

# Lytix Biopharma AS

Third quarter 2021 presentation

November 25, 2021





## Disclaimer

This presentation (the "Presentation") has been prepared by Lytix Biopharma AS ("Company") exclusively for information purposes.

The Presentation is being made only to, and is only directed at, persons to whom such presentation may lawfully be communicated ('relevant persons'). Any person who is not a relevant person should not act or rely on the Presentation or any of its contents.

The Presentation does not constitute an offering of securities or otherwise constitute an invitation or inducement to any person to underwrite, subscribe for or otherwise acquire securities in the Company. The release, publication or distribution of the Presentation in certain jurisdictions may be restricted by law, and therefore persons in such jurisdictions into which this Presentation is released, published or distributed should inform themselves about, and observe, such restrictions.

The Presentation contains certain forward-looking statements relating to the business, products, financial performance and results of the Company and/or the industry in which it operates. Forward-looking statements concern future circumstances and results and other statements that are not historical facts, sometimes identified by the words "believes", expects", "predicts", "intends", "projects", "plans", "estimates", "aims", "foresees", "anticipates", "targets", and similar expressions. The forward-looking statements contained in the Presentation, including assumptions, opinions and views of the Company or cited from third party sources are solely opinions and forecasts which are subject to risks, uncertainties and other factors that may cause actual events to differ materially from any anticipated development. Neither the Company nor its employees provides any assurance that the assumptions underlying such forward-looking statements are free from errors nor does any of them accept any responsibility for the future accuracy of the opinions expressed in the Presentation or the actual occurrence of the forecasted developments. The Company assumes no obligation, except as required by law, to update any forward-looking statements or to conform these forward-looking statements to its actual results.

The Presentation contains information obtained from third parties. You are advised that such third-party information has not been prepared specifically for inclusion in the Presentation and the Company has not undertaken any independent investigation to confirm the accuracy or completeness of such information.

An investment in the Company involves risk, and several factors could cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements that may be expressed or implied by statements and information in the Presentation, including, among others, the risk factors described in the Company's information document dated 14 June 2021. Should any risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in the Presentation.

No representation or warranty (express or implied) is made as to, and no reliance should be placed on, any information, including projections, estimates, targets and opinions, contained herein, and no liability whatsoever is accepted as to any errors, omissions or misstatements contained herein, and, accordingly, neither the Company nor its directors or employees accepts any liability whatsoever arising directly or indirectly from the use of the Presentation.

By attending or receiving the Presentation you acknowledge that you will be solely responsible for your own assessment of the market and the market position of the Company and that you will conduct your own analysis and be solely responsible for forming your own view of the potential future performance of the Company's business.

The Presentation speaks as of November 25, 2021. Neither the delivery of this Presentation nor any further discussions of the Company with any of the recipients shall, under any circumstances, create any implication that there has been no change in the affairs of the Company since such date.



## Today's presenters



#### 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.



#### **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.
- Dr. Currie holds a Ph.D. 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.

# Agenda

- Highlights of the quarter
- Company presentation
- Summary
- Interim Financial Statements



# Highlights of the quarter





## Highlights of third quarter 2021

Creating
Products of
Value

Protecting unique solutions

- ATLAS-IT-05 Phase II study in the US
  - Phase II combination study in the US with LTX-315 and pembrolizumab in patients with metastatic solid tumors initiated in July
  - Initiation of MD Anderson Cancer Center as first site
  - Screening of patients at first site initiated
  - Late-stage negotiations with other sites
- LTX-401 for intratumoral treatment of liver cancer
  - Preclinical preparations ongoing as planned, heading for submission of clinical trial application for phase I study
- Additional patents for LTX-315 approved in US
  - Two patents covering the use of LTX-315 in combination with chemotherapeutic agent and with the checkpoint inhibitor ipilimumab granted



## Events after end of third quarter 2021

Partnering with innovators

Creating
Products of
Value

Protecting unique solutions

- Verrica progressing towards phase II study in US
  - IND for LTX-315 in basal cell carcinoma accepted by FDA
- ATLAS-IT-04, LTX-315 for sarcoma fully enrolled
  - Last patient has been treated and is out of study
- Lytix Biopharma granted new European patent
  - LTX-315 in combination with chemotherapeutic agent

