

# Lytix Biopharma AS

## Q2 and H1 2024 presentation

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# Developing the future of cancer treatment



Clinical-stage, immunology company developing a new class of cancer therapy

Fighting cancer through local killing of tumor cells and activation of the immune system

Three ongoing phase II studies in Europe and the US on skin cancer diseases, such as basal cell carcinoma (BCC) and melanoma.

Licensing deal with Nasdaq-listed Verrica Pharmaceuticals for BCC. Phase II data shows 86% overall reduction in tumor size and 51% complete clearance.

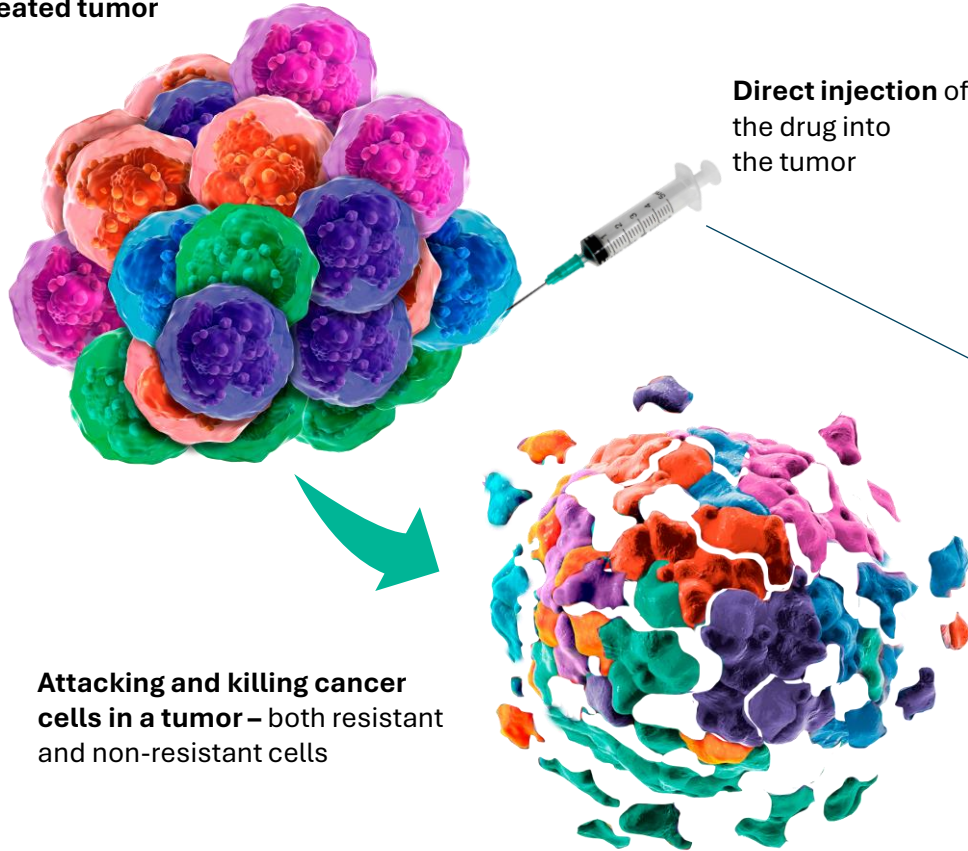
Nobel prize winner in immune oncology member of Lytix's Advisory Board

