

# Lytix Biopharma AS

## First quarter 2024 presentation

May 30<sup>th</sup>, 2024



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# Lytix is addressing a major challenge in cancer therapy

Each tumor has several different unique mutations making it difficult to treat

**Lytix's technology** overcomes this major challenge by generating broad tumor-specific immune responses in each patient







“Dedicated to being part of tomorrow’s cancer treatment”

Company overview

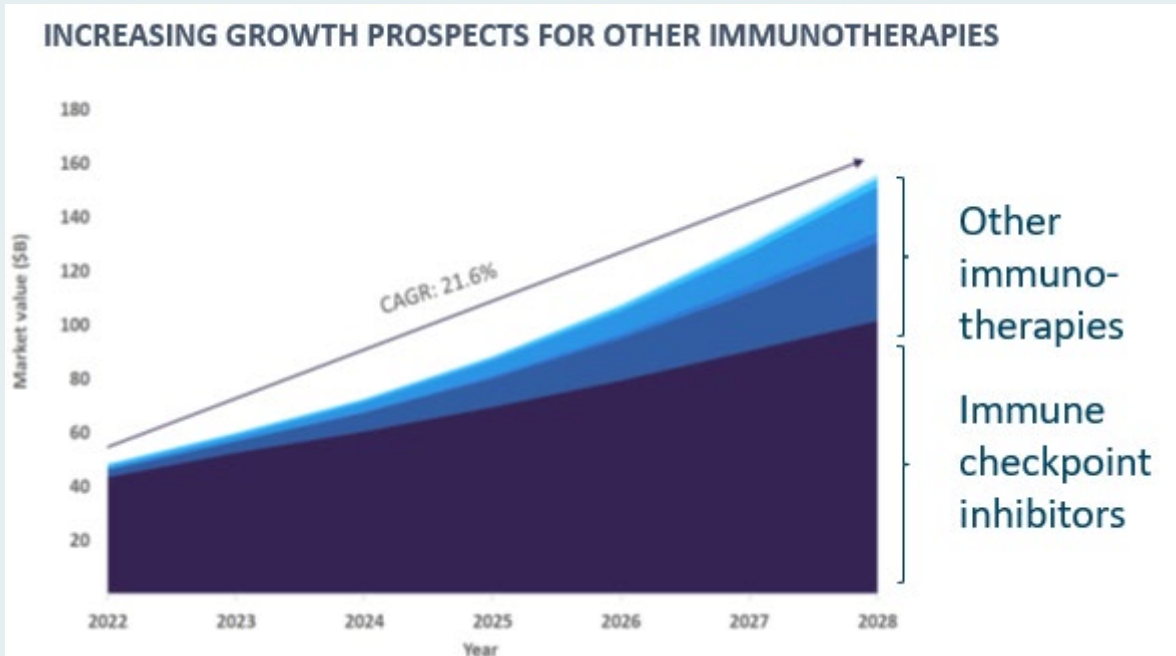
- Clinical-stage, immune oncology company
- Technology platform derived from world-leading research on host defense peptides
- Encouraging interim data in two ongoing Phase II studies
- International management team with presence in both US and Europe
- Licensing deal with Nasdaq-listed Verrica Pharmaceuticals

					
Øystein Rekdal, PhD	Gjest Breistein MEcon	Baldur Sveinbjörnsson, PhD	Gry Stensrud, PhD	Marie Fjällskog, MD, PhD	Stephen Worsley, MBA
CEO	CFO	CSO	CTO	CMO	Business Advisor

Product candidates and portfolio

PRODUCT	DESCRIPTION	CANCER TYPE	PROGRESS	RESULTS EXPECTED
LTX-315	 ATLAS-IT-05 (pembrolizumab)	Melanoma patients progressed on checkpoint inhibitors	Phase II	Interim H2 2025 Final H1 2026
	 Study by Verrica Pharmaceuticals (monotherapy)	Basal cell Carcinoma (skin cancer)	Phase II	Top line results Q2 2024
	 NeoLIPA Neoadjuvant (pembrolizumab)	Early-stage melanoma	Phase II	Interim H1 2025
LTX-401	 First in human (monotherapy)	Solid tumors	Preclinical	

# Extensive market potential for Lytix molecules



- The growth in immunotherapy is primarily driven by immune checkpoint inhibitors (ICIs)
- Therapies that address the shortcomings of ICIs are highly needed
- By addressing the challenge for patients who do not respond to ICIs Lytix molecules represent a large commercial potential
- Total market estimated to ~USD150bn within 2028 (both ICI and other immunotherapies).



