Lytix Biopharma AS

Encouraging efficacy signal emerging in ongoing Phase II trial

Third quarter 2023 presentation

November 9, 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 technology 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

- Over 30 years of drug development experience in both pharmaceutical and biotechnology companies
- Has successfully led drug development programs and has held key roles in the development of 8 approved drugs.
- Dr. Currie holds a PhD 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.

Scientifically and commercially validated technology

Unique oncology technology platform with broad pipeline opportunities

- *Lead candidate; one completed and promising preliminary results in two ongoing Phase II studies in melanoma and basal cell carcinoma*

Innovative pipeline that overcomes major challenges in cancer therapy

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

Our solution:

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

Scientifically and commercially validated

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

Highlights for the third quarter

- and post-period events

- **ATLAS -IT-05 – Encouraging preliminary data presented at ESMO 2023**
  - Disease control rate of 43% and one patient achieving a partial response to date
  - There is evidence of tumor shrinkage in both injected and non-injected lesions
- **Verrica Pharmaceuticals' Phase II study evaluating LTX-315 for the treatment of basal cell carcinoma (BCC)**
  - Complete clearance was observed in lesions treated with the highest dose tested
  - 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
- **Neoadjuvant study in earlier stage melanoma patients**
  - An investigator led Phase II study at Oslo University Hospital, Radiumhospitalet is being planned
  - The study protocol was presented at the 15th Nordic Melanoma Meeting, October 12th

Clinical/Operational update

ATLAS-IT-05

- Phase II study with LTX-315 and pembrolizumab in late-stage melanoma patients refractory to immune checkpoint inhibitors

- A study in advanced melanoma patients who have failed prior anti-PD-1/PD-L1 immune checkpoint therapy
- Aim of the study is to show whether LTX-315 has additional benefit in this very hard-to-treat patient population
- Recruitment of first 20 patients completed mid 2023
- Preliminary data presented at The European Society for Medical Oncology Congress (ESMO) on October 23rd, 2023

Positive data opens for expansion into additional cancer types e.g. TNBC, H&N, sarcoma

US sites

- The University of Texas MD Anderson Cancer Center
- UPMC Life Changing Medicine
- Levine Cancer Institute
- Mount Sinai

European sites

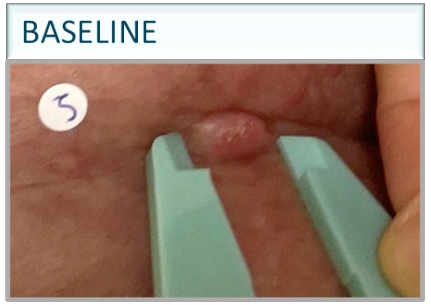
- Gustave Roussy Cancer Campus Grand Paris
- HCL Hospices Civils de Lyon
- Cima Universidad de Navarra
- CHU Lille
- Oslo University Hospital Norwegian Radium Hospital
- Akershus Universitetssykehus

Summary based on first data snapshot

- Early safety data (20 patients) and clinical efficacy data (14 patients)
  - Median duration of follow-up was 15 weeks
- The combination regimen demonstrates preliminary signs of tumor shrinkage and prolonged stabilization in heavily pre-treated patients with PD-1/PD-L1 inhibitor refractory metastatic melanoma.
  - Enrolled patients had generally poor prognostic factors and some patients had also failed on double checkpoint inhibition (ipi+nivo) or BRAF/MEK inhibition.
- The efficacy signal is encouraging with a disease control rate of 43% and 1 patient achieving a partial response to date.
- There is evidence of tumor shrinkage in both injected and in non-injected lesions.
- Intratumoral treatment with LTX-315 is well-tolerated with generally mild to moderate adverse events

Response in injected lesions

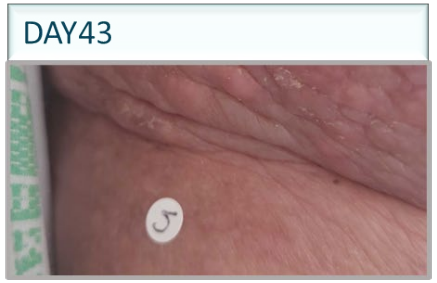
- 9 out of 21 (43%) **evaluable injected lesions** showed **100% complete regression** by CT scan after start of treatment
- Any **partial responses** were not captured in this assessment by CT
- Updated and more mature data on responses in injected lesions will be presented in the future