# Lytix's solution through two phases; Killing tumors locally and activating a broad immune response systemically

1

Directly injecting the cancer drug into the tumor

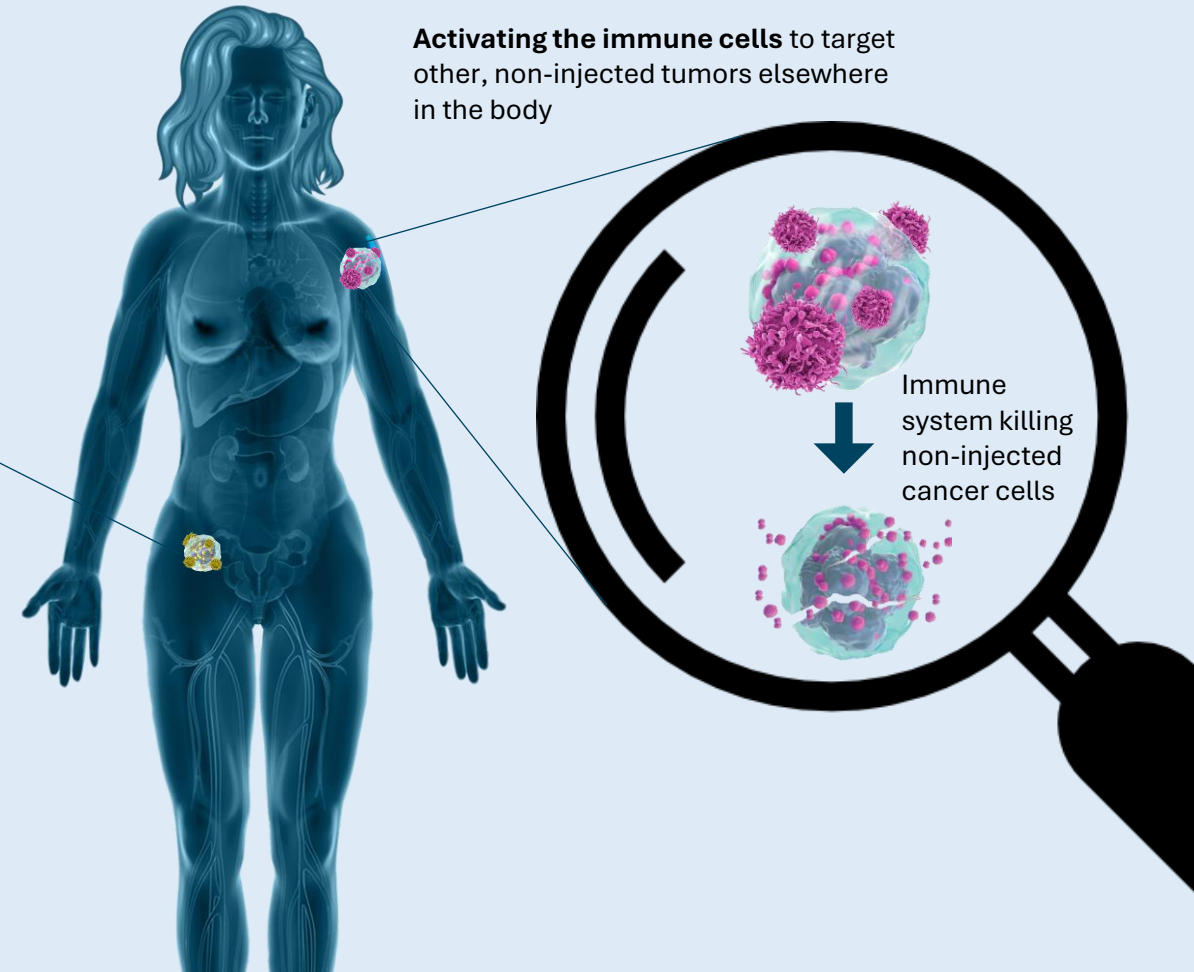
Untreated tumor



2

Broad activation of immune cells to target remaining tumors

Activating the immune cells to target other, non-injected tumors elsewhere in the body



# Highlights for the second quarter

- And post quarter end

## **Verrica Pharmaceuticals' Phase II study in basal cell carcinoma – Positive preliminary results**

- Positive top-line Phase II results in basal cell carcinoma (BCC)- the largest skin cancer disease globally
- 86 percent overall reduction of tumor size and complete clearance in 51 percent of the patients
- LTX-315 has the potential to be utilized as a first-line therapy in BCC

## **ATLAS-IT-05 phase II study ongoing – Encouraging new interim data from 20 late-stage and heavily pre-treated melanoma patients**

- Disease control in 40% of patients and with durable responses for up to approximately 17 months
- One new patient with confirmed partial response (PR), i.e. two patients with PR in total

## **Expanding to earlier stage melanoma patients with a stronger immune system (NeoLIPA)**

- An investigator led Phase II study at Oslo University Hospital, Radiumhospitalet, will be open for enrolment Q3 2024
- The clinical trial application for NeoLIPA trial was approved by the regulatory authorities April 2024

# Highlights for the second quarter

- And post quarter end

## A superior new formulation for LTX-401

- Could potentially represent a game-changer for Lytix's second lead candidate
- Strong effects in two “hard to treat” preclinical cancer models compared to “old” LTX-401 formulation
- A PCT patent application that could extend patent protection significantly was published in June 2024.

## Financials

- 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.
- Cash at the end of the period amounted to NOK 60 million.

# Clinical/Operational update

- 1 Phase II study: Basal cell carcinoma (Verrica Pharmaceuticals)
- 2 Phase II study: Late stage melanoma (ATLAS-IT-05)
- 3 New phase II study: Early stage melanoma (NeoLIPA)
- 4 LTX-401

# Lytix's lead drug candidate shows great potential in the largest cancer disease globally



The skin cancer disease basal cell carcinoma is the largest cancer indication globally



Lytix's lead cancer drug is addressing this large and growing market **expected to grow to USD 11.5bn in 2028**



A licensing deal already in place with US-based Verrica Pharmaceuticals, **potentially up to USD 110m + royalties on future sale**



Preliminary top-line data from the phase II trial with Verrica **showing 86 percent reduction in tumor size**



Phase II indicates the potential to be utilized as a first-line therapy, an instrumental milestone towards commercialization