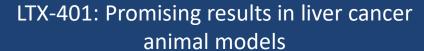


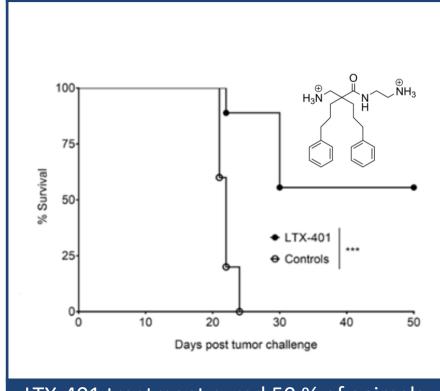
## Verrica - Operational update

- Verrica in-licensed LTX-315 for certain skin cancer types in August 2020
  - Potential future milestone payments at USD 111 mill.
  - Royalty payments from low to mid double digit
- Verrica intends to focus initially on basal cell and squamous cell carcinoma as the lead indications for development
- Basal cell carcinoma is the most common malignancy in humans<sup>1</sup>
  - Estimated 5.4 million diagnoses of basal cell (BCC) and cutaneous squamous cell (CSCC) carcinomas annually in the US alone
- US IND for the treatment of basal cell carcinoma (BCC) was accepted by FDA in November.
  - Verrica expects to initiate phase II trial in BCC in Q1 2022.



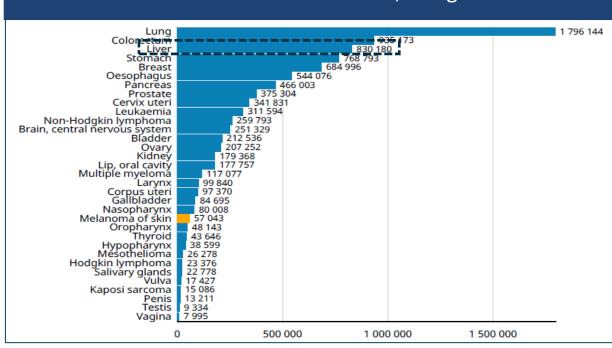
# LTX-401 a next generation oncolytic molecule for visceral lesions targeting liver cancer





LTX-401 treatment cured 50 % of animals with only 2 injections

#### Number of deaths in 2020, all ages



Third most common cause of cancer related death globally, where hepatocellular carcinoma accounts for 80-90 % of the cases

Unmet need is high due to disease severity and low survival rates



# Liver cancer represents a major commercial opportunity for LTX-401

- A pre-clinical safety program is ongoing at Aptuit with expected completion in 2022
  - Favorable safety data received so far confirms the suitability of LTX-401 injections in deep seated lesions
    - LTX-401 is well tolerated in animals
    - Maximum tolerated dose established
  - Preparations ongoing for a phase I study to be performed in Europe



# ATLAS IT-05: Building value in metastatic setting through our US clinical Phase II study

- A phase II combination study with LTX-315 and pembrolizumab in patients with solid tumors
- Study opened in July
- Ongoing recruitment process
- Aim of the study:
  - Document LTX-315's ability to enhance number of cancer patients responding to checkpoint inhibitors
- Designed with inputs from top experts in US and Europe, including Nobel laureate Jim Allison
- Multicenter US trial







# ATLAS IT-05: Building value in metastatic setting through our US clinical Phase II study

- Actions addressing challenges in recruitment undertaken
  - Fewer patients available for studies due to COVID-19
  - Operational team in US strengthened
  - Meetings with key opinion leaders in US
- Number of sites will be increased.
  - Agreement made with the CRO Oncobay that offer a "Justin-Time" (JIT) enrollment that brings larger network of clinical sites with short activation time
  - Other opportunities for increasing patient enrollment are currently being explored