Mean of two longest perpendicular diameters

12mm

NE

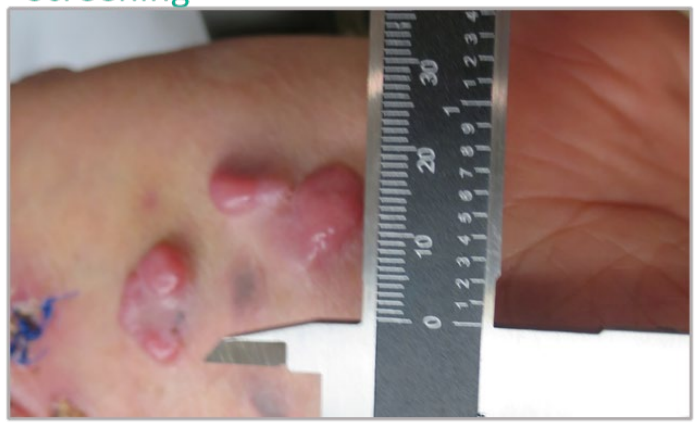


0 mm

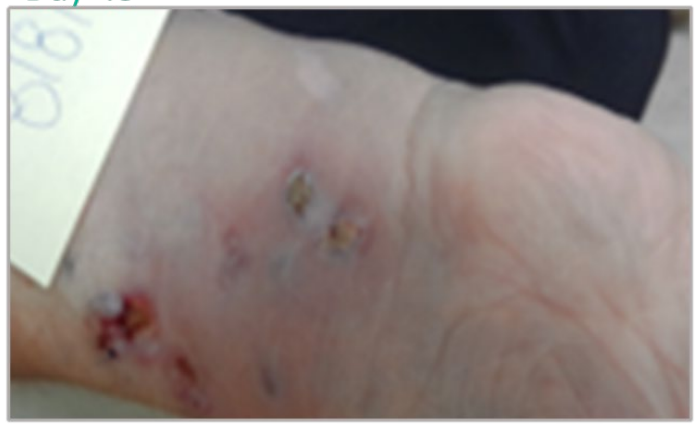
Response in injected lesions

- Patient with multiple large tumor lesions on right forearm that were injected with LTX-315*
- Clear signs of necrosis and regression of injected tumor lesions on Day 43

Screening



Day 43



*Patient was technically classified as PD due to emergence of a small lesion in the finger and the patient is continuing in the study

Case #1 - Melanoma patient with clinically relevant local and systemic response

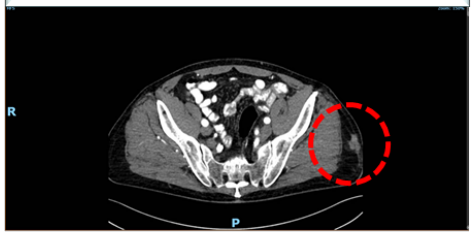
75-year-old male, Stage IVm1a, melanoma (BRAF positive)