# Strong preliminary results in Phase II trial

LTX-315 named VP-315 in Verrica Pharmaceuticals study

## KEY RESULTS SUMMARY – 90 PATIENTS

**86%**

Overall reduction  
of tumor size

**51%**

Complete clearance  
rate of basal cell  
carcinomas

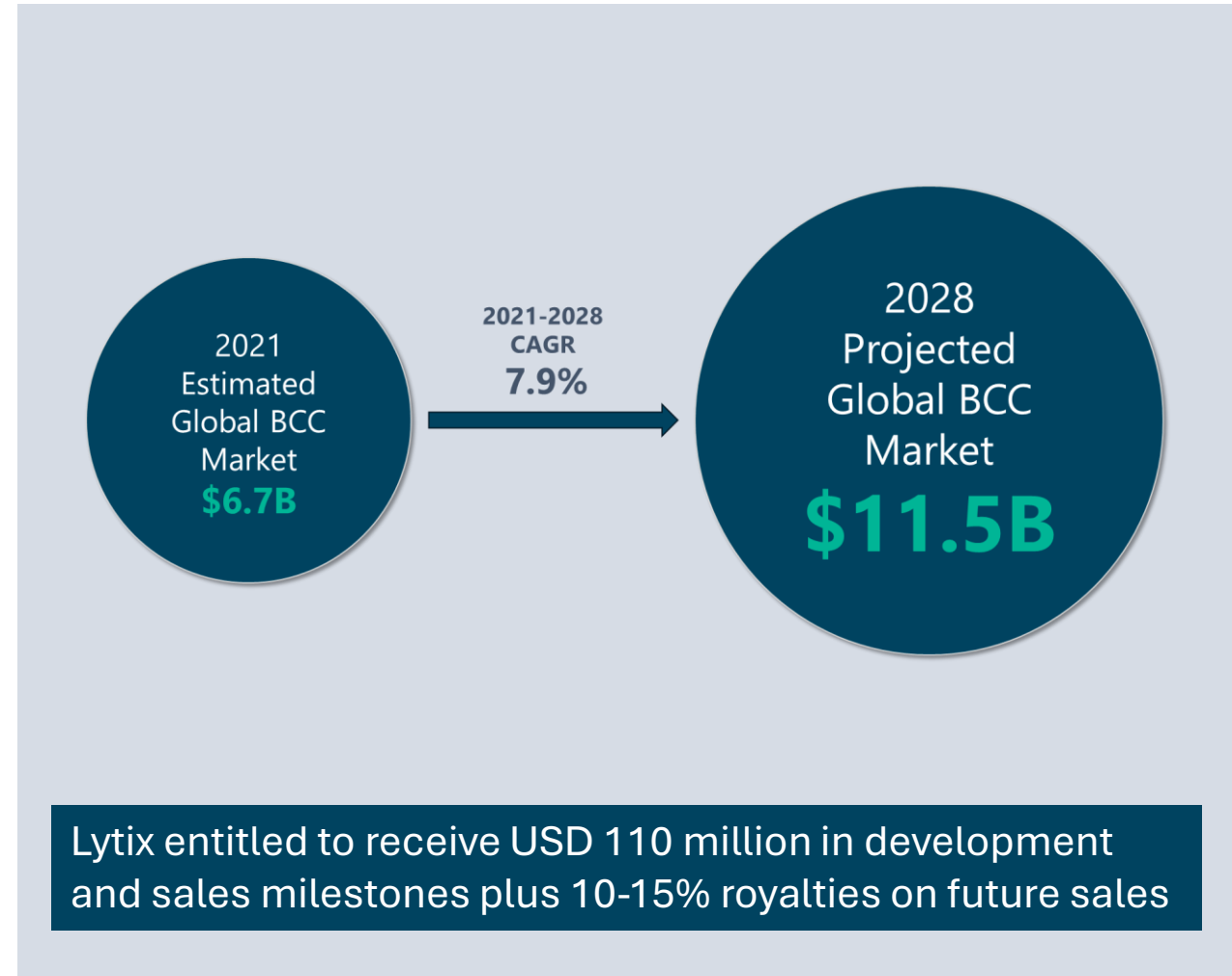
**71%**

Reduction in tumor  
size on patients with  
residual carcinomas

No serious adverse events

# BCC represents a multi-billion-dollar global market

- BCC is the **most common cancer (3.6 mill US cases diagnosed per year)**, with **increasing incidence rates** worldwide
- More than one out of every three new cancers are skin cancers, and the vast majority are BCCs<sup>(1)</sup>
- Diagnosed BCC patients have a **35% chance of new lesion** within 3 years, and **50% within 5 years**<sup>(2,3)</sup>



# LTX-315: First line treatment potential, less invasive for patients

- BCCs are typically found in skin more exposed to the sun, with ~80% located on the face and head
- ~95 % of BCC patients are treated with surgery.
- Surgery often cause scarring that are larger than the visible BCC lesion
- LTX-315 Treatment:
  - Complete clearance (51%)
    - No need for surgery
    - No scarring
  - Partial clearance (49%)
    - Significant reduction in size of lesion before surgery (71%)
    - Significant reduction in size of scar
- Potential decreased risk of occurrence of new lesions due to LTX-315` s documented ability to induce cancer-specific immune responses

Current treatment options are invasive

*Before*



*After*



*After*



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

# Commercially validated through partnering with Verrica Pharmaceuticals

i

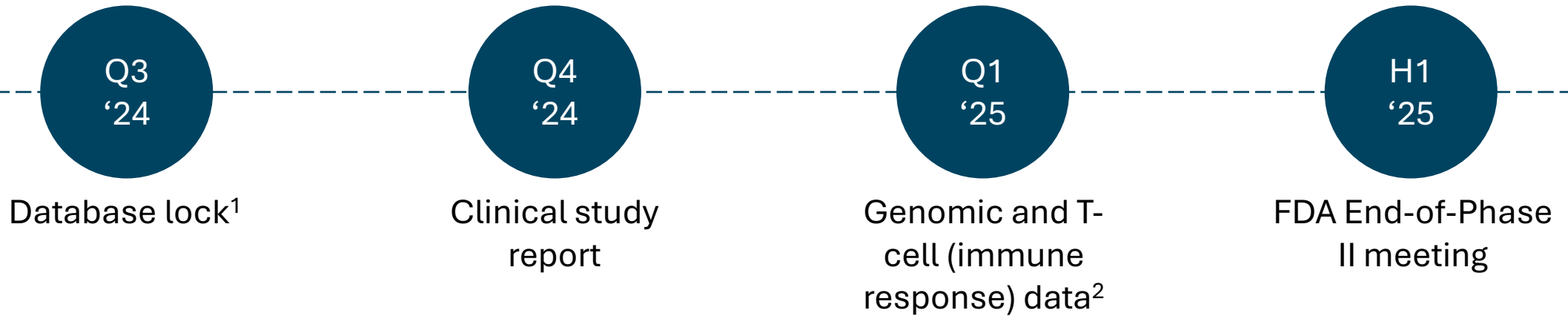
## THE PARTNERSHIP

- Verrica Pharmaceuticals has a **worldwide license to develop and commercialize LTX-315 for dermatological oncology indications\*** from 2020.
- **Phase II trial in basal cell carcinoma with LTX-315** (named VP-315 in Verrica's study)
- Under the license agreement, **Lytix may receive aggregate payments of up to USD 110 million upon achieving certain clinical, regulatory, and sales milestones** and tiered royalty payments in the double-digit teens.