## IMMUNE CHECKPOINT INHIBITORS

Checkpoint inhibitors are a type of immunotherapy. They block proteins that stop the immune system from attacking the cancer cells

# Highlights for the first quarter

## *- and post-period events*

- **Verrica Pharmaceuticals' Phase II study in basal cell carcinoma – Positive early results**
  - In January 2024, Verrica reported that all patients had been dosed with LTX-315 (VP-315).
  - Preliminary Phase II Top-Line Data Expected Q2 2024.
  
- **ATLAS -IT-05 study ongoing – Encouraging interim data from 20 late-stage melanoma patients**
  - Disease control in approximately half the patients and with durable responses for up to one year
  - One patient achieving a durable partial response.
  - New update will be given during H2 2024.
  
- **Expanding to earlier stage melanoma patients with a stronger immune system**
  - An investigator led Phase II study at Oslo University Hospital, Radiumhospitalet planned to start mid 2024.
  - In April 2024, the clinical trial application for the NeoLIPA trial was approved by the regulatory authorities.

# Highlights for the first quarter

*- and post-period events*

## 🌐 Financials

- During the quarter Lytix generated a revenue of NOK 10.5 million for sale of LTX-315 to Verrica for use in their clinical trial.
- In April 2024, Lytix successfully raised NOK 50 million in gross proceeds in a share offering primarily directed towards existing shareholders, extending the cash runway into 2025.

## 🌐 CEO Øystein Rekdal held a presentation at Immuno 2024 in London, April 26<sup>th</sup>

- Cutting-edge presentations by leading speakers on the latest advancements in the field of immunology



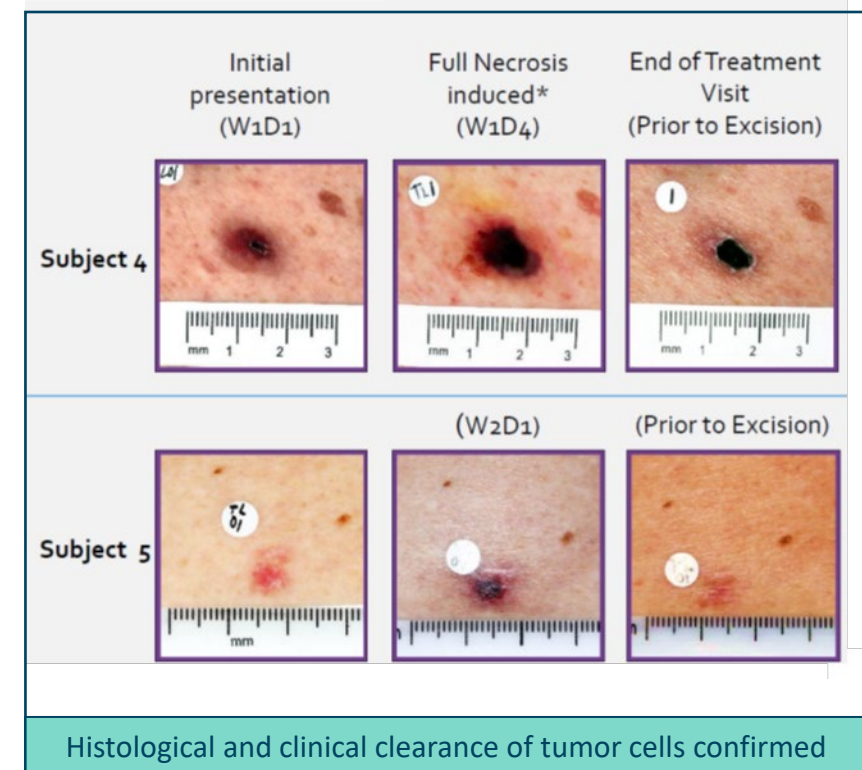
# Clinical/Operational update



# Encouraging early results from Phase II study in basal cell carcinoma

## A two-part phase II study

- ⊗ Part 1
  - LTX-315 (VP-315) showed a favorable safety and tolerability profile
  - Patients receiving the higher range of dosing experienced a consistent response of clinical tumor necrosis.
- ⊗ Part 2
  - Gain information on safety, tolerability and dosing regimen to support a pivotal Phase III study
  - Top-line results expected Q2 2024



