

# Developing the future of cancer treatment

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

## Q3 2024 results presentation

19.11.2024



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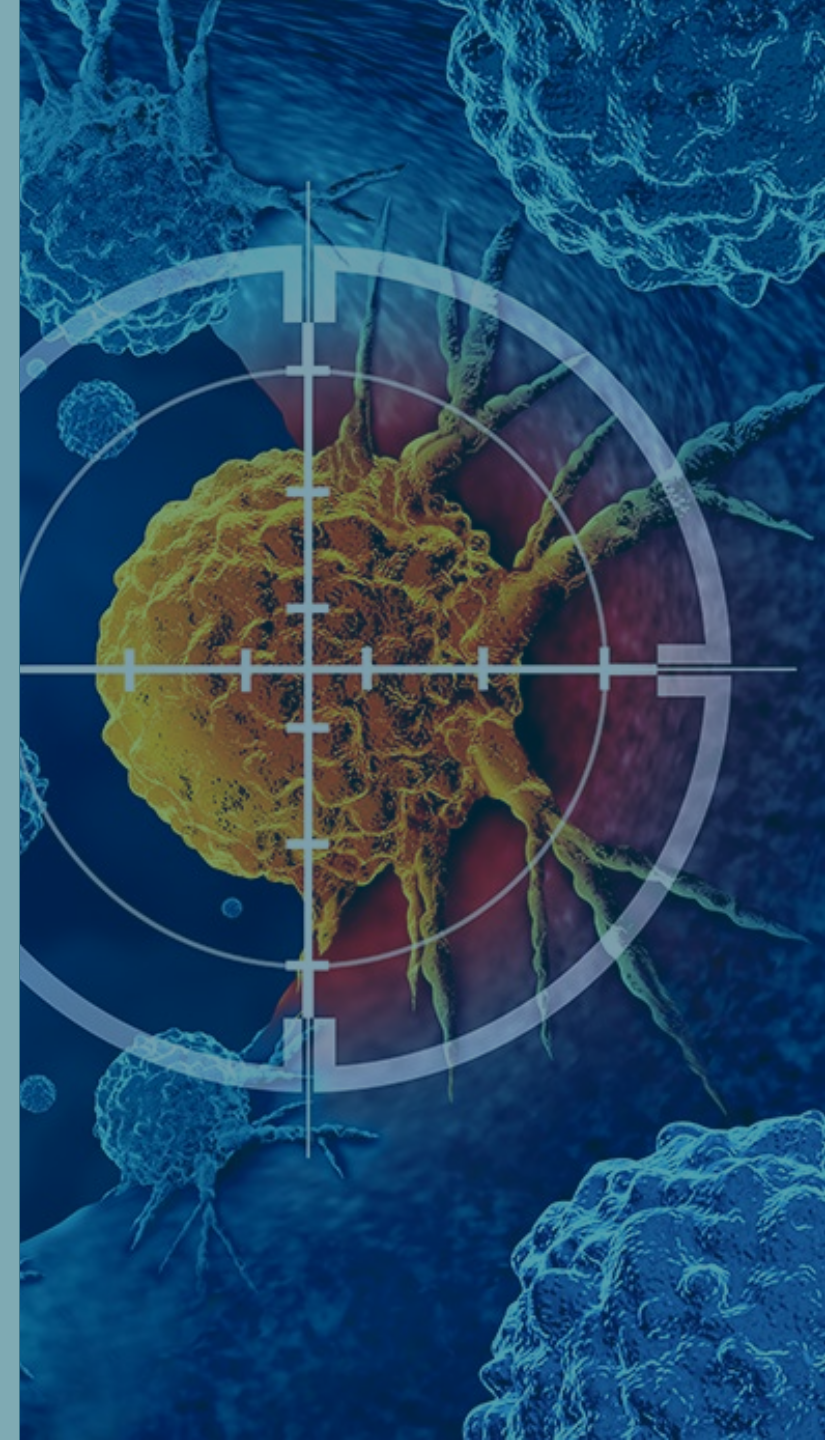
## **Øystein Rekdal, CEO**

Co-founder of Lytix Biopharma, Dr. Rekdal has served as CEO twice, most recently since 2019. With a PhD in tumor immunology, his expertise in anticancer molecules from host defense peptides underpins Lytix's technology. He is a regular speaker at international oncology conferences and was instrumental for the licensing deal with Verrica Pharmaceuticals.