## About Verrica Pharmaceuticals

- US-based (Nasdaq: VRCA) dermatology therapeutics company developing medications for skin diseases requiring medical interventions
- With a strong focus on addressing unmet needs in dermatology, Verrica is making significant strides in improving patient care and advancing skin health.
- In 2023, Verrica's lead product, YCANTH™ (cantharidin), became the first treatment approved by the FDA to treat pediatric and adult patients with molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6m in the US, primarily children

# Verrica Pharmaceuticals aims to complete the Phase II study with a strategy of continuing the development of VP-315



# Clinical/Operational update

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- 4 LTX-401

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

- LTX-315 and anti PD-1 inhibitor pembrolizumab are being tested in late-stage melanoma 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

## ! Positive interim data from 20 evaluable patients

- Disease control in 40% of the patients with Stabilization of the disease up to 17 months
- Two patients achieving a durable partial response
- Impressive effects in both injected and non-injected lesions

Complete regression in injected tumor lesions



Before Treatment

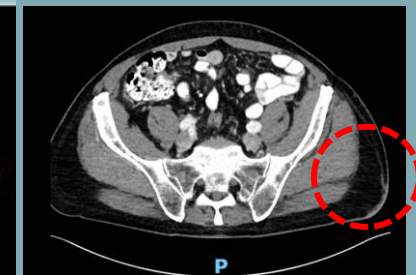


Day 43

Non-injected tumor lesion almost eradicated



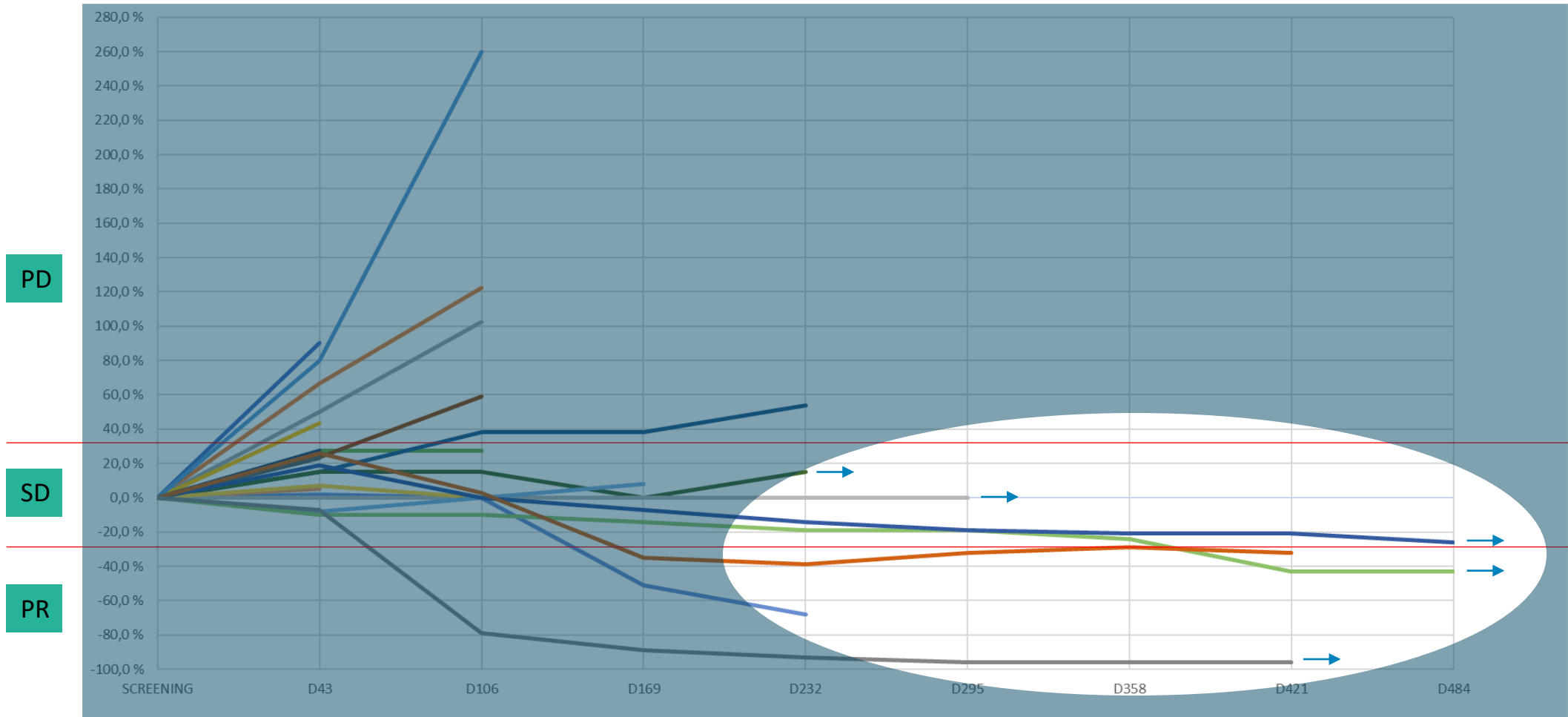
Before Treatment-  
28mm



Day 421 – 1mm

# 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



# Clinical/Operational update

- 1 Phase II study: Basal cell carcinoma (Verrica Pharmaceuticals)
- 2 Phase II study: Late stage melanoma (ATLAS-IT-05)
- 3 **New phase II study: Early stage melanoma (NeoLIPA)**
- 4 LTX-401

