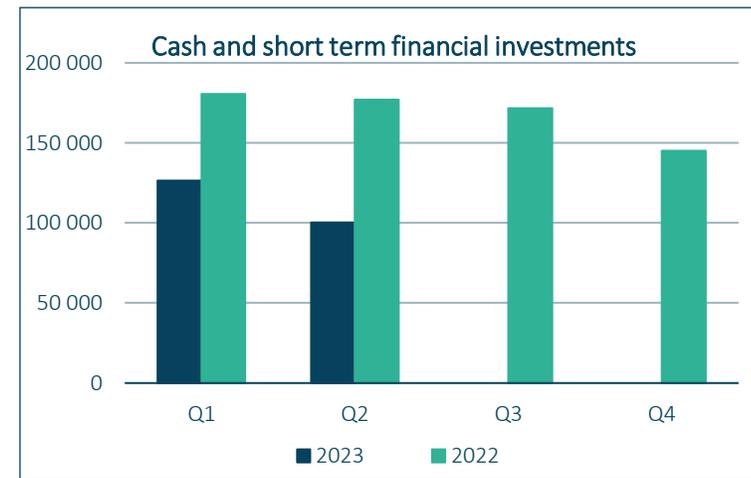
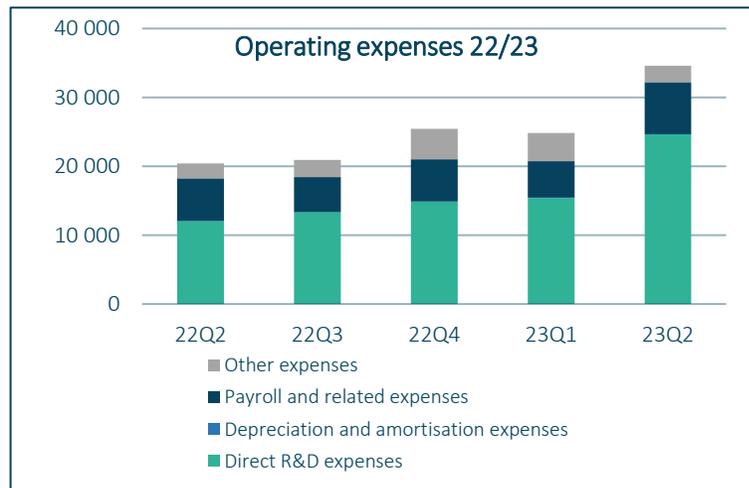
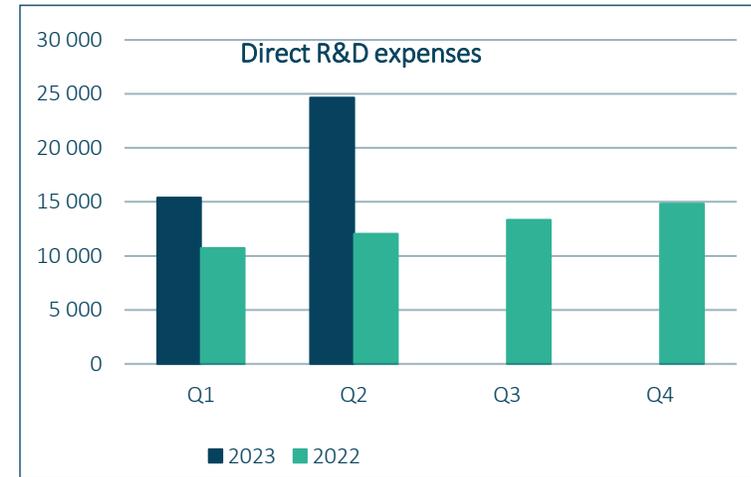
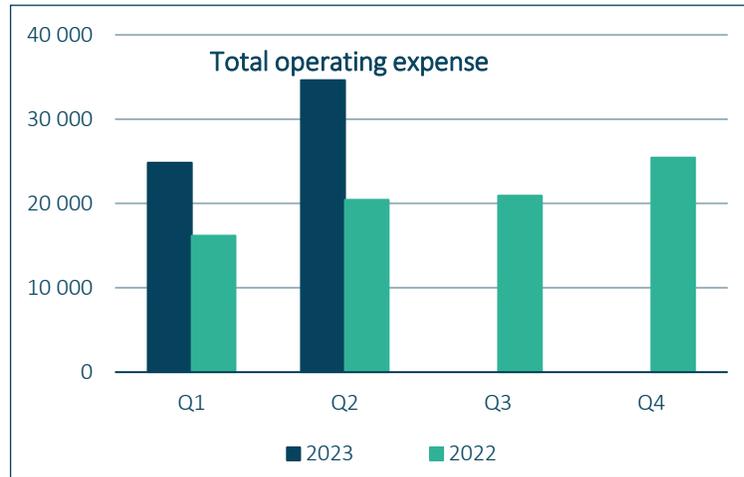
## Key figures – profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2023	<i>Unaudited</i> Q2 2022	FY 2022
Total operating income	449	11,177	17,273
Total operating expenses	(34,607)	(20,418)	(82,968)
<b>Loss from operations</b>	<b>(34,159)</b>	<b>(9,241)</b>	<b>(65,695)</b>
<b>Loss for the period</b>	<b>(31,435)</b>	<b>(433)</b>	<b>(56,006)</b>