Multiple metastases in lymph nodes and gluteal muscle at baseline

Prior treatment with nivolumab and BRAF/Mek inhibitor

NON-INJECTED LESION

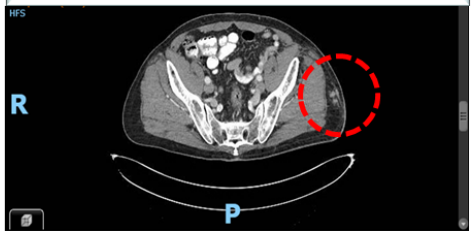
BASELINE



Target lesion size

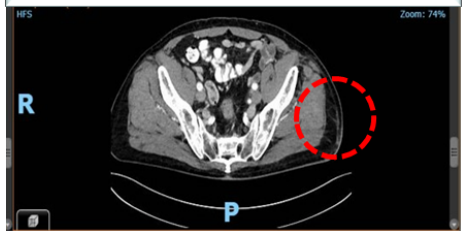
28 mm

DAY43



26 mm

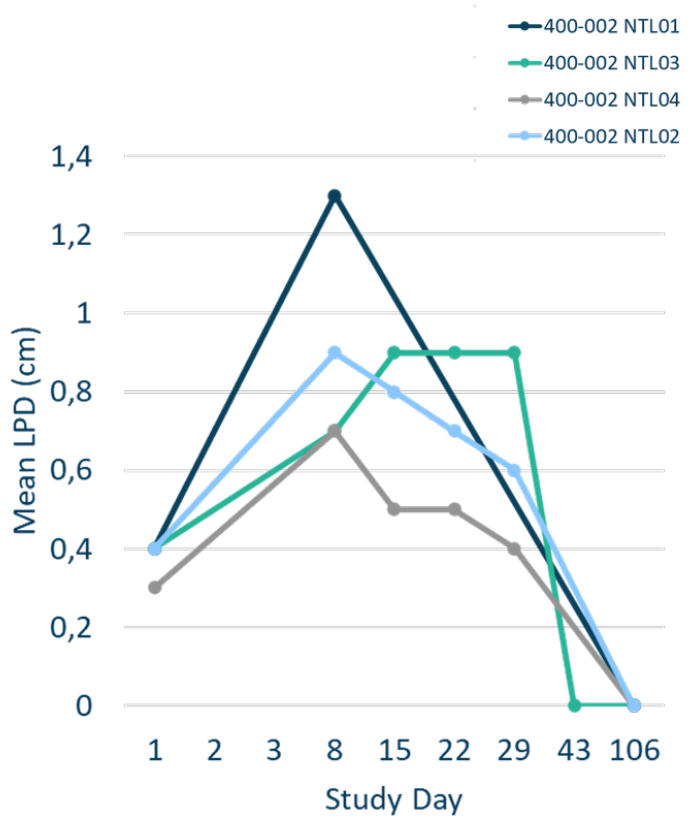
DAY 169



3 mm

89% tumor shrinkage

INJECTED LESIONS



- **Complete regression of all injected lesions**

Case #2 – Melanoma patient with clinically systemic response but PD due to new lesion

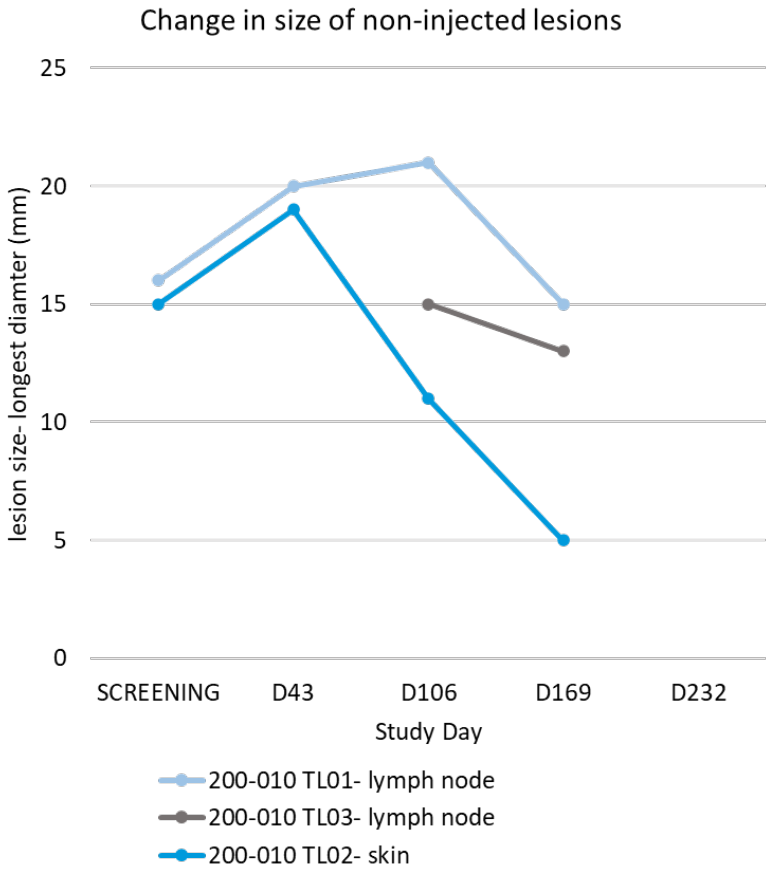
77-year-old female patient with stage IVm1a melanoma

Prior treatment: nivolumab

Treated 1 lesion on 6 prescribed dosing days and 2 cycles (200 mg) + 4 cycles (400 mg) pembrolizumab