## **Gjest Breistein, CFO**

Mr. Breistein, a state-authorized public accountant, joined Lytix in 2017 after advising companies at PwC on capital market transactions. He holds Master's degrees in Applied Economics and Finance (Copenhagen Business School) and Professional Accountancy (BI Norwegian School of Management).



# Company introduction

# Developing the future of cancer treatment



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

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

Positive phase II results in basal cell carcinoma and melanoma

Licensing deal with Nasdaq-listed Verrica Pharmaceuticals Inc.

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



# Lytix is addressing the two major shortcomings in current cancer immunotherapy

CHALLENGE

Cancer cells vary from one another in solid tumors (tumor heterogeneity) leading to therapy resistance

SOLUTION

**Lytix** technology able to kill all cancer cell variants in treated tumors and activate a broad immune response

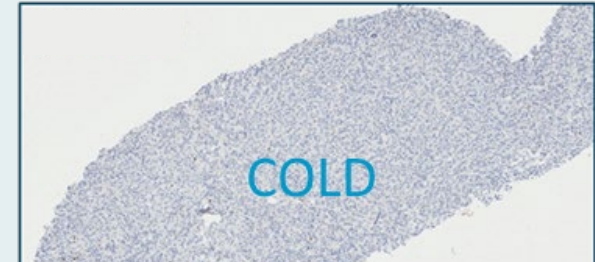
CHALLENGE

Majority of cancer patients have “**cold**” tumors and therefore do not respond to current immunotherapy