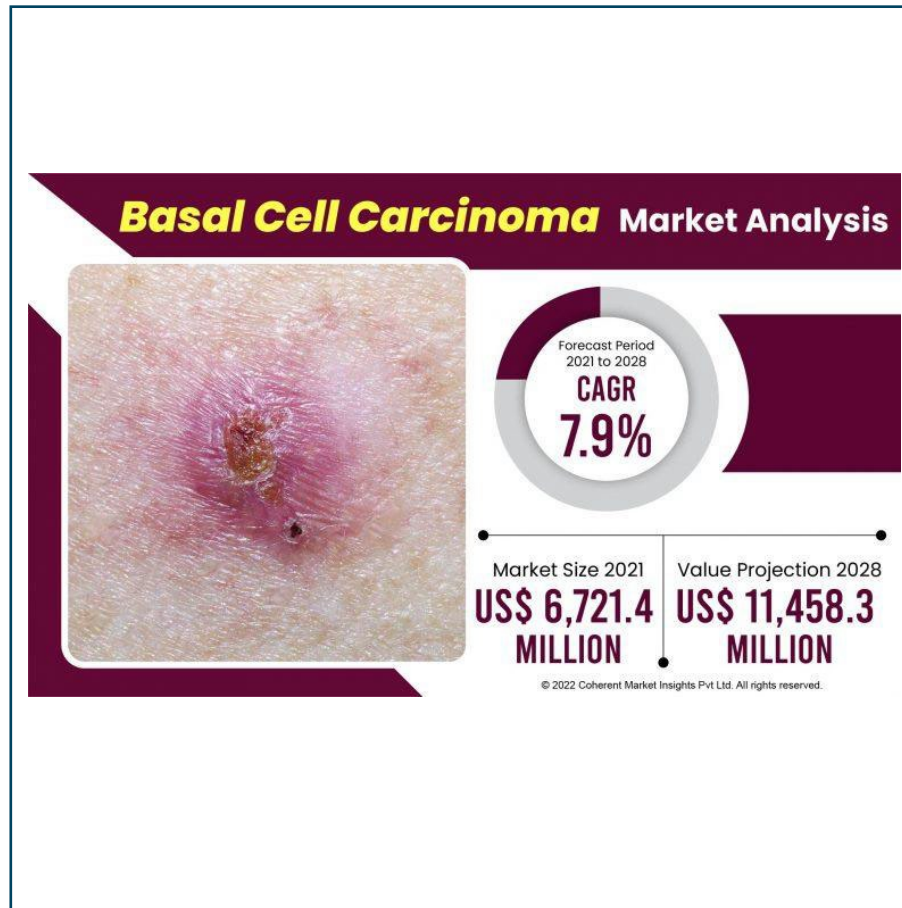
# LTX-315 represent a non-surgical alternative for BCC patients

- Alternative to current surgical procedures
- Local and gentle treatment, adjusted for each patient
- Avoid scarring and other physical side-effects related to surgical treatments
- Potential decreased risk of occurrence of new lesions



Source: <https://www.tv2.no/nyheter/viral/kenneth-40-trodde-han-hadde-kvise-pa-nesen-fikk-alvorlig-beskjed-hos-legen/14511455>

# Market approval for LTX-315 in BCC market could potentially generate high revenue for Lytix shareholders



- Verrica has global rights for basal cell carcinoma, squamous cell carcinoma, non-metastatic melanoma and non-metastatic Merkel cell carcinoma (skin cancer)

- The BCC market size alone 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
  - Lytix has to date received USD 3.5 million
  - Next milestone is initiation of Phase III study
  - USD 110 million in future development and sales milestones
  - Plus 10-15% royalties on future sales

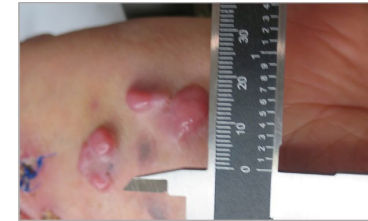
# ATLAS-IT-05 (ongoing): Promising effects of LTX-315 in heavily pre-treated patients with late-stage melanoma

- As a new class of immunotherapeutic drug LTX-315 has to be tested in late-stage patients that have failed to respond to standard of care
- LTX-315 and anti PD-1 inhibitor pembrolizumab are being tested in patients that have previously failed to respond to PD-(L)1 inhibitor therapy
- Enrolled patients had failed  $\leq 3$  prior lines of treatment, e.g. double checkpoint inhibition or BRAF/MEK inhibition or oncolytic virus
- Recruitment of patients completed August 2023

## Positive interim data from 20 evaluable patients

- Stabilization of disease in approximately half of the patients
- One patient achieving a durable partial response
- Effects in both injected and non-injected lesions