Non-treated target lesions in lymph node and skin

The patient is continuing in the study



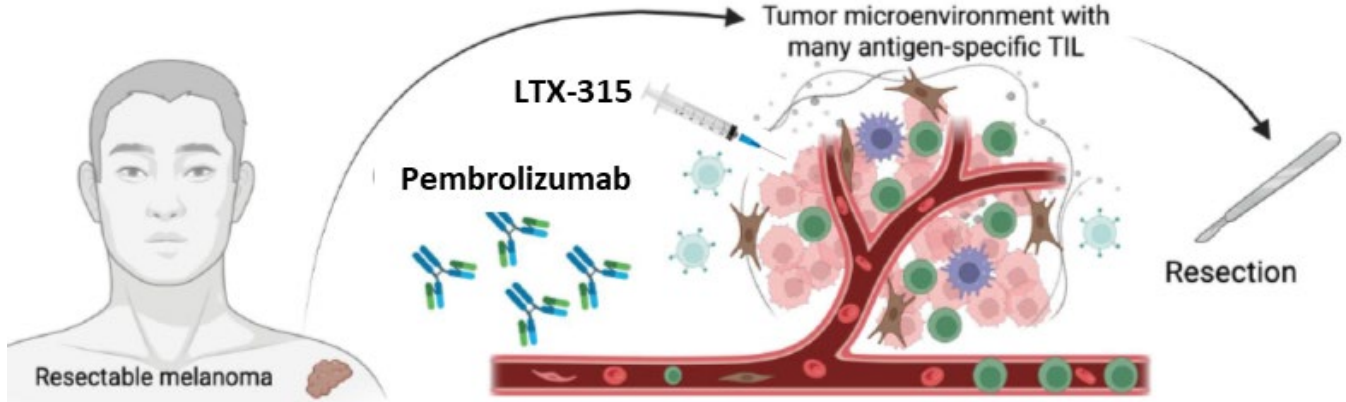
- Two non-injected lesions (TL01 and TL02) reduced in size (-36%)
- One new lesion (TL03 - lymph node) appeared at day 106
- By RECIST 1.1 criteria the patient has a progressive disease

Planned neoadjuvant study with LTX-315 in earlier stage melanoma patients

- Neoadjuvant LTX-315 added to the currently recommended neoadjuvant treatment (immune checkpoint inhibitor, pembrolizumab) for resectable stage III/IV melanoma
- Principal investigator, dr. Henrik Jespersen, Head of melanoma oncology, Oslo University Hospital - Radiumhospitalet
- Study start: 1H 2024
- Rationale:
  - Investigate any added clinical effect of LTX-315 in earlier stage patients with a stronger immune system
  - Expected to result in more effective T-cell priming and reduce risk of relapse compared with pembrolizumab monotherapy

Neoadjuvant therapy: Treatment before surgery

Lytix molecules may have a potential in neoadjuvant setting in several cancer indications



Source: Figure adapted and modified from Saad & Tarhini, Current Oncology Reports 2023

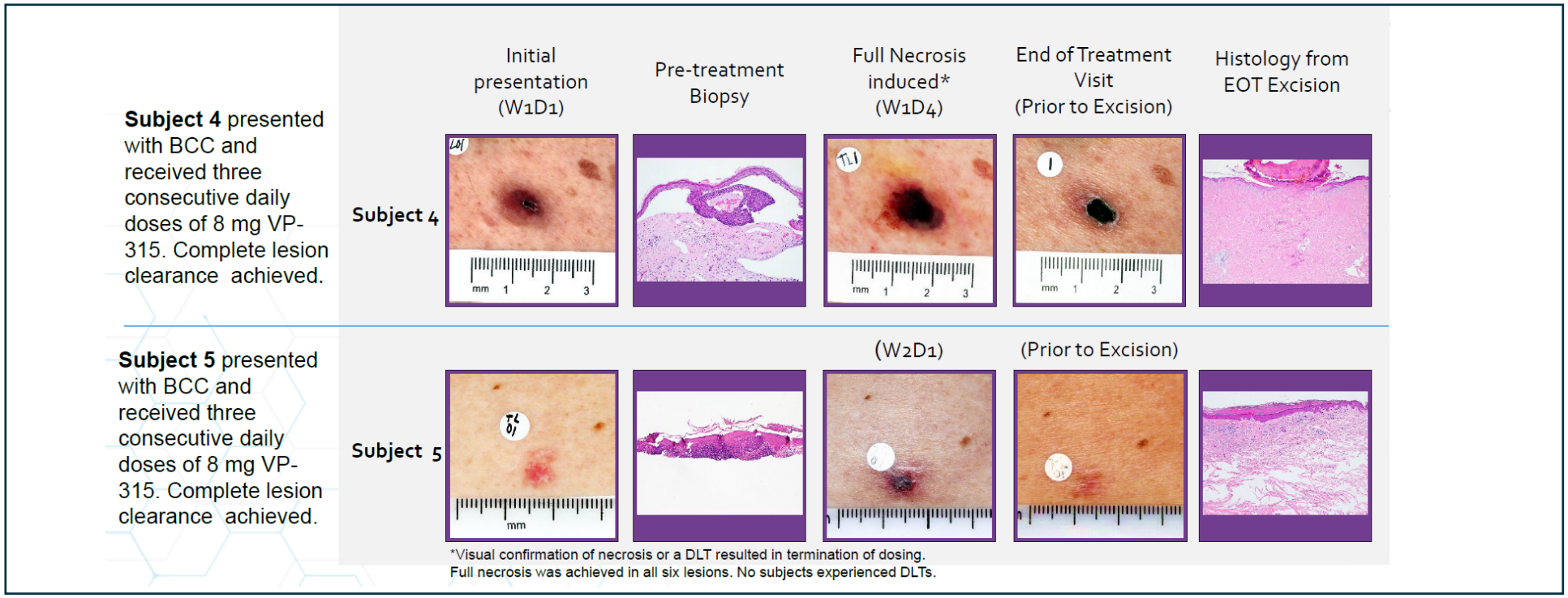
Verrica Pharmaceuticals

- Phase II study in good progress

- Verrica reported promising interim Phase II data with LTX-315 (VP-315) at the 2023 AAD Innovation Meeting on August 11th
- 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.