- Due to the significant increase in sites and recruited patients during the second quarter of 2023 the total operating expenses increased to NOK 34.6 million from NOK 20.4 million for the same period in 2022.

# Key figures

- *high level of activity*

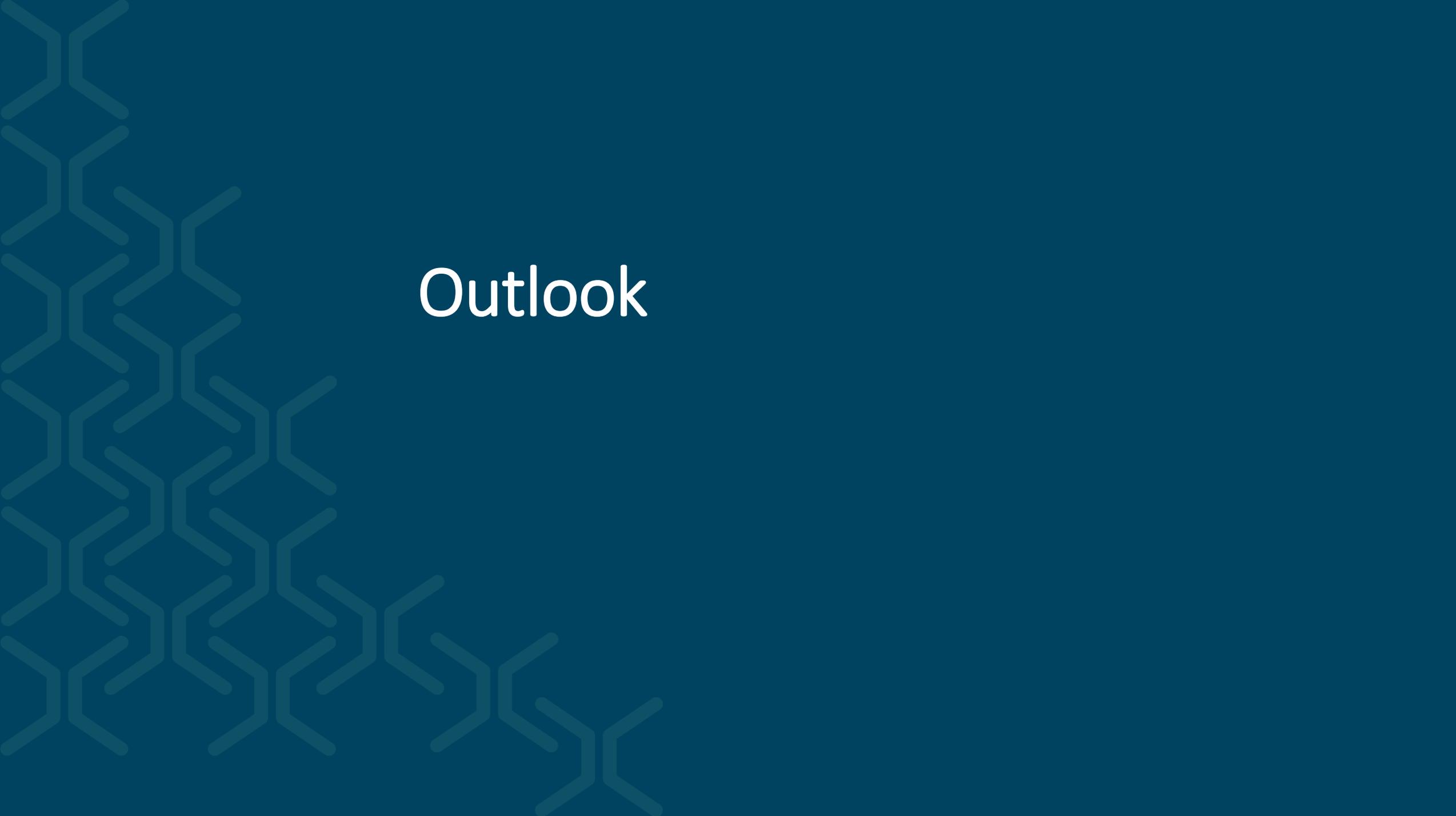


# Key figures

## – balance sheet

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2023	<i>Unaudited</i> 30.06.2022	31.12.2022
<b>Assets</b>			
Property, plant and equipment	144	132	124
Trade and other receivables	5,959	7,643	6,735
Short-term financial investments	41,961	-	50,606
Cash and cash equivalents	58,257	177,084	94,552
<b>Total assets</b>	<b>106,321</b>	<b>184,858</b>	<b>152,017</b>
<b>Shareholder's equity and liabilities</b>			
Total equity	86,122	174,717	135,126