SOLUTION

**Lytix technology** converts «**cold**» tumors to «**hot**» tumors that respond better to immune therapy

Tumor before treatment



No immune cells – Non-responsive

Tumor after treatment



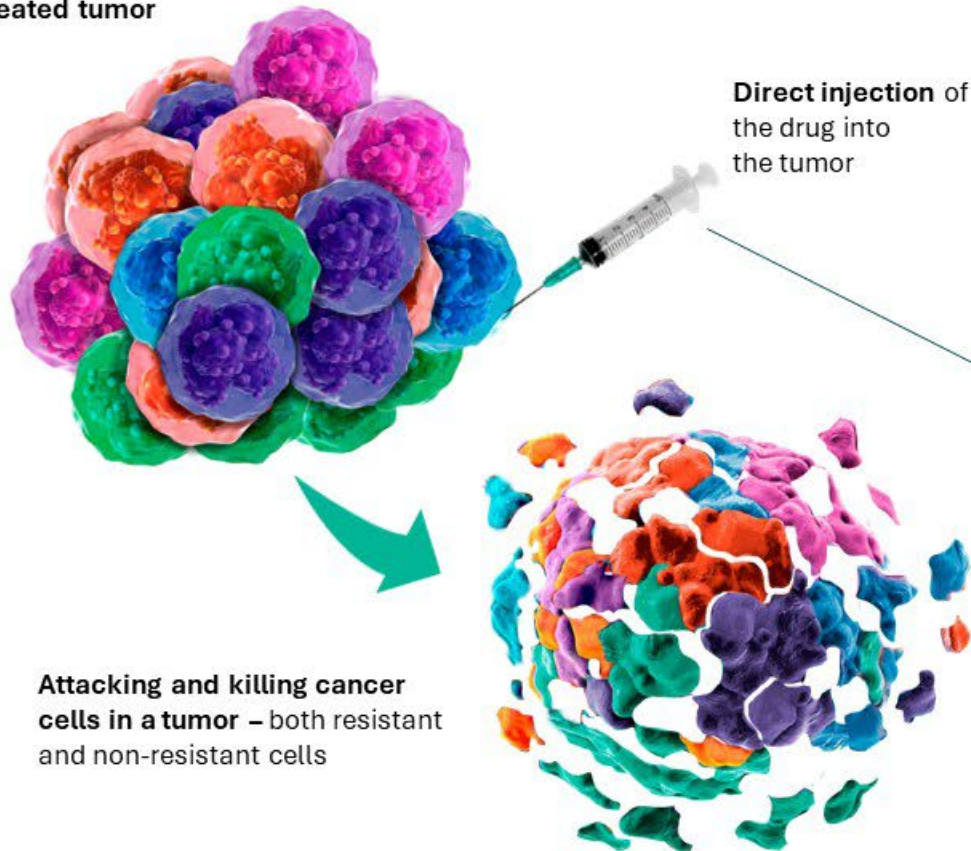
Many immune cells – Responsive

# Lytix's solution works through two phases; killing tumors locally and activating a systemic broad immune response

1

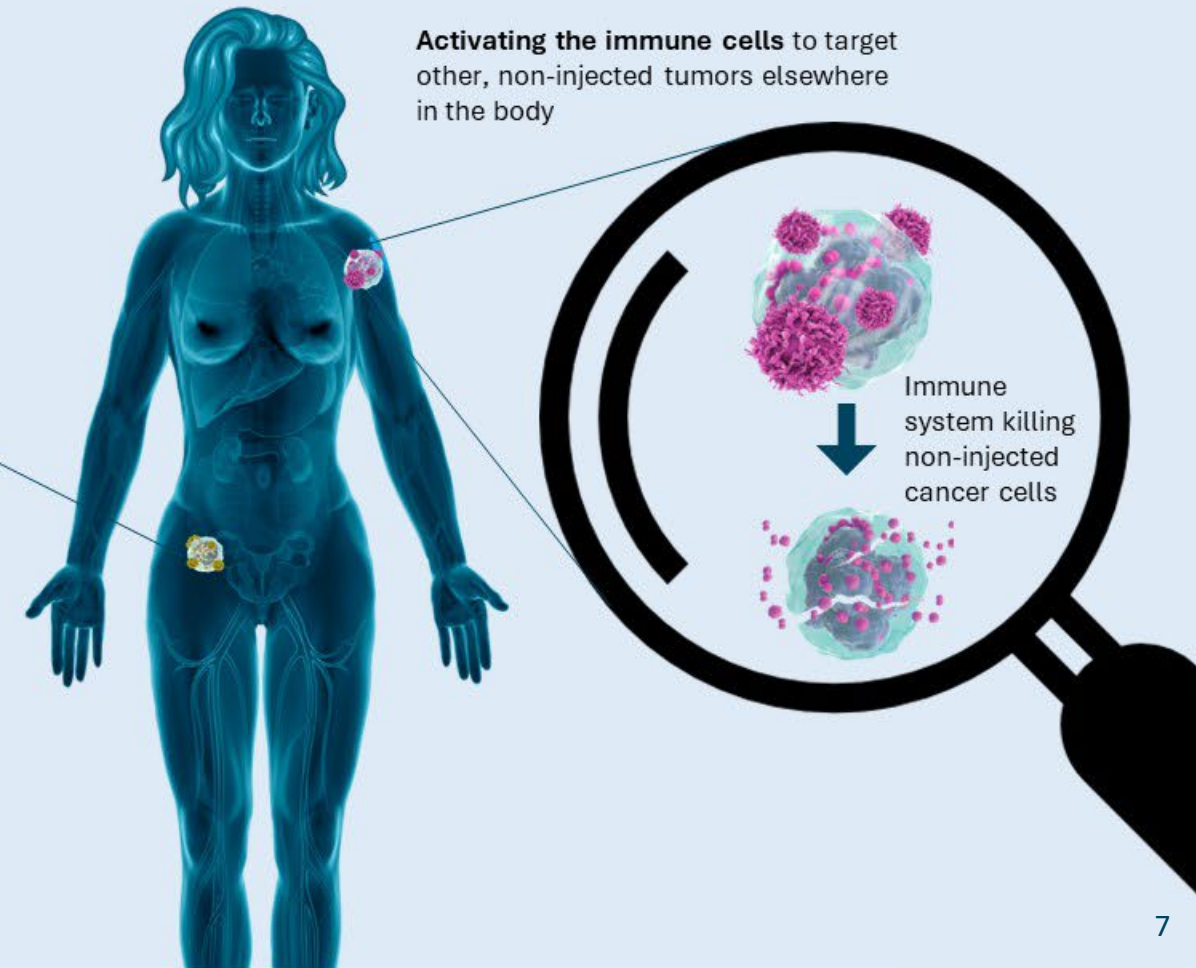
Directly injecting the cancer drug into the tumor