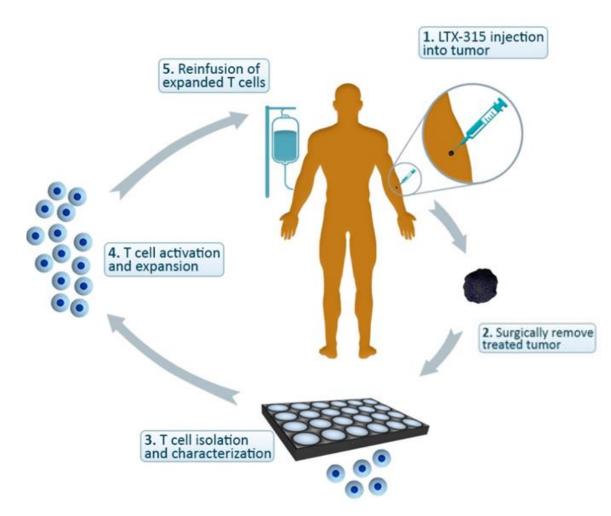






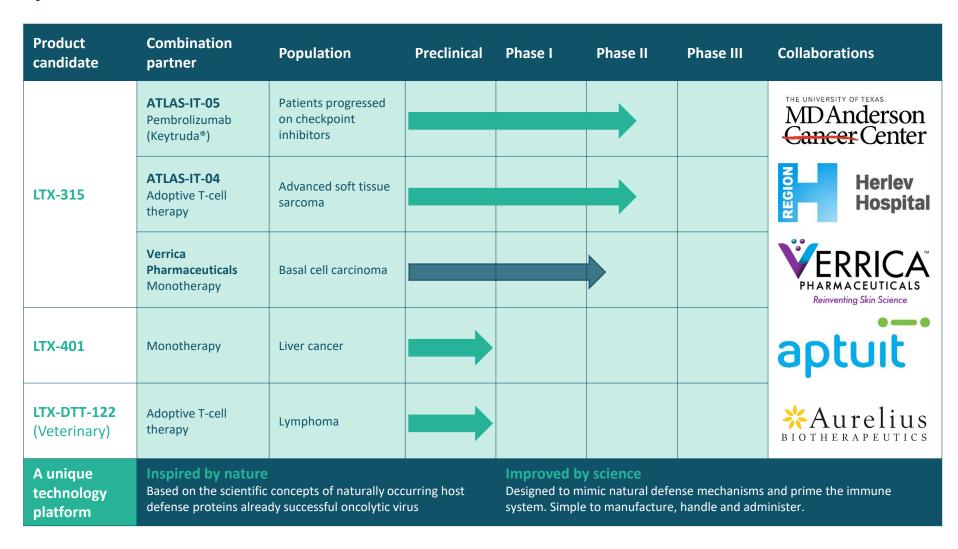
# ATLAS-IT-04, LTX-315 in combination with Adoptive Cell Transfer

- A proof of principle study (n=6) in sarcoma patients
- The study is fully enrolled
- Revealing the generation of tumor specific antigen T cells will provide strong evidence on LTX-315's unique mechanism of action and its clinical potential
- Data cleaning and analysis is ongoing





# A unique technology platform with high commercial potential



## Lytix targets large market opportunities













\* GLOBALDATA REPORTS. Estimated annual diagnosed patients in 2026 and onwards, and the value of the total forecasted drug sales in the indication



# Key figures

Amounts in NOK thousands	Unaudited Q3 2021	Unaudited Q3 2020	Unaudited YTD Q3 2021	Unaudited YTD Q3 2020	2020
Total operating income	1,907	3,482	25,108	4,727	6,678
Total operating expense	(20,703)	(18,775)	(56,757)	(34,453)	(49,050)
Loss from operations	(18,796)	(15,293)	(31,649)	(29,726)	(42,372)
Loss for the period	(18,906)	(15,178)	(31,654)	(29,597)	(42,088)
Cash position at the end of the period			209,177	34,532	28,450
Trade and other receivables			4,957	5,672	4,168
Total assets			214,134	40,204	32,617
Total equity			205,310	31,633	19,889
Total liabilities			8,825	8,571	12,728
Total equity and liabilities			214,134	40,204	32,617

- Third quarter shows higher costs than previous quarter due to increased R&D activities
- Lytix maintains a lean organization with low overhead