Positive early results from ongoing Phase II study in basal cell carcinoma

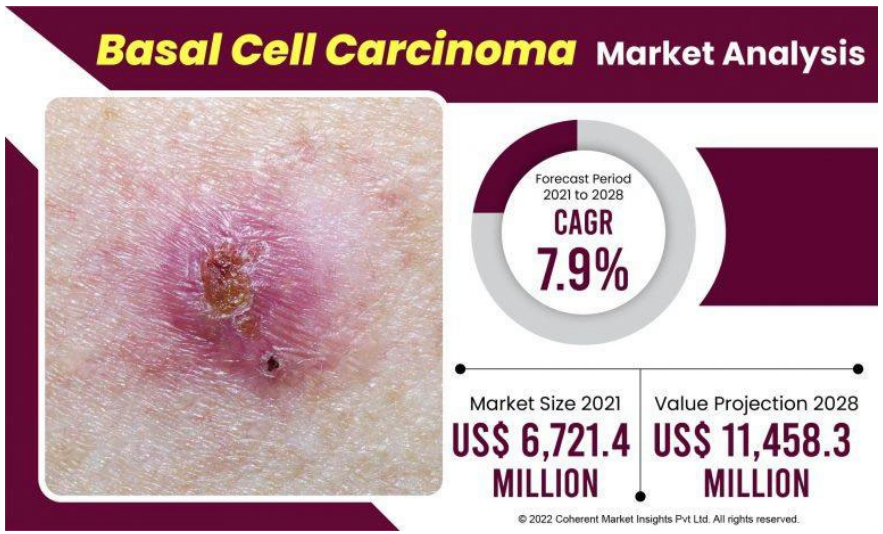
- Of the six patients treated with LTX-315 at the highest dose, complete clearance was observed in four injected lesions, 95% and 30% clearance in two other injected lesions



Phase II study expected to be completed mid 2024

Source: Dr. Neal Bhatia; AAD INNOVATION ACADEMY 2023, August 10-13th, Tampa Florida

A success in basal cell carcinoma represents a significant value increase for Lytix



Verrica has also global rights to enter into squamous cell carcinoma

- Current treatment(s) for BCC are invasive, painful, disfiguring, and may require destruction of healthy tissue
  - LTX-315 represent a non-surgical alternative for patients suffering from skin cancer
- The BCC market size is expected to increase from 6.7 billion USD in 2021 to 11.4 billion USD by 2028
- Worldwide license agreement with LTX-315 for specific types of skin cancer
  - Regulatory and sales milestones at >100 mill. USD
- Royalty rates from low double-digits to mid-teens (net sales)

Source: 2022 Coherent Market Insights Pvt Ltd.

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		*COMPLETED*			
LTX-401	Monotherapy	Solid tumors (deep-seated lesions)					
Undisclosed chemistry		Not applicable					