Untreated tumor



2

Broad activation of immune cells to target remaining tumors



# Clinical progress

Product candidate	Study/partner	Indication	Discovery	Phase I	Phase II	Phase III
LTX-315	ATLAS-IT-05	Melanoma patients progressed on checkpoint inhibitors In combination with Keytruda®	Phase II			
	Verrica Pharmaceuticals	Basal cell carcinoma	Phase II			Phase III TBD H1 '25
	NeoLIPA	Neoadjuvant Early-stage melanoma In combination with Keytruda®	Phase II			
LTX-401	Monotherapy	Solid tumors (included deep seated lesions)	Preclinical	In preparation		



# Q3 Highlights

# Highlights for the third quarter (I/II)

- And post quarter end

## **Very promising top-line Results achieved in Phase II study in basal cell carcinoma (BCC)**

- An 86% overall reduction in tumor size was observed, with complete clearance achieved in 51% of patients.
- LTX-315 demonstrates the potential as a first-line treatment option for BCC.
- The positive top-line results were presented at the 2024 Fall Clinical Dermatology Conference (October 24-27<sup>th</sup>).

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

- 40% of patients experienced disease control, with stabilization lasting up to 20 months.
- Sustained partial response obtained in two patients.

## **The first patient has been treated in the new phase II NeoLIPA study**

- This study examines the impact of Lytix's lead drug candidate, LTX-315, in early-stage melanoma patients.
- Melanoma, the most severe type of skin cancer with increasing global incidence, is projected to reach a global market size of USD 11 billion by 2030<sup>1</sup>.

# Highlights for the third quarter (II/II)

- And post quarter end

**The new superior formulation of LTX-401 may represent a significant advancement for Lytix's second lead candidate.**

- This new formulation of LTX-401 has demonstrated substantially improved anticancer effects, with the added benefit of extending patent life.
- Lytix is preparing to seek scientific advice from European regulatory authorities to strategically advance this formulation into clinical development.

## **Financials**

- Cash at the end of the period amounted to NOK 43.5 million. The cash runway is expected to take Lytix into 2025.



# Clinical/Operational update

# 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



Basal Cell Carcinoma (BCC) represent a large and growing market **expected to grow to USD 11.5bn in 2028**



BCCs are typically found in skin more exposed to the sun, **95% of the patients are treated with surgery**



Diagnosed BCC patients have a **35% chance of new lesion** within 3 years, and **50% within 5 years<sup>(1,2)</sup>**



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



A licensing deal in place with US-based Verrica Pharmaceuticals with global rights for skin cancer (except mMelanoma and mMerkel cell carcinoma), **potentially up to USD 110m + royalties on future sale**



# 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 histological clearance (51%)**
    - No need for surgery
  - **Partial clearance (49%)**
    - Significant reduction in size of lesion that did not achieve complete clearance (71%)
    - Significant reduction in size of target surgical area and any potential surgical scar
- Immune and genomic data is being generated to confirm previous evidence from Lytix studies of LTX-315's 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

## RECENT DEVELOPMENTS

- **The partnership**
  - LTX-315 (VP-315) remains a core asset for both Verrica and Lytix with positive phase II results in BCC and melanoma, respectively for each company.
  - Lytix remains fully committed to support Verrica in driving efficient development and any future commercialization efforts for LTX-315 for basal cell carcinoma (BCC)
- **Verrica has implemented several actions to improve profitability:**
  - **New leadership:**
    - Jayson Rieger, PhD, MBA, new CEO of Verrica.
    - He brings 20 years of experience across business development, operations, drug discovery, and product development in life sciences.
    - Dr. Rieger has served as a member of Lytix's Board of Directors since 2021 and is well-positioned with knowledge about LTX-315 to help drive the advancement of LTX-315 in basal cell carcinoma.
  - **Financial Support:** Jefferies, a leading global investment bank, have been engaged by Verrica to explore funding solutions.

## 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, in addition to sales milestones and tiered royalty payments in the double-digit teens.