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

Study start – Q3 2024

## Study details

- Encouraging results from Phase II studies in BCC and 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 Oslo University Hospital Radiumhospitalet - Low cost for Lytix
- Quick read-out with pathologic complete response (pCR) rate as primary endpoint
- Time to relapse and overall survival – secondary endpoints

## 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



# Clinical/Operational update

- 1 Phase II study: Basal cell carcinoma (Verrica Pharmaceuticals)
- 2 Phase II study: Late stage melanoma (ATLAS-IT-05)
- 3 New phase II study: Early stage melanoma (NeoLIPA)
- 4 **LTX-401**

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

## Small oncolytic molecule in development

- Increased commercial interest with a clinical validation of our lead candidate LTX-315
- Meeting with regulatory authorities in Europe, to seek advice on how to bring this novel and potentially transformative LTX-401 formulation to patient is planned



## 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



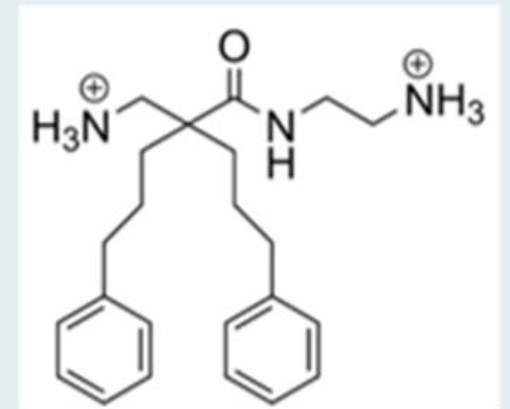
## New superior formulation

Improved anti-cancer effects and potential to extend patent life for LTX-401



## Synergy effects

Demonstrates strong synergy with checkpoint inhibitors

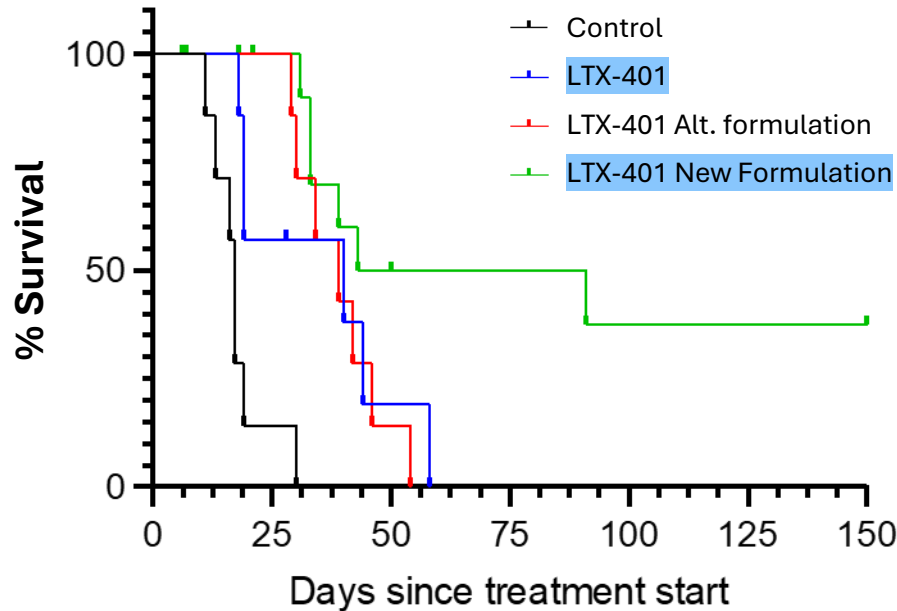


LTX-401

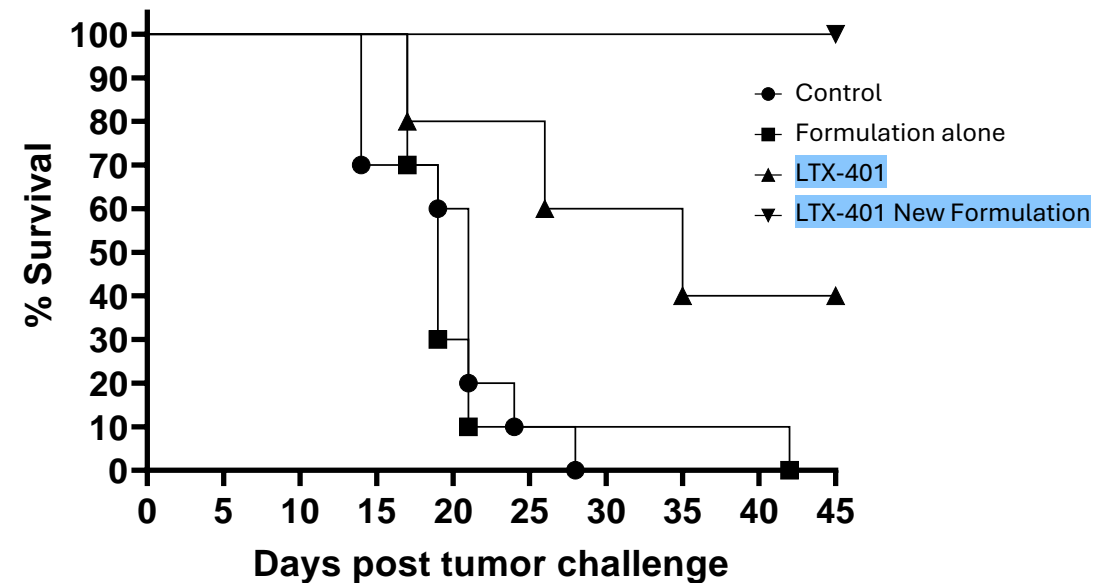
# Superior efficacy with LTX-401 in new formulation compared to “old” LTX-401 in «hard to treat» cancer models