# Company presentation





#### FIRST IN CLASS

Unique therapeutic approach with universal mechanism of action

Promising efficacy signals in patients



# ENTERING PHASE II STUDIES IN U.S.

LTX-315 in Phase II development in US led by # 1 cancer hospital globally



#### **VALIDATED**

Nobel Price winner at the advisory board

Commercial deal within skin cancer





FIRST IN CLASS



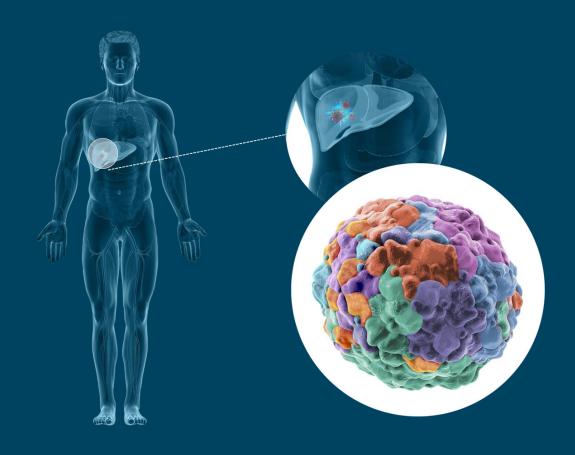
ENTERING PHASE II STUDIES IN U.S.



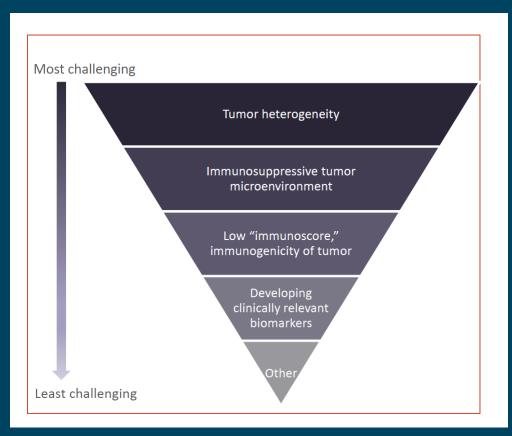
VALIDATED



# Oncolytic molecules solve one of the major challenges in current cancer therapy



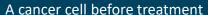
Tumors consist of many different cancer cells with different mutations

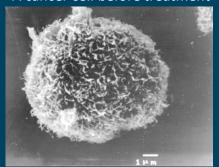


Source: GlobalData High-Prescriber Survey (December, 2020)

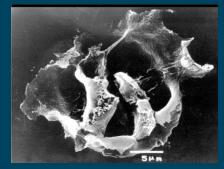


## Oncolytic molecules provides a new in situ vaccination principle

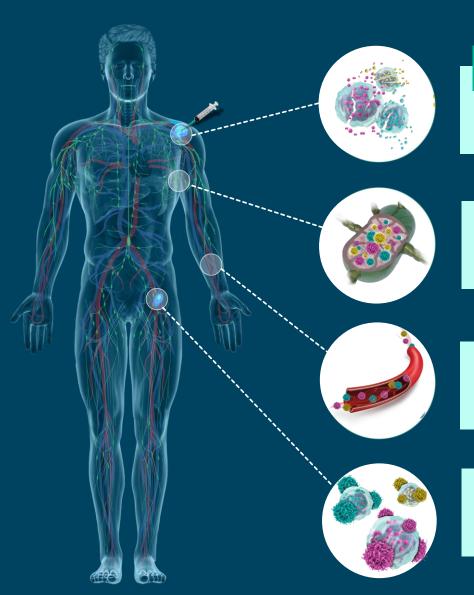




A cancer cell after treatment



Immunogenic cell death



#### **TREATED TUMOR**

Exposure of mutations (tumor antigens) from all dead cancer cells

#### LYMPH NODE

Generating T cells that recognize the different mutations (tumor antigens)