# 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 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 20 months
- Two patients achieving a durable partial response
- Impressive effects in both injected and non-injected lesions
- Three patients still receiving study treatment (pembrolizumab)

Study:  
ATLAS-IT-05  
Ongoing



Complete regression in injected tumors



Before Treatment



Day 43

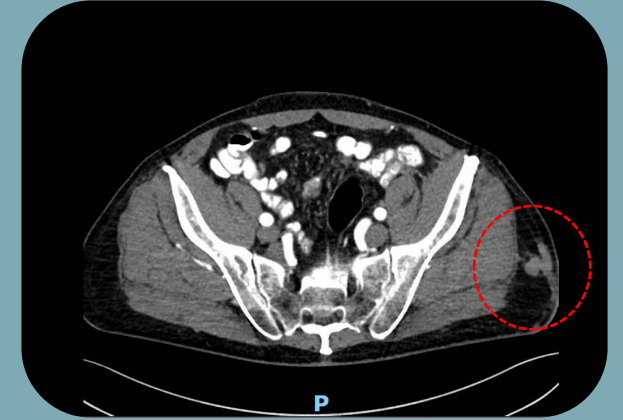
# Impressive tumor shrinkage in patient with partial response

- Prior treatment with nivolumab (PD-1 inhibitor) and BRAF/MEK inhibitors
- **Complete response** in all 4 LTX-315 injected lesions
- **Complete response** in a non-injected lesion
- Duration of response of >1,5 years and patient still on study treatment (pembrolizumab)

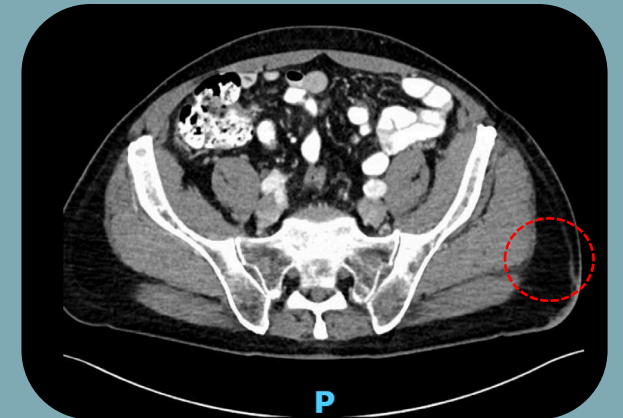


Complete regression in non-injected tumors

Baseline scan –  
**28 mm** lesion in  
left gluteus  
muscle



Day 547 scan –  
**no** lesion in left  
gluteus muscle



# Clinical/Operational update

- 1 Phase II study: Basal cell carcinoma (Verrica Pharmaceuticals)
- 2 Phase II study: Late stage melanoma (ATLAS-IT-05)
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# NeoLIPA – Moving to early-stage melanoma

## Study Overview

- Evaluate LTX-315 in combination with pembrolizumab (PD-1 inhibitor), administered prior to surgery, to reduce relapse risk in patients with resectable melanoma
- Investigator driven study led by Dr. Henrik Jespersen, Head of Melanoma at Oslo University Hospital, ensuring low costs for Lytix
- First patient treated with LTX-315 in November '24

## Study design and Expectations

- Early-stage melanoma patients with a stronger immune system
- Quick read-out with effect on treated tumor before surgery as the primary endpoint; secondary endpoints include time to relapse and overall survival
- Enrollment of approximately 27 patients, with interim results expected in H2 2025 and final top-line results anticipated in H1 2026

## Commercial Rationale

- Early-stage melanoma patients have less advanced disease and a more robust immune system, increasing the likelihood of response to Lytix's immunotherapy
- This patient population is larger, translating into significant commercial potential





# Clinical/Operational update

- 1 Phase II study: Basal cell carcinoma (Verrica Pharmaceuticals)
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# 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 planned Q4 2024