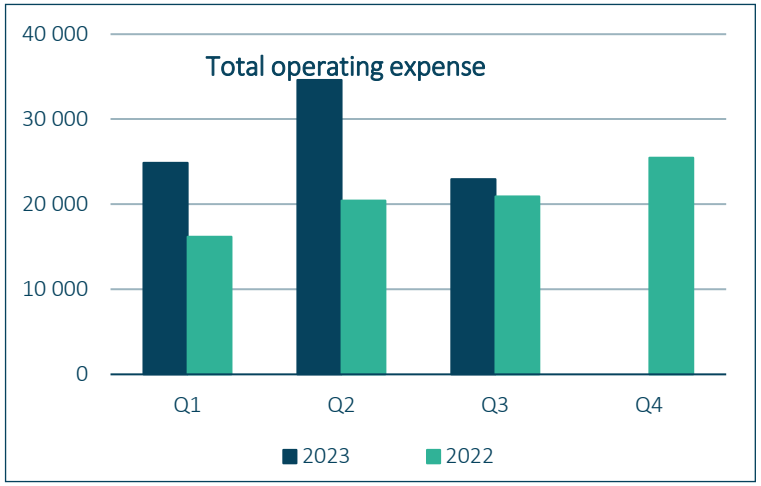
Key figures

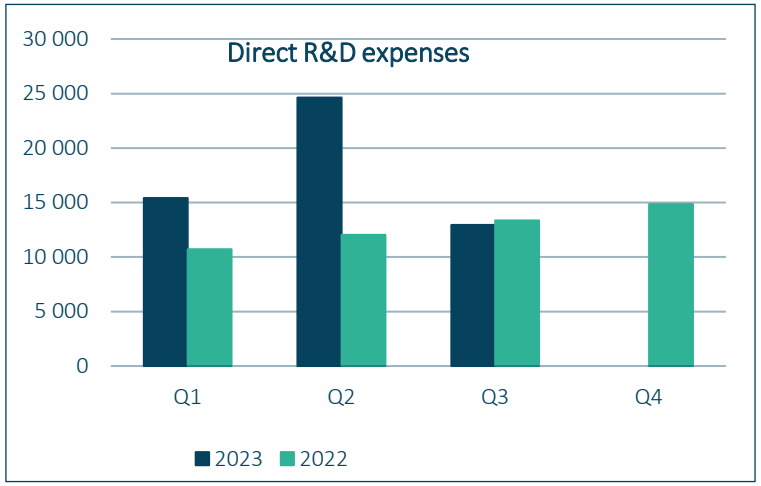
Key figures – profit and loss

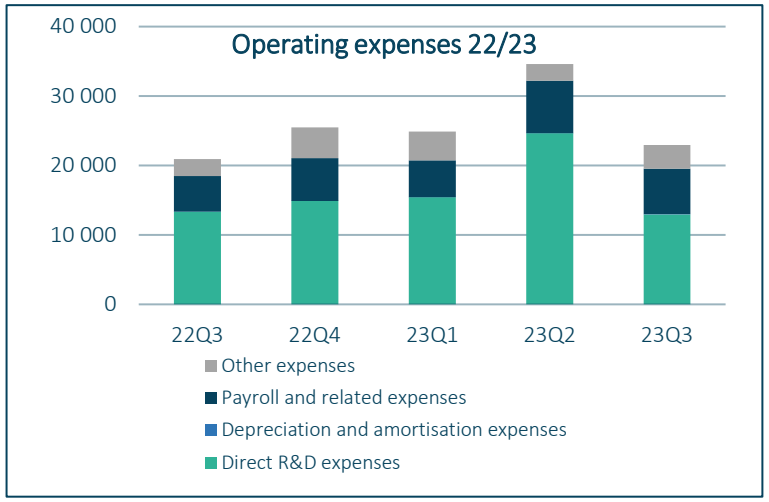
Amounts in NOK thousands	*Unaudited* Q3 2023	*Unaudited* Q3 2022	FY 2022
Total operating income	**4,292**	2,972	17,273
Total operating expenses	**(22,936)**	(20,915)	(82,968)
Loss from operations	**(18,643)**	(17,944)	(65,695)
Loss for the period	**(18,248)**	(11,148)	(56,006)

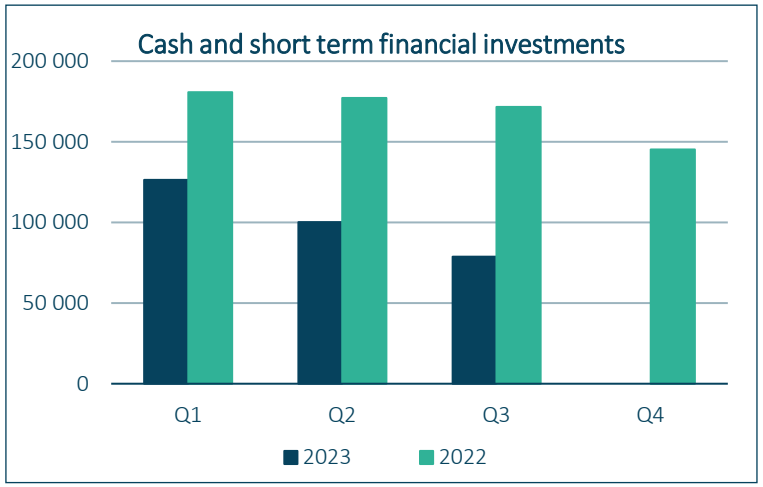
- Total operating income for Q3 2023 includes NOK 3,917 thousand in revenue from our licensing partner Verrica. This revenue is for sale of LTX 315 for use in Verrica's development program
- Total operating expenses increased by NOK 2,020 compared to same period last year but decreased compared to Q2 2023. The reason for the decrease is lower activity in July and August