### Complete regression in injected tumor lesions



Before Treatment



Day 43

### Non-injected tumor lesion almost eradicated



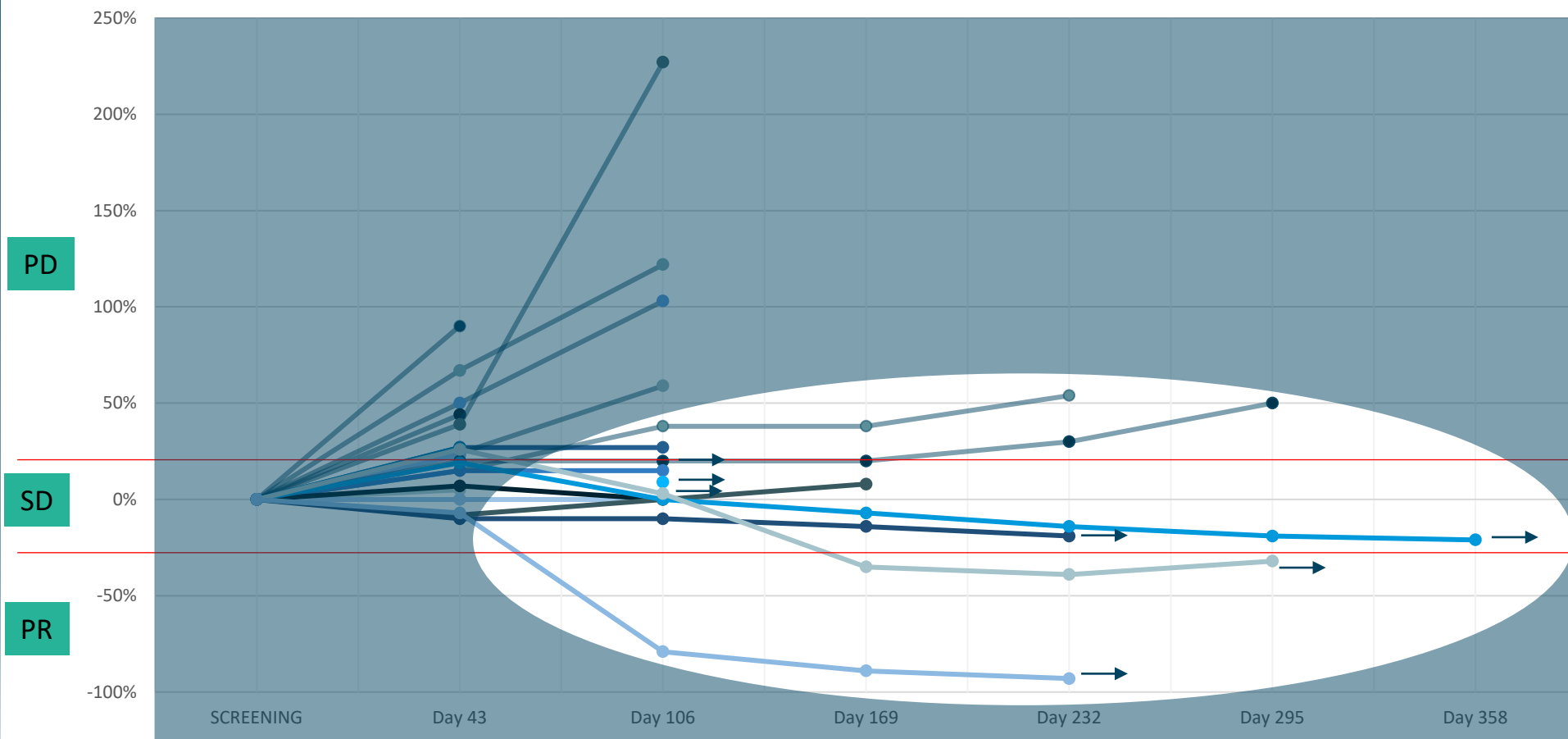
Before Treatment- 28mm



Day 169 – 3mm

# Several patients with prolonged clinically relevant response

- *Some patients still in early stage of the study*



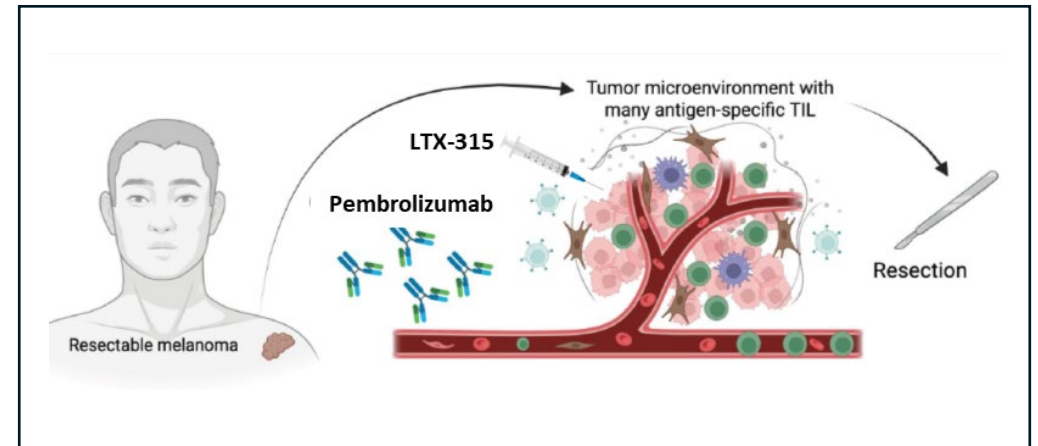
Each line in the figure represent one patient  
 PD: progressive disease, SD: stable disease, PR: partial response, CR; complete response

# NeoLIPA – Expanding to earlier-stage melanoma patients with a stronger immune system

- Encouraging results from late-stage patients opens for study in earlier-stage patients
- LTX-315 and pembrolizumab will be given prior to surgery – aiming to reduce relapse risk
- Study will be led by Radiumhospitalet (OUH) → Low cost for Lytix (drug supply)
- Quick read-out with pathologic complete response (pCR) rate as primary endpoint
- Time to relapse and overall survival – secondary endpoints
- Study start – mid 2024

## Commercial rationale

- Patients with resectable tumors have less advanced disease, and a stronger immune system