#### **BLOOD VESSELS**

T cells enter the blood stream searching for cancer cells

#### **NON-TREATED TUMOR**

T cells infiltrate and eradicate distant cancer cells





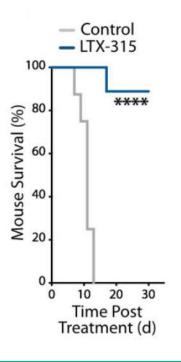


## LTX-315 is effective in "hard to treat" cancer models

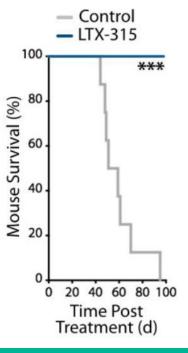
#### **B16F10 MELANOMA**

#### **BRAF MUTATED MELANOMA**



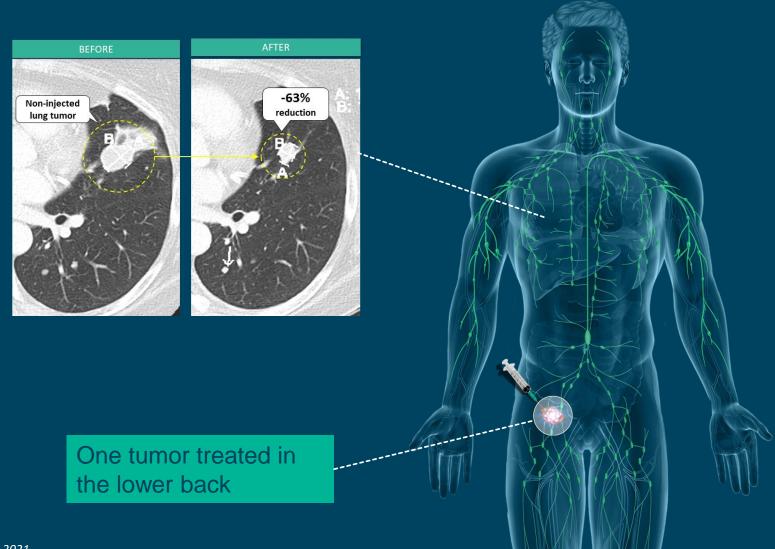






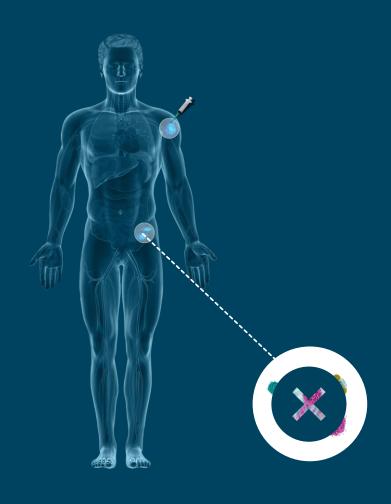
No effect of chemotherapy or immune checkpoint inhibitors in the BRAF mutated melanoma model