### 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



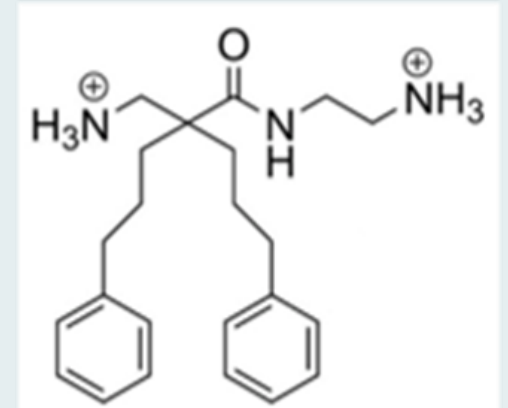
### New superior formulation

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



### Synergy effects

Demonstrates strong synergy with checkpoint inhibitors



LTX-401

# Financials and outlook

# Key figures – profit and loss

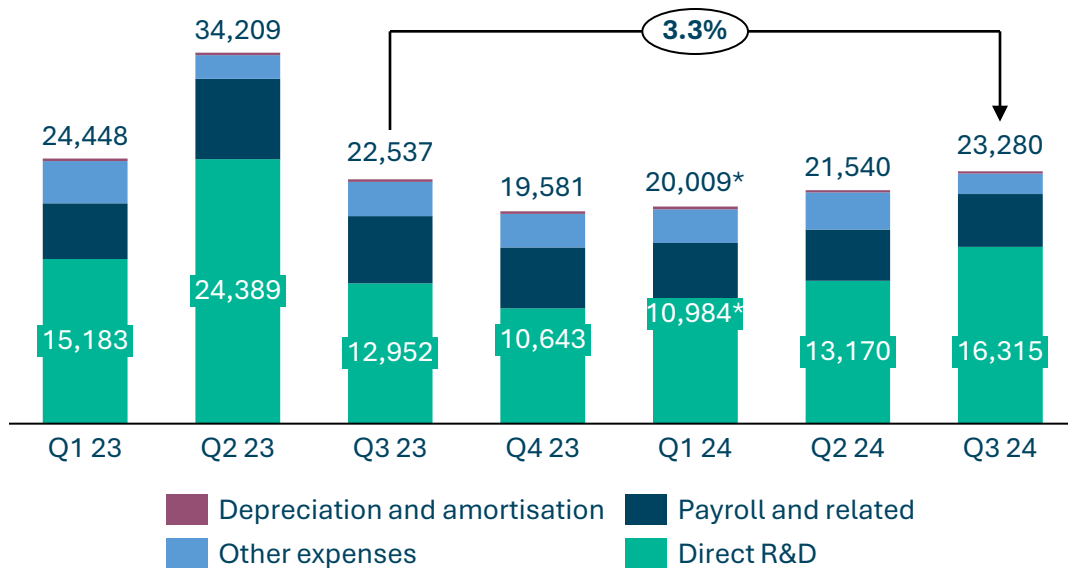
Amounts in NOK '000	Q3 2024	Q3 2023	FY 2023
Total operating income	231	3,917	3,991
Total operating expenses	(23,280)	(22,537)	(100,776)
Loss from operations	(23,049)	(18,620)	(96,785)
Loss for the period	(22,738)	(18,237)	(87,897)

- Operating income for the period primarily arises from stability testing of LTX-315 performed on behalf of Verrica
- The rise in total operating expenses is mainly due to increased direct R&D costs. The ATLAS-IT-05 study maintains high activity as patient treatments continue across multiple hospitals. Additionally, preparations for a Phase I trial of the newly formulated LTX-401 are underway