Improved survival with LTX-401 new formulation

100% survival with LTX-401 new formulation



Model: K7M2 Osteosarcoma model



Model: B16F1 Melanoma model



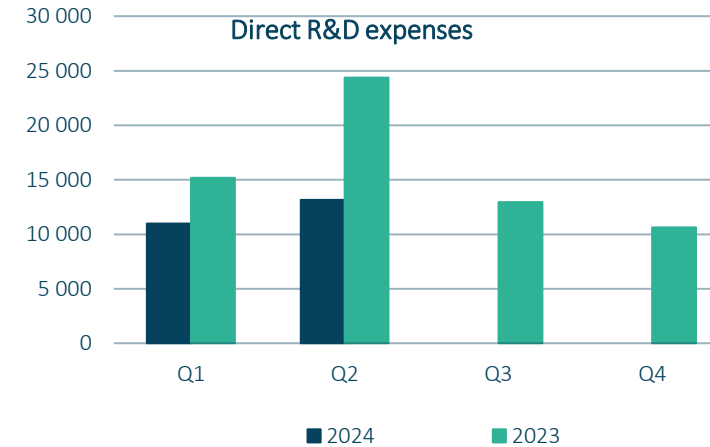
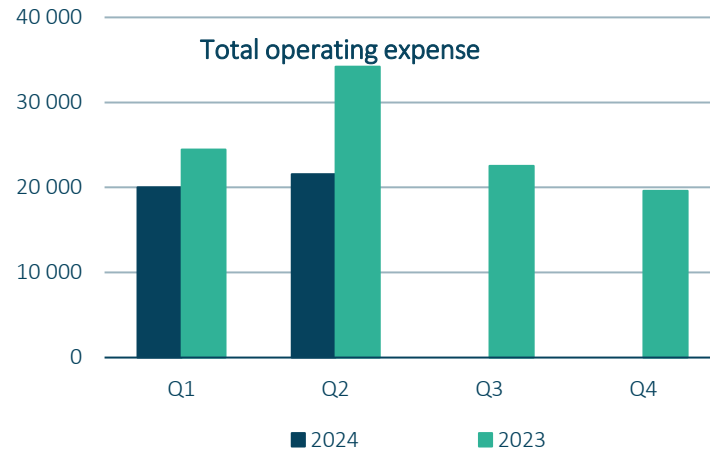
# Key figures

# Key figures – profit and loss

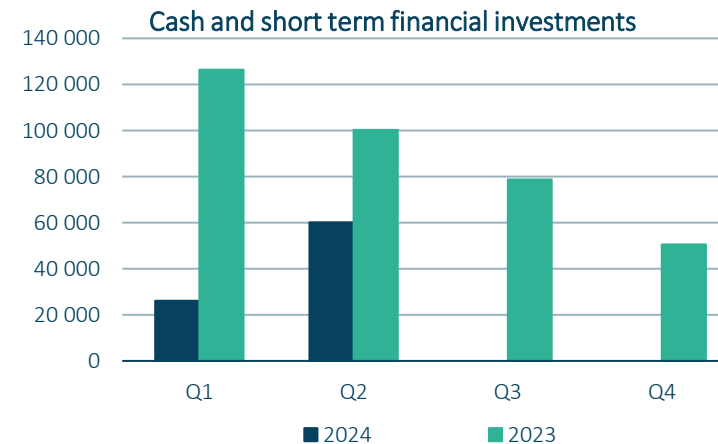
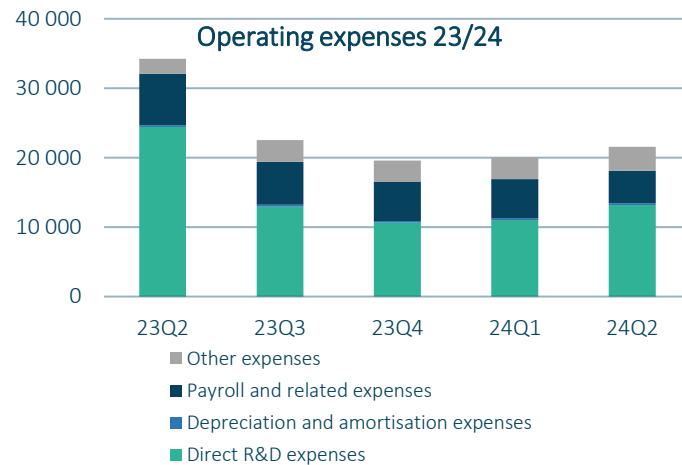
<i>Amounts in NOK thousands</i>	<i>Unaudited</i>	<i>Unaudited</i>	
	Q2 2024	Q2 2023	FY 2023
Total operating income	-	74	3,991
Total operating expenses	(21,540)	(34,209)	(100,776)
<b>Loss from operations</b>	<b>(21,540)</b>	<b>(34,135)</b>	<b>(96,785)</b>
<b>Loss for the period</b>	<b>(21,435)</b>	<b>(31,427)</b>	<b>(87,897)</b>

- Total operating expenses for the three months ended 30 June 2024 amounted to NOK 21.5 million compared to NOK 34.4 million for the same period in 2023.
  - The decrease in operating expenses is mainly a result of lower activity in the ATLAS-IT-05 as it is through its most active phase. Several patients are still on the trial and continue to receive treatment. In addition, Lytix has implemented a cost-saving initiative aimed at enhancing its operations and organizational efficiency to prioritize the Company’s clinical development efforts.