## Case study: Proof of Principle - Anti cancer effects in distant nontreated tumors confirmed in cancer patients

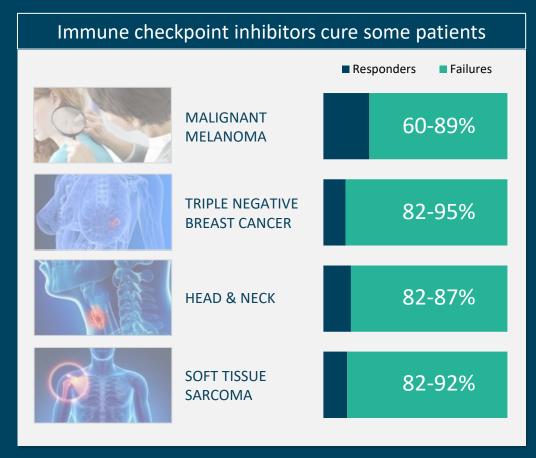




## Immune checkpoint inhibitors solve a different problem in cancer therapy

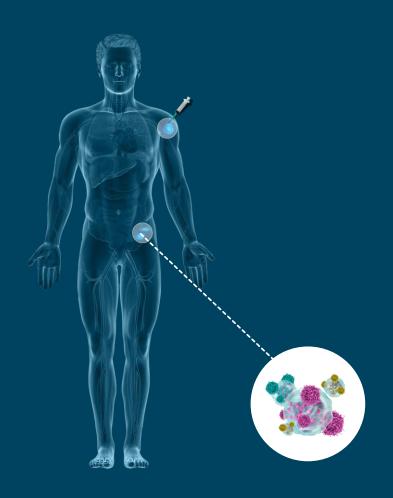


Some cancers can protect themselves by activating brakes in the immune system

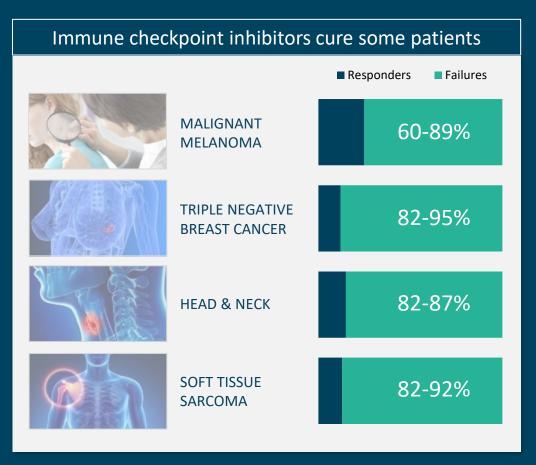




## Immune checkpoint inhibitors solve a different problem in cancer therapy

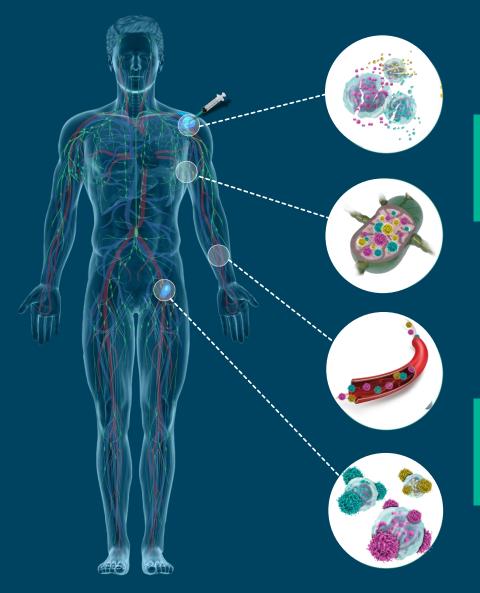


# Immune checkpoint inhibitors can remove these brakes and keep the immune system ON





## Combination therapy with immune checkpoint inhibitors



## Oncolytic molecules

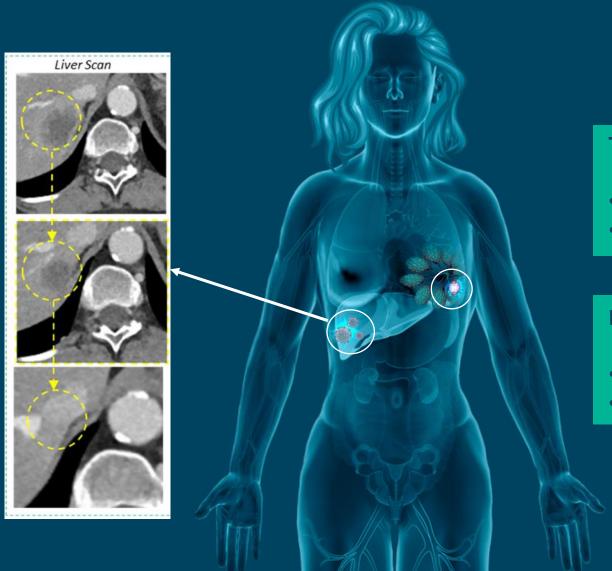
generate T cells that recognize different cancer cells



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



Case study: Proof of Principle - LTX-315 + checkpoint inhibitor showed effects not obtained with same checkpoint inhibitor alone in breast cancer patient



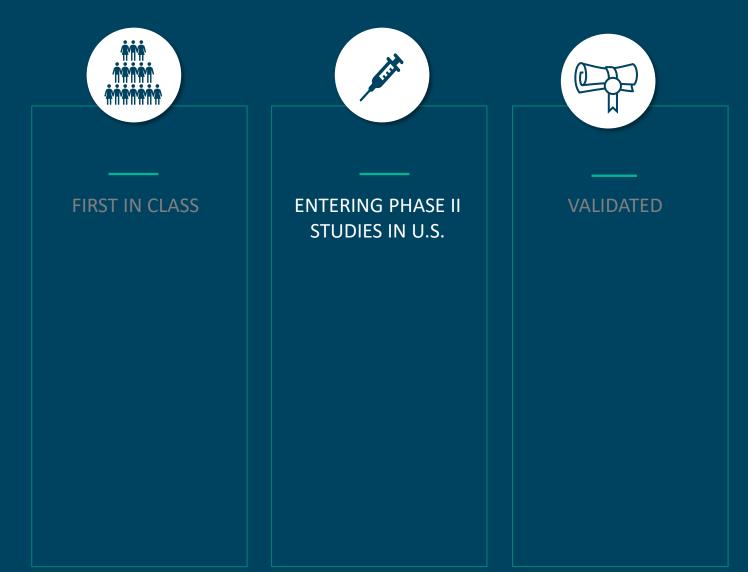
The checkpoint inhibitor pembrolizumab alone