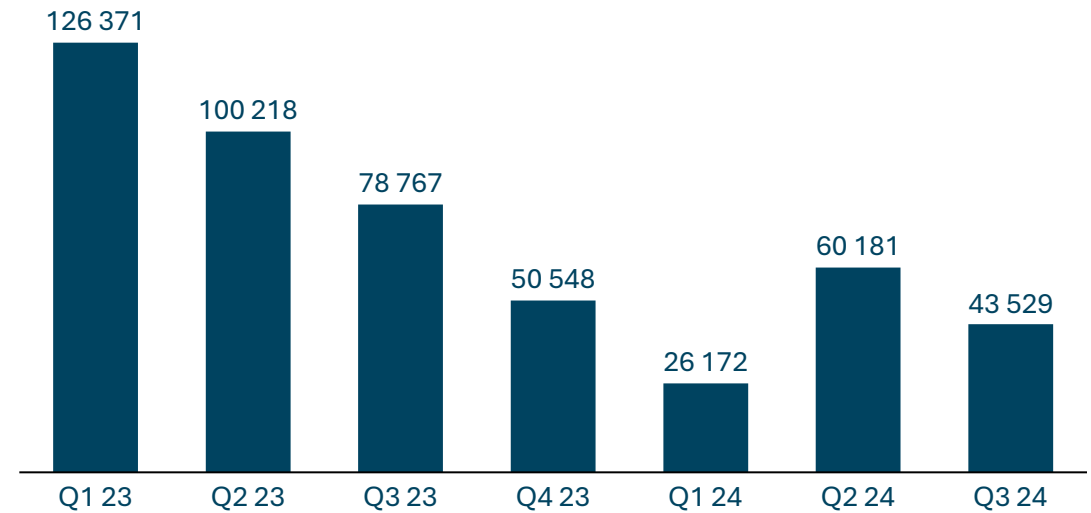
# Financial costs and cash position

*Stable cost development despite significant R&D activities*

## Total operating expenses



## Cash and short-term financial investments



- Direct R&D expenses rose by NOK 3.4 million compared to Q3 2023. The ATLAS-IT-05 trial is currently at a stage where a few patients remain in the study, while we are concurrently closing down sites and activities that are no longer essential. This approach aims to efficiently conclude the study.
- Payroll and related expenses decreased by NOK 1.3 million compared to Q3 2023 while other expenses decreased by NOK 1.3 million and is a result of the cost-saving initiative aimed at enhancing its operations and organizational efficiency to prioritize the Company's clinical development efforts.



# Key figures – balance sheet

Amounts in NOK '000	30.09.2024	30.09.2023	31.12.2023
<b>Assets</b>			
Property, plant and equipment	59	127	110
Right-of-use assets	2,793	663	438
Trade and other receivables	9,902	1,252	12,777
Short-term financial investments	-	32,609	23,183
Cash and cash equivalents	43,529	46,158	27,365
<b>Total assets</b>	<b>56,283</b>	<b>80,810</b>	<b>63,874</b>
<b>Shareholder's equity and liabilities</b>			
Total equity	36,830	68,884	51,319
Total liabilities	19,453	11,925	12,555
<b>Total equity and liabilities</b>	<b>56,283</b>	<b>80,810</b>	<b>63,874</b>

- At the end of the period, cash plus short-term financial investments were NOK 43.5 million, compared to NOK 50.5 million as of 31 December 2023 and NOK 78.8 million as of September 30, 2023.
- In last quarter, Lytix raised NOK 50 million in a share offering primarily directed towards existing shareholders. The cash runway is expected to take Lytix into Q2 2025.

# 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

- Interim results from NeoLIPA (**2025**)
- LTX-401 meeting with regulatory authorities (**Q4 2024**)
- Finalization of ATLAS-IT-05 study (**H2 2025**)

## ● Lytix Business Development

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



# Lytix Biopharma's roadmap to create shareholder value



## Non-metastatic skin cancer

LTX-315: Clear path towards commercialization, demonstrated through licensing with Verrica Pharmaceuticals

Milestone payments and royalties secured for future revenue streams

## Metastatic skin cancer

LTX-315: Phase II results in NeoLIPA  
Interim data H2 2025  
Final results H1 2026

Start dialog with mid-size/big pharma  
H2-2025 - 2026

## Deep seated cancer

LTX-401: Phase I study in deep seated tumors (2026)  
Technology partly validated by LTX-315

Start dialog with mis-size/big pharma  
H2 2025 - 2026

# Q&A

# Interim financial statements

# Condensed interim statement of profit and loss

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q3 2024	<i>Unaudited</i> Q3 2023	<i>Unaudited</i> YTD 2024	<i>Unaudited</i> YTD 2023	FY 2023
Revenue	231	3,917	10,757	3,991	3,991
Other operating income	-	-	-	-	-
<b>Total operating income</b>	<b>231</b>	<b>3,917</b>	<b>10,757</b>	<b>3,991</b>	<b>3,991</b>
Payroll and related expenses	(4,859)	(6,192)	(15,237)	(18,749)	(24,344)
Depreciation and amortization expenses	(221)	(242)	(693)	(720)	(962)
Direct R&D expenses	(16,315)	(12,952)	(49,671)	(52,524)	(63,167)
Other expenses	(1,884)	(3,151)	(8,429)	(9,201)	(12,303)
<b>Total operating expenses</b>	<b>(23,280)</b>	<b>(22,537)</b>	<b>(74,031)</b>	<b>(81,195)</b>	<b>(100,776)</b>
<b>Loss from operations</b>	<b>(23,049)</b>	<b>(18,620)</b>	<b>(63,274)</b>	<b>(77,203)</b>	<b>(96,785)</b>
Net financial items	311	383	919	7,872	8,887
<b>Loss before tax</b>	<b>(22,738)</b>	<b>(18,237)</b>	<b>(62,355)</b>	<b>(69,331)</b>	<b>(87,897)</b>
Tax expense	-	-	-	-	-
<b>Loss for the period</b>	<b>(22,738)</b>	<b>(18,237)</b>	<b>(62,355)</b>	<b>(69,331)</b>	<b>(87,897)</b>