# Maintaining strict cost control while prioritizing clinical activities



- Operating expenses/Direct R&D expenses for Q1 2024 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.





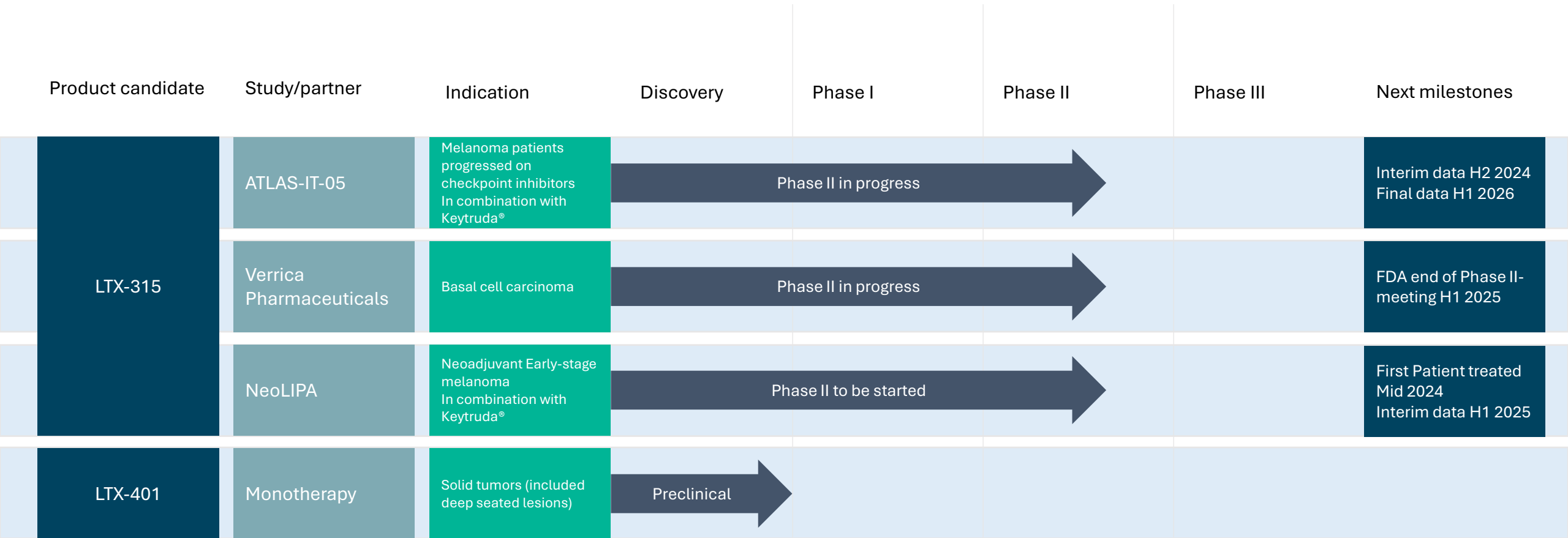
# Key figures – balance sheet

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2024	<i>Unaudited</i> 30.06.2023	31.12.2023
<b>Assets</b>			
Property, plant and equipment	76	144	110
Right-of-use assets	2,998	888	438
Trade and other receivables	14,410	5,959	12,777
Short-term financial investments	-	41,961	23,183
Cash and cash equivalents	60,181	58,257	27,365
<b>Total assets</b>	<b>77,665</b>	<b>107,209</b>	<b>63,874</b>
<b>Shareholder's equity and liabilities</b>			
Total equity	59,221	86,037	51,319
Total liabilities	18,444	21,166	12,555
<b>Total equity and liabilities</b>	<b>77,665</b>	<b>107,209</b>	<b>63,874</b>

- At the end of the period, cash plus short-term financial investments were NOK 60.2 million, compared to NOK 50.5 million as of 31 December 2023 and NOK 100.2 million as of June 30, 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

# Clinical roadmap: Exiting times ahead



# Executing on our strategy – upcoming events

## ● Verrica - BCC

- Clinical Study Report (**Q4 2024**)
- Analysis of Immune responses (**Q1 2025**)
- FDA- End of Phase 2 meeting (**H1 2025**)

## ● Lytix Clinical Development

- Initiation of NeoLIPA study (**Q3 2024**)
- Interim results from NeoLIPA (**2025**)
- LTX-401 meeting with regulatory authorities (**Q1 2025**)
- Finalization of ATLAS-IT study (**H2 2025**)

## ● Lytix – Business Development

- Continue to aim for late-stage development and commercialization through partnerships



# Q&A

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# Interim Financial Statements