- No effect in liver metastasis
- 5 % overall response rate (ORR)

LTX-315 + pembrolizumab

- Significant effects in liver metastasis
- 12,5% overall response rates







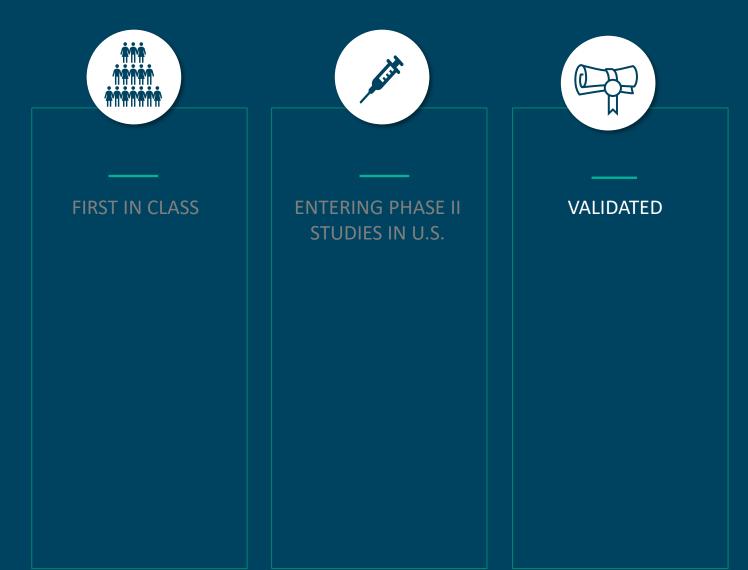


# Clinical study with LTX-315 and the immune checkpoint inhibitor pembrolizumab is ongoing in US



- The study is led by MD Anderson Hospital
  - Ranks as No. 1 globally in cancer care









# Science behind Lytix' technology documented by world leading cancer research institutions

National Cancer Institute
at the National Institutes of Health















Nobel laureate Jim Allison, who discovered the first immune checkpoint inhibitor, is a member of our scientific advisory board

"The ability of an activated immune response to generate a **diverse** T-cell repertoire that adapts to **heterogeneous** and genetically unstable tumors (...) make it **absolutely essential** to expand our efforts to find rational **combinations** to unleash antitumor immune responses for the benefit of cancer patients."

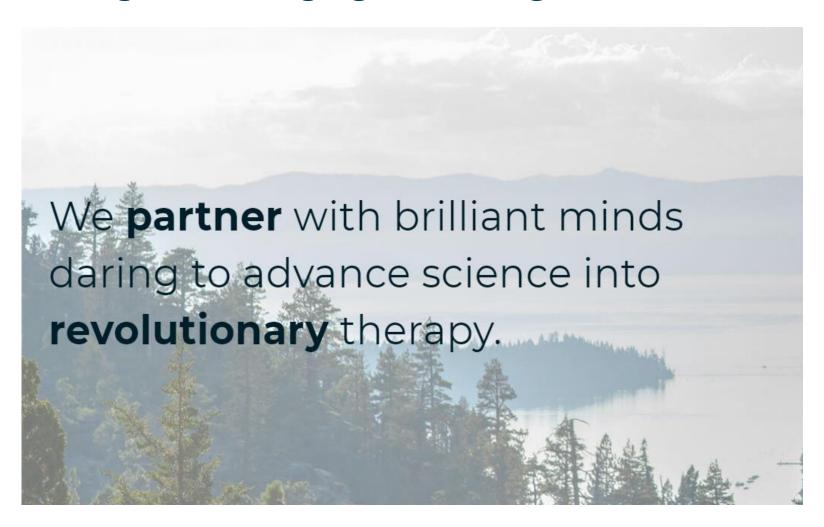


#### Jim Allison

- of the first immune checkpoint inhibitor
- 2019 Member of Lytix Advisory Board



# Lytix investor - the US healthcare specialist PBM Capital invest in game changing technologies





## Our technology already commercially validated

- US-based biotech focused on novel treatments for skin diseases
- License of LTX-315 for the treatment of certain skin cancers