- This patient population has a better chance of responding to Lytix' immunotherapy
- The relevant patient population is larger, representing a better commercial opportunity



Source: Adapted from Saad & Tarhini, Current Oncology Reports 2023

# LTX-401 – a small oncolytic molecule with a large commercial potential in deep seated cancer

## Small oncolytic molecule in development

- Being prepared for Phase I study
- Increased commercial interest with a clinical validation of our lead candidate LTX-315



### Small molecule

Similar mode-of-action as LTX-315 with superior effects in liver cancer models



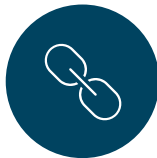
### Significant commercial potential

Suited for treatment of various solid tumor types, including deep-seated lesions



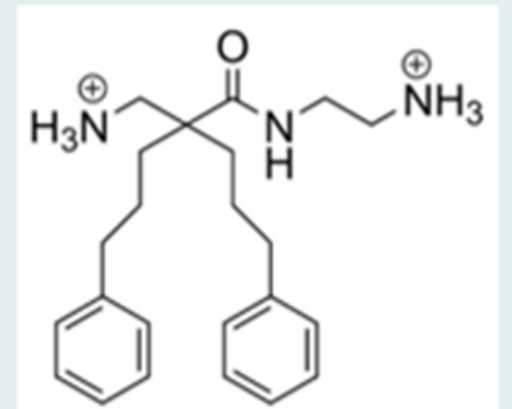
### Good tolerance

Shown to be safe and well tolerated in preclinical safety studies



### Synergy effects

Demonstrates strong synergy with checkpoint inhibitors



LTX-401



# Key figures

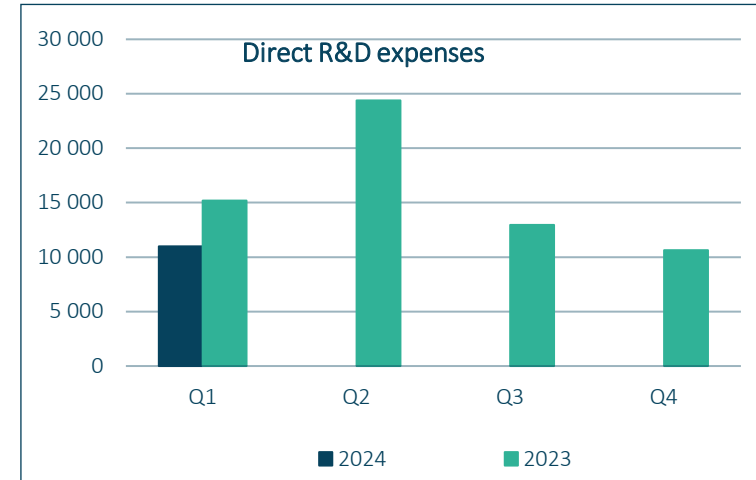
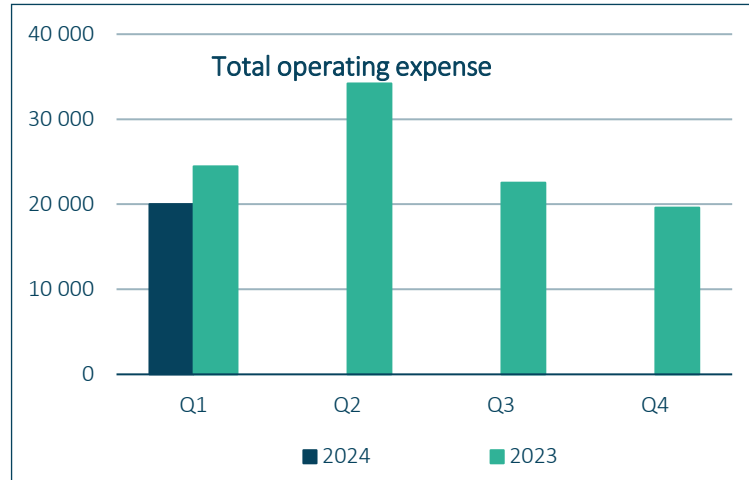