Key figures


Total operating expense
40 000
30 000
20 000
10 000
0
Q1
Q2
Q3
Q4
2023
2022


Direct R&D expenses
30 000
25 000
20 000
15 000
10 000
5 000
0
Q1
Q2
Q3
Q4
2023
2022


Operating expenses 22/23
40 000
30 000
20 000
10 000
0
22Q3
22Q4
23Q1
23Q2
23Q3
Other expenses
Payroll and related expenses
Depreciation and amortisation expenses
Direct R&D expenses


Cash and short term financial investments
200 000
150 000
100 000
50 000
0
Q1
Q2
Q3
Q4
2023
2022

Key figures
– *balance sheet*

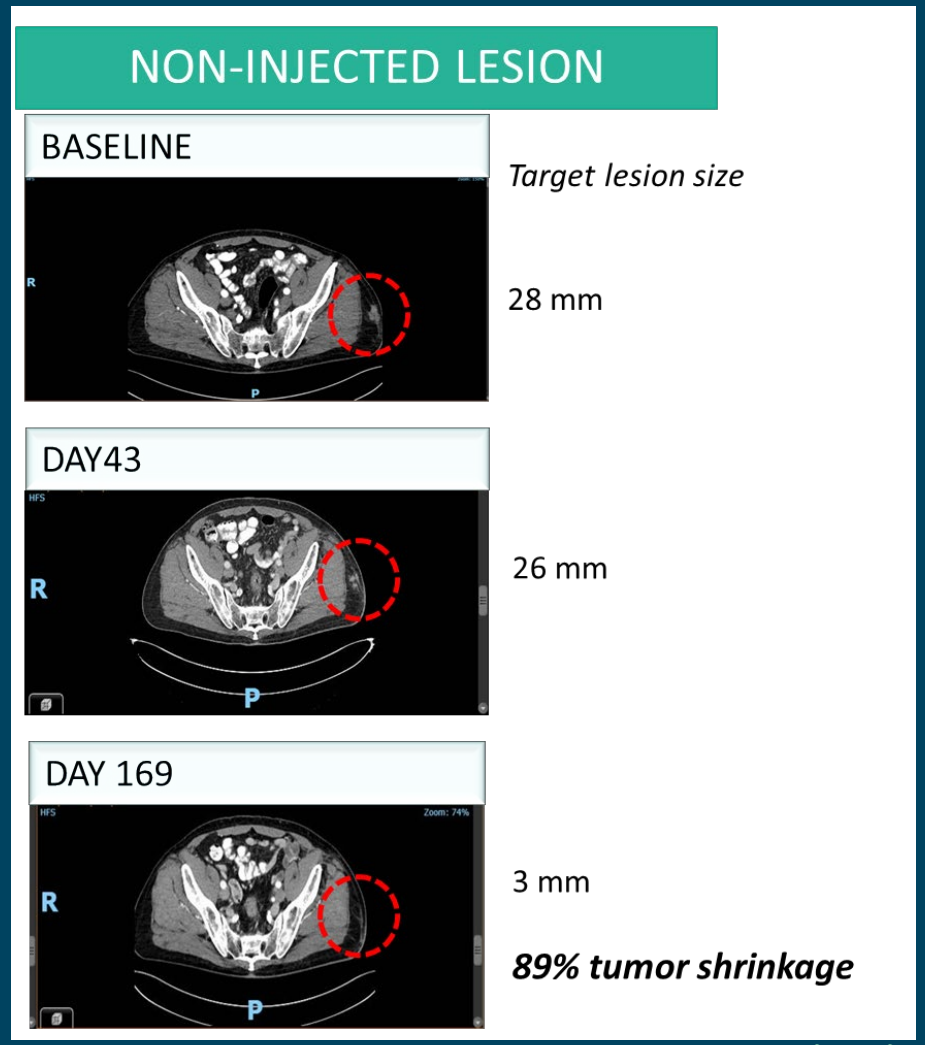
Amounts in NOK thousands	*Unaudited* 30.09.2023	*Unaudited* 30.09.2022	31.12.2022
Assets			
Property, plant and equipment	**127**	137	124
Trade and other receivables	**1,252**	5,656	6,735
Short-term financial investments	**32,609**	49,909	50,606
Cash and cash equivalents	**46,158**	121,671	94,552
Total assets	**80,147**	**177,374**	**152,017**
Shareholder's equity and liabilities			
Total equity	**68,952**	163,883	135,126
Total liabilities	**11,195**	13,491	16,891
Total equity and liabilities	**80,147**	**177,374**	**152,017**

- At the end of the period, cash plus short-term financial investments were NOK 78.8 million, compared to NOK 145.2 million as of 31 December 2022 and NOK 171.6 million as of 30 September 2022.