Total liabilities	20,199	10,141	16,891
<b>Total equity and liabilities</b>	<b>106,321</b>	<b>184,858</b>	<b>152,017</b>

- At the end of the period, cash plus short-term financial investments were NOK 100.2 million, compared to NOK 145.2 million as of 31 December 2022 and NOK 177.1 million at 30 June 2022.



# Outlook

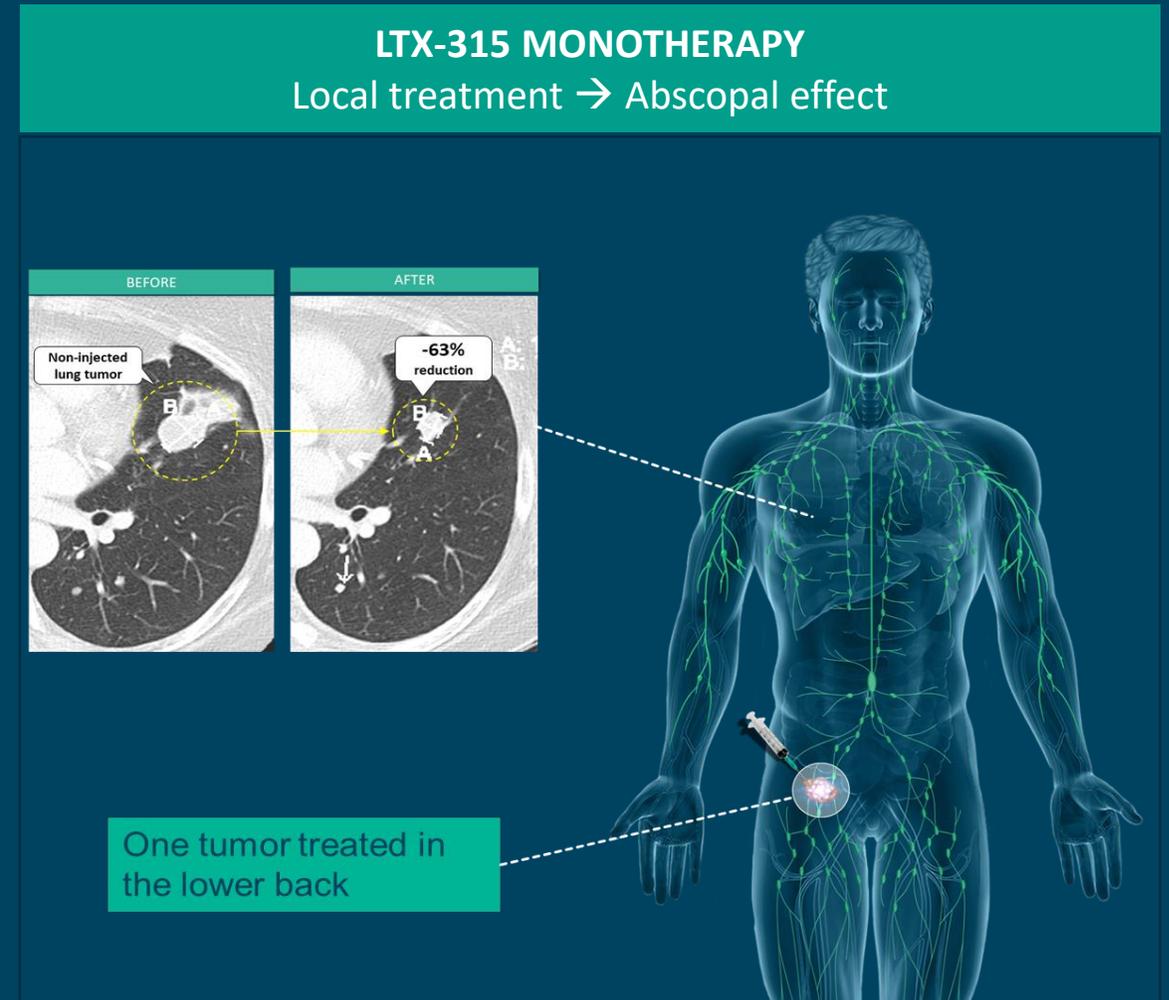
# Key objectives moving forward

## ✕ Clinical development

- Analysis of interim results from ATLAS-IT-05 study for presentation at ESMO in October
- Continue to support Verrica Pharmaceuticals' Phase II trial with LTX-315 in BCC
- Support and initiate the investigator driven Phase II study with LTX-315 in the neoadjuvant setting
- Validate additional opportunities to leverage our innovative pipeline of molecules