## Key figures – profit and loss

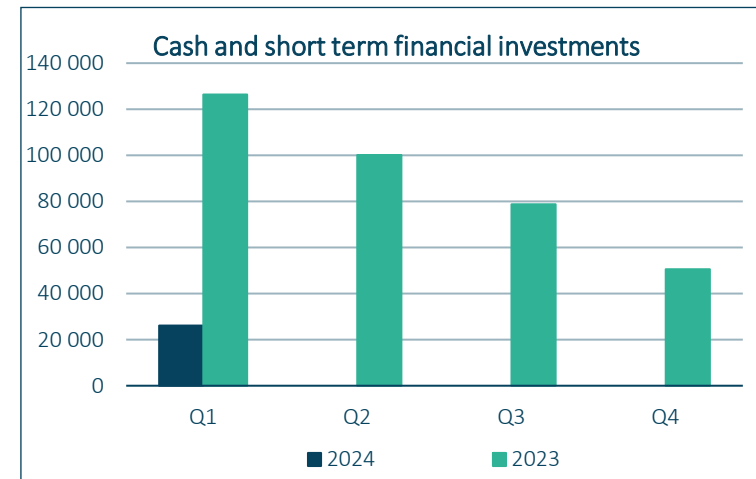
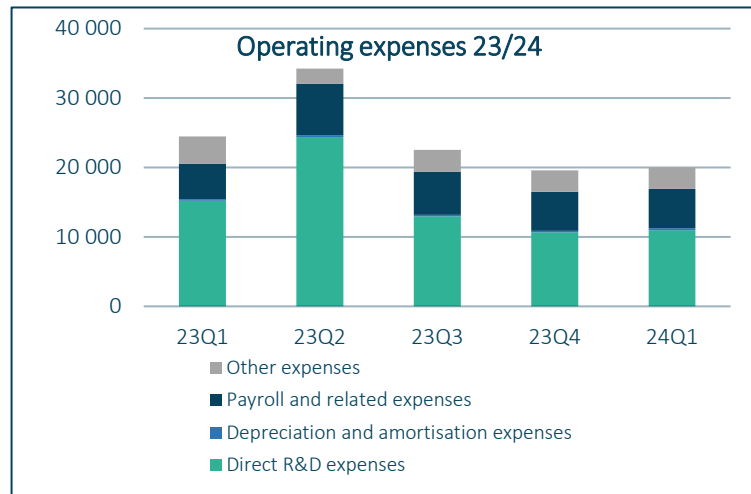
	Unaudited		FY 2023
	Q1 2024	Q1 2023	
<i>Amounts in NOK thousands</i>			
Total operating income	10,526	-	3,991
Total operating expenses	(29,212)	(24,448)	(100,776)
<b>Loss from operations</b>	<b>(18,685)</b>	<b>(24,448)</b>	<b>(96,785)</b>
<b>Loss for the period</b>	<b>(18,183)</b>	<b>(19,668)</b>	<b>(87,897)</b>

- ⦿ As the annual report 2023 was prepared in accordance with IFRS Accounting Standards, the Q1 2024 interim financials are based on the same standards.
- ⦿ Total operating income for the three months ended 31 March 2024 was NOK 10,526 million, compared to nil for the same period in 2023. The revenue is from sale of LTX-315 to Verrica for use in their clinical trial.
- ⦿ Total operating expenses for the three months ended 31 March 2024 amounted to NOK 29.2 million compared to NOK 24.5 million for the same period in 2023.
  - In Q1 2024 Lytix produced and sold LTX-315 to Verrica for use in Verrica’s clinical trial which increased the operating expenses by NOK 9.2 million.