Outlook

Key objectives

- Clinical development
  - Continue to monitor the 20 patients enrolled in ATLAS-IT-05 study (Top line data will be shared Q1 2024)
  - An amendment for the initiation of an expansion cohort with up to 20 additional patients in process to be submitted
  - 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
  - Commercial collaborations
  - Partnering



Q&A

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Interim Financial Statements

Condensed Interim statement of profit and loss

Amounts in NOK thousands	*Unaudited* Q3 2023	*Unaudited* Q3 2022	*Unaudited* YTD 2023	*Unaudited* YTD 2022	FY 2022
Revenue	3,917	1,409	3,991	1,409	1,409
Other operating income	375	1,563	1,125	14,249	15,864
Total operating income	**4,292**	**2,972**	**5,116**	**15,658**	**17,273**
Payroll and related expenses	(6,567)	(5,090)	(19,405)	(14,965)	(21,133)
Depreciation and amortization expenses	(17)	(11)	(45)	(17)	(30)
Direct R&D expenses	(12,952)	(13,347)	(52,994)	(36,127)	(50,974)
Other expenses	(3,399)	(2,467)	(9,945)	(6,406)	(10,832)
Total operating expenses	**(22,936)**	**(20,915)**	**(82,389)**	**(57,516)**	**(82,968)**
Loss from operations	**(18,643)**	**(17,944)**	**(77,273)**	**(41,858)**	**(65,695)**
Net financial items	**395**	**6,796**	**7,916**	**15,046**	**9,689**
Loss before tax	**(18,248)**	**(11,148)**	**(69,357)**	**(26,812)**	**(56,006)**
Tax expense	-	-			-
Loss for the period	**(18,248)**	**(11,148)**	**(69,357)**	**(26,812)**	**(56,006)**

Condensed Interim statement of financial position

Amounts in NOK thousands	*Unaudited* 30.09.2023	*Unaudited* 30.09.2022	31.12.2022
Assets			
Non-current assets			
Property, plant and equipment	127	137	124
Total non-current assets	**127**	**137**	**124**
Current assets			
Trade and other receivables	1,252	5,656	6,735
Short-term financial investments	32,609	49,909	50,606
Cash and cash equivalents	46,158	121,671	94,552
Total current assets	**80,019**	**177,237**	**151,893**
Total assets	**80,147**	**177,374**	**152,017**
Shareholder's equity and liabilities			
Issued capital and reserves			
Share capital	4,007	4,007	4,007
Share premium reserve	64,945	159,876	131,119
Total equity	**68,952**	**163,883**	**135,126**
Liabilities			
Current liabilities			
Trade payables	22	6,426	6,997
Other current liabilities	11,173	7,065	9,894
Total current liabilities	**11,195**	**13,491**	**16,891**
Total liabilities	**11,195**	**13,491**	**16,891**
Total equity and liabilities	**80,147**	**177,374**	**152,017**

Condensed Interim statement of cash flows

Amounts in NOK thousands	*Unaudited* Q3 2023	*Unaudited* Q3 2022	*Unaudited* YTD 2023	*Unaudited* YTD 2022	FY 2022
Cash flows from operating activities					
Loss for the period	(18,248)	(11,148)	(69,357)	(26,812)	56,006)
Adjustments for:					
Depreciation of property, plant and equipment	17	11	45	17	30
Share-based payment expense	1,078	313	3,182	938	1,376
Interest received	(573)		(1,917)		
Increase/decrease in trade and other receivables	4,707	1,987	5,483	24	(1,055)
Increase/decrease in trade and other payables	(9,004)	3,350	(5,696)	153	3,553
Cash generated from operations	(22,024)	(5,487)	(68,259)	(25,680)	(52,102)
Income tax paid	-	-	-	-	-
Net cash flows from operations	(22,024)	(5,487)	(68,259)	(25,680)	52,102)
Investing activities					
Investments in tangible assets	-	(17)	(49)	(154)	(154)
Interest received	573		1,917		
Increase/decrease in other investments	9,353	(49,909)	17,998	(49,909)	(50,606)
Net cash from/(used in) investing activities	9,926	(49,926)	19,866	(50,063)	(50,761)
Financing activities					
Proceeds from share issue, not yet registered	-	-	-	133	133
Net cash from/(used in) financing activities	-	-	-	133	133
Net increase/(decrease) in cash and cash equivalents	(12,098)	(55,412)	(48,393)	(75,610)	(102,730)
Cash and cash equivalents at the beginning of the period	58,257	177,084	94,552	197,282	197,282
Cash and cash equivalents at the end of the period	46,158	121,671	46,158	121,671	94,552