## ✕ Continue to capture value in the immuno-oncology space

- Strong footprint in US
- Commercial collaborations
- Partnering



# Q&A

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# Interim Financial Statements

# Condensed Interim statement of profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2023	<i>Unaudited</i> Q2 2022	FY 2022
Revenue	74	-	1,409
Other operating income	375	11,177	15,864
<b>Total operating income</b>	<b>449</b>	<b>11,177</b>	<b>17,273</b>
Payroll and related expenses	(7,549)	(6,175)	(21,133)
Depreciation and amortization expenses	(14)	(6)	(30)
Direct R&D expenses	(24,632)	(12,055)	(50,974)
Other expenses	(2,413)	(2,182)	(10,832)
<b>Total operating expenses</b>	<b>(34,607)</b>	<b>(20,418)</b>	<b>(82,968)</b>
<b>Loss from operations</b>	<b>(34,159)</b>	<b>(9,241)</b>	<b>(65,695)</b>
<b>Net financial items</b>	<b>(2,732)</b>	<b>(8,808)</b>	<b>9,689</b>
<b>Loss before tax</b>	<b>(31,435)</b>	<b>(49,769)</b>	<b>(56,006)</b>
Tax expense	-	-	-
<b>Loss for the period</b>	<b>(31,435)</b>	<b>(49,769)</b>	<b>(56,006)</b>

# Condensed Interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2023	<i>Unaudited</i> 30.06.2022	31.12.2022
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	144	132	124
<b>Total non-current assets</b>	<b>144</b>	<b>132</b>	<b>124</b>
<b>Current assets</b>			
Trade and other receivables	5,959	7,643	6,735
Short-term financial investments	41,961	-	50,606
Cash and cash equivalents	58,257	177,084	94,552
<b>Total current assets</b>	<b>106,177</b>	<b>184,727</b>	<b>151,893</b>
<b>Total assets</b>	<b>106,321</b>	<b>184,858</b>	<b>152,017</b>
<b>Shareholder's equity and liabilities</b>			
<b>Issued capital and reserves</b>			
Share capital	4,007	4,007	4,007
Share premium reserve	82,115	170,710	131,119
<b>Total equity</b>	<b>86,122</b>	<b>174,717</b>	<b>135,126</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade payables	5,889	2,557	6,997
Other current liabilities	14,310	7,585	9,894
<b>Total current liabilities</b>	<b>20,199</b>	<b>10,141</b>	<b>16,891</b>
<b>Total liabilities</b>	<b>20,199</b>	<b>10,141</b>	<b>16,891</b>
<b>Total equity and liabilities</b>	<b>106,321</b>	<b>184,858</b>	<b>152,017</b>

# Condensed Interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2023	<i>Unaudited</i> Q2 2022	FY 2022
<b>Cash flows from operating activities</b>			
Loss for the period	(31,435)	(433)	56,006
<b>Adjustments for:</b>			
Depreciation of property, plant and equipment	14	6	30
Share-based payment expense	1,086	344	1,376
Interest received	(660)		
Increase/decrease in trade and other receivables	1,114	(401)	(1,055)
Increase/decrease in trade and other payables	3,101	(2,994)	3,553
<b>Cash generated from operations</b>	<b>(26,779)</b>	<b>(3,479)</b>	<b>(52,102)</b>
Income tax paid			-
<b>Net cash flows from operations</b>	<b>(26,779)</b>	<b>(3,479)</b>	<b>52,102</b>
<b>Investing activities</b>			
Investments in tangible assets	(32)	(102)	(154)
Interest received	660		
Increase/decrease in other investments	9,352		(50,606)
<b>Net cash from/(used in) investing activities</b>	<b>9,980</b>	<b>(102)</b>	<b>(50,761)</b>
<b>Financing activities</b>			
Proceeds from share issue, not yet registered	-	-	133
<b>Net cash from/(used in) financing activities</b>	<b>-</b>	<b>-</b>	<b>133</b>
Net increase/(decrease) in cash and cash equivalents	(16,800)	(3,582)	(102,730)
Cash and cash equivalents at the beginning of the period	75,057	180,666	197,282
<b>Cash and cash equivalents at the end of the period</b>	<b>58,257</b>	<b>177,084</b>	<b>94,552</b>