# Maintaining strict cost control while prioritizing clinical activities



Operating expenses on this slide is presented excluding the NOK 9.2 million paid for LTX -315 that was immediately sold to Verrica. This way the figures are more comparable to the 2023 figures.



## Key figures – balance sheet

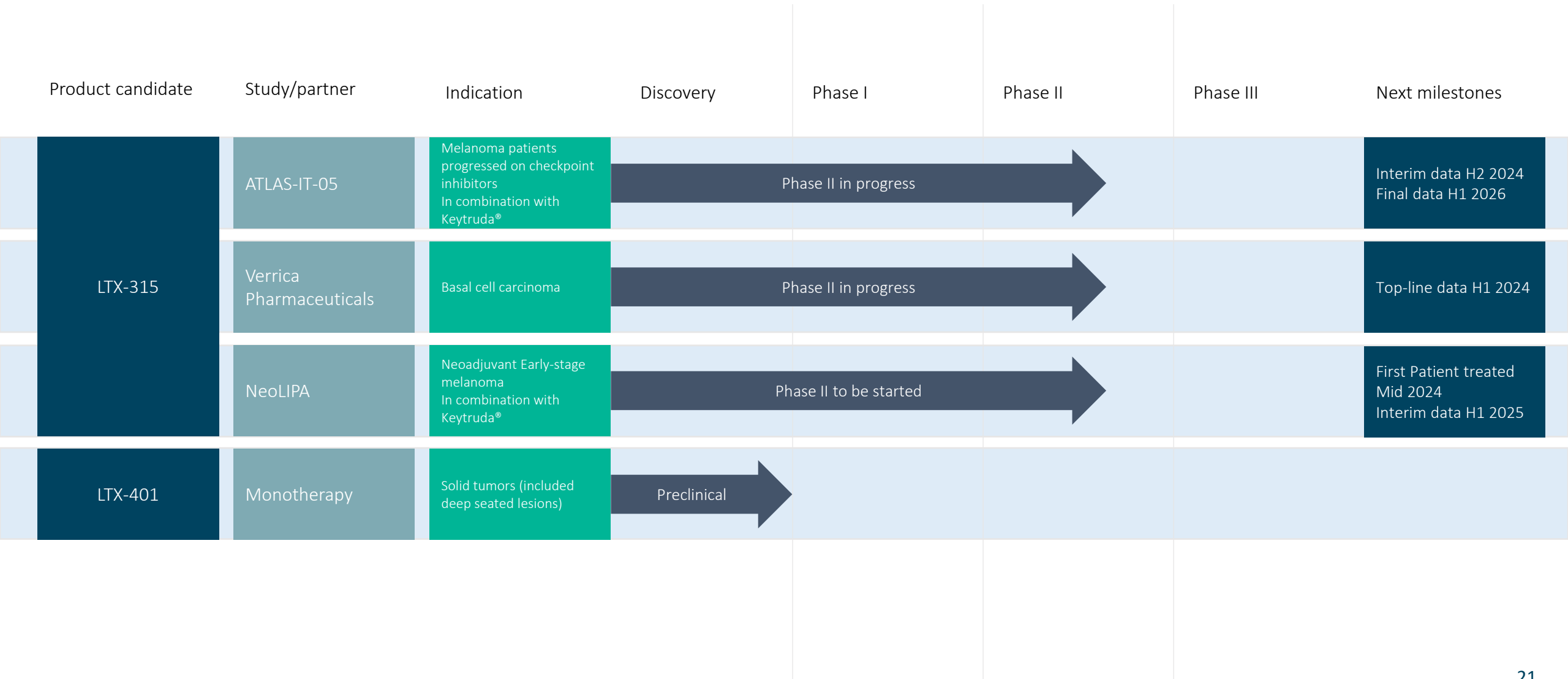
<i>Amounts in NOK thousands</i>	<i>Unaudited</i>	<i>Unaudited</i>	
	<b>31.03.2024</b>	31.03.2023	31.12.2023
<b>Assets</b>			
Property, plant and equipment	93	126	110
Right-of-use assets	213	1,113	438
Trade and other receivables	18,840	7,073	12,777
Short-term financial investments	13,511	51,314	23,183
Cash and cash equivalents	12,661	75,057	27,365
<b>Total assets</b>	<b>45,319</b>	134,682	<b>63,874</b>
<b>Shareholder's equity and liabilities</b>			
Total equity	33,771	116,384	51,319
Total liabilities	11,548	18,298	12,555
<b>Total equity and liabilities</b>	<b>45,319</b>	134,682	<b>63,874</b>

- ⊗ At the end of the period, cash plus short-term financial investments were NOK 26.2 million, compared to NOK 50.5 million as of 31 December 2023
- ⊗ In April 2024, Lytix raised NOK 50 million in a share offering primarily directed towards existing shareholders extending the cash runway into 2025.