- Regulatory milestones based on development goals and sales milestones at >100 mill. USD
- Royalty rates from the low double-digits to the mid-teens based on net sales USD



# Summary





## Why we will succeed



#### UNIQUE APPROACH

Lytix's molecules represent the missing piece

Ideal combination partners for checkpoint inhibitors



#### **SCIENCE**

Science confirmed by top notch US and European cancer research institutions

Nobel Laureate advisory board member



#### **VALIDATION**

Commercial deal within skin cancer

US health specialist fund as cornerstone investor



#### **EXECUTION**

Management
Board
Advisory Board
Competent investors

Ongoing clinical study in US led by No 1 cancer hospital

# **Interim Financial Statements**





# Interim statement of profit or loss

Amounts in NOK thousands	Unaudited <b>Q3 2020</b>	Unaudited Q3 2020	Unaudited YTD Q3 2021	Unaudited YTD Q3 2020	FY 2020
Amounts in Nor thousands	<u> </u>	<b>Q5 2020</b>	110 Q0 2021	115 Q5 2020	112020
Revenue	-	-	17	3	3
Other operating income	1,907	3,482	25,091	4,724	6,675
Total operating income	1,907	3,482	25,108	4,727	6,678
Payroll and related expenses	(5,608)	(11,175)	(22,905)	(17,856)	(23,416)
Direct R&D expenses	(13,087)	(4,946)	(22,656)	(8,905)	(16,008)
Other expenses	(2,008)	(2,654)	(11,196)	(7,692)	(9,626)
Total operating expenses	(20,703)	(18,775)	(56,757)	(34,453)	(49,050)
Loss from operations	(18,796)	(15,293)	(31,649)	(29,726)	(42,372)
Net financial items	(110)	115	(5)	129	284
Loss before tax	(18,906)	(15,178)	(31,654)	(29,597)	(42,088)
Tax expense	-	-	-	-	-
Loss for the period	(18,906)	(15,178)	(31,654)	(29,597)	(42,088)



# Interim statement of financial position

	Unaudited	Unaudited	
Amounts in NOK thousands	30.09.2021	30.09.2020	31.12.2020
Assets			
Current assets			
Trade and other receivables	4,957	5,672	4,168
Cash and cash equivalents	209,177	34,532	28,450
Total current assets	214,134	40,204	32,617
Total assets	214,134	40,204	32,617
Shareholder's equity and liabilities			
Issued capital and reserves			
Share capital	3,874	2,623	2,623
Share premium reserve	201,436	29,010	17,266
Total equity	205,310	31,633	19,889
Liabilities			
Current liabilities			
Trade payables	1,366	1,012	3,284
Other current liabilities	7,458	7,559	9,444
Total current liabilities	8,825	8,571	12,728
Total liabilities	8,825	8,571	12,728
Total equity and liabilities	214,134	40,204	32,617



## Interim statement of cash flows

	Unaudited	Unaudited	
Amounts in NOK thousands	YTD Q3 2021	YTD Q3 2020	FY 2020
Cash flows from operating activities			
Loss for the period	(31,654)	(29,597)	(42,088)
Adjustments for:			
Share-based payment expense	3,346	7,649	8,397
Increased/decreased in trade and other receivables	(790)	(1,033)	471
Increased/decreased in trade and other payables	(3,903)	4,717	8,874
Cash generated from operations	(33,000)	(18,264)	(24,347)
Income tax paid	-	-	-
Net cash flows from operations	(33,000)	(18,264)	(24,347)
Financing activities			
Proceeds from share issue	213,728	40,000	40,000
Net cash from/(used in) financing activities	213,728	40,000	40,000
Net increase in cash and cash equivalents	180,728	21,736	15,653
Cash and cash equivalents at the beginning of the period	28,450	12,796	12,796
Cash and cash equivalents at the end of the period	209,177	34,532	28,450