# Condensed interim statement of financial position

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> 30.09.2024	<i>Unaudited</i> 30.09.2023	31.12.2023
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	59	127	110
Right-of-use assets	2,793	663	438
<b>Total non-current assets</b>	<b>2,853</b>	<b>790</b>	<b>548</b>
<b>Current assets</b>			
Trade and other receivables	9,902	1,252	12,777
Short-term financial investments	-	32,609	23,183
Cash and cash equivalents	43,529	46,158	27,365
<b>Total current assets</b>	<b>53,431</b>	<b>80,019</b>	<b>63,326</b>
<b>Total assets</b>	<b>56,283</b>	<b>80,810</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	31,869	64,878	47,312
<b>Total equity</b>	<b>36,830</b>	<b>68,884</b>	<b>51,319</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Lease liabilities	2,074	41	41
<b>Total current liabilities</b>	<b>2,074</b>	<b>41</b>	<b>41</b>
<b>Current liabilities</b>			
Trade payables	2,443	22	3,572
Other current liabilities	14,190	11,173	8,492
Lease liabilities	746	690	451
<b>Total current liabilities</b>	<b>17,379</b>	<b>11,885</b>	<b>12,514</b>
<b>Total liabilities</b>	<b>19,453</b>	<b>11,925</b>	<b>12,555</b>
<b>Total equity and liabilities</b>	<b>56,283</b>	<b>80,810</b>	<b>63,874</b>

# Condensed interim statement of cash flows

<i>Amounts in NOK thousands</i>	<i>Unaudited</i> Q3 2024	<i>Unaudited</i> Q3 2023	<i>Unaudited</i> YTD 2024	<i>Unaudited</i> YTD 2023	FY 2023
<b>Cash flows from operating activities</b>					
Loss for the period	(22,738)	(18,236)	(62,355)	(69,331)	(87,897)
<b>Adjustments for:</b>					
Depreciation of property, plant and equipment	17	17	51	45	62
Depreciation of right-of-use assets	204	225	643	675	900
Interest income/(expense), net	(70)	(573)	(434)	(1,915)	(2,348)
Share-based payment expense	347	1,078	877	3,182	4,183
Increased/decreased in trade and other receivables	4,508	4,707	2,875	5,483	(6,042)
Increased/decreased in trade and other payables	1,187	(9,004)	4,569	(5,696)	(4,828)
<b>Cash generated from operations</b>	<b>(16,545)</b>	<b>(21,787)</b>	<b>(53,774)</b>	<b>(67,557)</b>	<b>(95,969)</b>
Income tax paid	-	-	-	-	-
<b>Net cash flows from operations</b>	<b>(16,545)</b>	<b>(21,787)</b>	<b>(53,774)</b>	<b>(67,557)</b>	<b>(95,969)</b>
<b>Investing activities</b>					
Investments in tangible assets	-	-	-	(49)	(49)
Interest received	72	573	435	1,917	2,315
Increase/decrease in other investments	-	9,353	23,183	17,998	27,423
<b>Net cash from/(used in) investing activities</b>	<b>72</b>	<b>9,926</b>	<b>23,619</b>	<b>19,866</b>	<b>(29,725)</b>
<b>Financing activities</b>					
Interest paid	(2)	-	(2)	(2)	(3)
Proceeds from share issue	-	-	50,000	-	-
Transaction cost	-	-	(3,011)	-	-
Payment of principal portion of lease liabilities	(177)	(236)	(668)	(700)	(940)
<b>Net cash from/(used in) financing activities</b>	<b>(179)</b>	<b>(236)</b>	<b>46,319</b>	<b>(702)</b>	<b>(943)</b>
Net increase/(decrease) in cash and cash equivalents	(16,652)	(12,098)	16,164	(48,393)	(67,187)
Cash and cash equivalents at the beginning of the period	60,181	58,257	27,365	94,552	94,552
<b>Cash and cash equivalents at the end of the period</b>	<b>(43,529)</b>	<b>46,158</b>	<b>43,529</b>	<b>46,158</b>	<b>27,365</b>