# Outlook

# Exiting time ahead



# Q&A

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# Interim Financial Statements

# Condensed interim statement of comprehensive income

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q1 2024	<i>Unaudited</i> Q1 2023	FY 2023
Revenue	10,526	-	3,991
<b>Total operating income</b>	<b>10,526</b>	<b>-</b>	<b>3,991</b>
Payroll and related expenses	(5,663)	(5,141)	(24,344)
Depreciation and amortization expenses	(242)	(239)	(962)
Direct R&D expenses	(20,186)	(15,183)	(63,167)
Other expenses	(3,121)	(3,885)	(12,303)
<b>Total operating expenses</b>	<b>(29,212)</b>	<b>(24,448)</b>	<b>(100,776)</b>
<b>Loss from operations</b>	<b>(18,685)</b>	<b>(24,448)</b>	<b>(96,785)</b>
<b>Net financial items</b>	<b>503</b>	<b>4,780</b>	<b>8,887</b>
<b>Loss before tax</b>	<b>(18,183)</b>	<b>(19,668)</b>	<b>(87,897)</b>
Tax expense	-	-	-
<b>Loss for the period</b>	<b>(18,183)</b>	<b>(19,668)</b>	<b>(87,897)</b>



# Condensed interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 31.03.2024	<i>Unaudited</i> 31.03.2023	31.12.2023
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	93	126	110
Right-of-use assets	213	1,113	438
<b>Total non-current assets</b>	<b>307</b>	<b>1,239</b>	<b>548</b>
<b>Current assets</b>			
Trade and other receivables	18,840	7,073	12,777
Short-term financial investments	13,511	51,314	23,183
Cash and cash equivalents	12,661	75,057	27,365
<b>Total current assets</b>	<b>45,012</b>	<b>133,443</b>	<b>63,326</b>
<b>Total assets</b>	<b>45,319</b>	<b>134,682</b>	<b>63,874</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	29,764	112,377	47,312
<b>Total equity</b>	<b>33,771</b>	<b>116,384</b>	<b>51,319</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities	41	249	41
<b>Total current liabilities</b>	<b>41</b>	<b>249</b>	<b>41</b>
<b>Current liabilities</b>			
Trade payables	4,970	7,144	3,572
Other current liabilities	6,329	9,954	8,492
Lease liabilities	208	951	451
<b>Total current liabilities</b>	<b>11,508</b>	<b>18,049</b>	<b>12,514</b>
<b>Total liabilities</b>	<b>11,548</b>	<b>18,298</b>	<b>12,555</b>
<b>Total equity and liabilities</b>	<b>45,319</b>	<b>134,682</b>	<b>63,874</b>

# Condensed Interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> <b>Q1 2024</b>	<i>Unaudited</i> Q1 2023	FY 2023
<b>Cash flows from operating activities</b>			
Loss for the period	<b>(18,183)</b>	(19,668)	(87,897)
<b>Adjustments for:</b>			
Depreciation of property, plant and equipment	17	14	62
Depreciation of right-of-use assets	225	225	900
Interest income/(expense), net	(181)	(682)	(2,348)
Share-based payment expense	63	1,019	4,183
Increased/decreased in trade and other receivables	(6,063)	(338)	(6,042)
Increased/decreased in trade and other payables	(764)	207	(4,828)
<b>Cash generated from operations</b>	<b>(24,315)</b>	(19,223)	(95,969)
Income tax paid	-	-	-
<b>Net cash flows from operations</b>	<b>(24,315)</b>	(19,223)	(95,969)
<b>Investing activities</b>			
Investments in tangible assets	-	(16)	(49)
Interest received	181	684	2,351
Investment in other short-term investments	9,673	(707)	27,423
<b>Net cash from/(used in) investing activities</b>	<b>9,854</b>	(39)	29,725
<b>Financing activities</b>			
Interest paid	-	(2)	(3)
Payment of principal portion of lease liabilities	(242)	(231)	(940)
Proceeds from share issue	-	-	-
Transaction cost	-	-	-
<b>Net cash from/(used in) financing activities</b>	<b>(242)</b>	(233)	(943)
Net increase/(decrease) in cash and cash equivalents	<b>(14,704)</b>	(19,495)	(67,187)
Cash and cash equivalents at the beginning of the period	<b>27,365</b>	94,552	94,552
<b>Cash and cash equivalents at the end of the period</b>	<b>12,661</b>	75,057	27,365