# Condensed interim statement of comprehensive income

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2024	<i>Unaudited</i> Q2 2023	<i>Unaudited</i> H1 2024	<i>Unaudited</i> H2 2023	FY 2023
Revenue	-	74	10,526	74	3,991
<b>Total operating income</b>	<b>-</b>	<b>74</b>	<b>-</b>	<b>74</b>	<b>3,991</b>
Payroll and related expenses	(4,715)	(7,417)	(10,378)	(12,557)	(24,344)
Depreciation and amortization expenses	(230)	(239)	(472)	(478)	(962)
Direct R&D expenses	(13,170)	(24,389)	(33,356)	(39,572)	(63,167)
Other expenses	(3,424)	(2,165)	(6,545)	(6,050)	(12,303)
<b>Total operating expenses</b>	<b>(21,540)</b>	<b>(34,209)</b>	<b>(50,751)</b>	<b>(58,657)</b>	<b>(100,776)</b>
<b>Loss from operations</b>	<b>(21,540)</b>	<b>(34,135)</b>	<b>(40,225)</b>	<b>(58,584)</b>	<b>(96,785)</b>
<b>Net financial items</b>	<b>105</b>	<b>2,709</b>	<b>608</b>	<b>7,489</b>	<b>8,887</b>
<b>Loss before tax</b>	<b>(21,435)</b>	<b>(31,427)</b>	<b>(39,617)</b>	<b>(51,095)</b>	<b>(87,897)</b>
Tax expense	-	-	-	-	-
<b>Loss for the period</b>	<b>(21,435)</b>	<b>(31,427)</b>	<b>(39,617)</b>	<b>(51,095)</b>	<b>(87,897)</b>

# Condensed interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.06.2024	<i>Unaudited</i> 30.06.2023	31.12.2023
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	76	144	110
Right-of-use assets	2,998	888	438
<b>Total non-current assets</b>	<b>3,074</b>	<b>1,032</b>	<b>548</b>
<b>Current assets</b>			
Trade and other receivables	14,410	5,959	12,777
Short-term financial investments	-	41,961	23,183
Cash and cash equivalents	60,181	58,257	27,365
<b>Total current assets</b>	<b>74,591</b>	<b>106,177</b>	<b>63,326</b>
<b>Total assets</b>	<b>77,665</b>	<b>107,209</b>	<b>63,874</b>
<b>Shareholder's equity and liabilities</b>			
<b>Issued capital and reserves</b>			
Share capital	4,961	4,007	4,007
Share premium reserve	54,260	82,037	47,312
<b>Total equity</b>	<b>59,221</b>	<b>86,043</b>	<b>51,319</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities	2,266	41	41
<b>Total current liabilities</b>	<b>2,266</b>		<b>41</b>
<b>Current liabilities</b>			
Trade payables	4,196	5,889	3,572
Other current liabilities	11,251	14,310	8,492
Lease liabilities	731	926	451
<b>Total current liabilities</b>	<b>16,178</b>	<b>21,125</b>	<b>12,514</b>
<b>Total liabilities</b>	<b>18,444</b>	<b>21,166</b>	<b>12,555</b>
<b>Total equity and liabilities</b>	<b>77,665</b>	<b>107,209</b>	<b>63,874</b>



# Condensed Interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q2 2024	<i>Unaudited</i> Q2 2023	<i>Unaudited</i> H1 2024	<i>Unaudited</i> H12023	FY 2023
<b>Cash flows from operating activities</b>					
Loss for the period	(21,435)	(31,427)	(39,617)	(51,095)	(87,897)
<b>Adjustments for:</b>					
Depreciation of property, plant and equipment	17	14	34	28	62
Depreciation of right-of-use assets	213	225	438	450	900
Interest income/(expense), net	(182)	(660)	(363)	(1,342)	(2,348)
Share-based payment expense	(105)	1,086	529	2,104	4,183
Increased/decreased in trade and other receivables	4,430	1,114	(1,633)	776	(6,042)
Increased/decreased in trade and other payables	4,147	3,101	3,383	3,308	(4,828)
<b>Cash generated from operations</b>	<b>(12,914)</b>	<b>(26,546)</b>	<b>(37,229)</b>	<b>(45,769)</b>	<b>(95,969)</b>
Income tax paid	-	-	-	-	-
<b>Net cash flows from operations</b>	<b>(12,914)</b>	<b>(26,546)</b>	<b>(37,229)</b>	<b>(47,769)</b>	<b>(95,969)</b>
<b>Investing activities</b>					
Investments in tangible assets	-	(32)	-	(49)	(49)
Interest received	182	660	363	1,344	2,351
Investment in other short-term investments	13,511	9,352	23,183	8645	27,423
<b>Net cash from/(used in) investing activities</b>	<b>13,693</b>	<b>9,980</b>	<b>23,548</b>	<b>9,940</b>	<b>29,725</b>
<b>Financing activities</b>					
Interest paid	-	-	-	(2)	(3)
Payment of principal portion of lease liabilities	(249)	(233)	(491)	(464)	(940)
Proceeds from share issue	50,000	-	50,000	-	-
Transaction cost	(3,011)	-	(3,011)	-	-
<b>Net cash from/(used in) financing activities</b>	<b>46,740</b>	<b>(23)</b>	<b>46,498</b>	<b>(466)</b>	<b>(943)</b>
Net increase/(decrease) in cash and cash equivalents	47,519	(16,800)	32,816	(36,295)	(67,187)
Cash and cash equivalents at the beginning of the period	12,661	75,057	27,365	94,552	94,552
<b>Cash and cash equivalents at the end of the period</b>	<b>60,181</b>	<b>58,257</b>	<b>60,181</b>	<b>58,257</b>	<b>27,365</b>