



# Interim report

Second quarter and first half 2022

## Letter from the CEO

# New encouraging clinical data

The first six months of 2022 have been fueled by clinical development and clinical data presentations across international conferences alongside seeing our partner Verrica Pharmaceuticals advance its Phase II study evaluating LTX-315 for basal cell carcinoma.

For Lytx, the most significant clinical trial development was the completion of the Phase II study evaluating LTX-315 in combination with adoptive therapy (ACT) in soft tissue sarcoma patients. The encouraging results from this study were presented at the American Society of Clinical Oncology (ASCO) in June. We reported that this combination treatment provided meaningful clinical benefit for the patients as it stabilized the disease in patients with progressive metastatic soft tissue sarcoma. Despite the trial enrolling a smaller number of patients, the results clearly show the potential of using LTX-315 in combination with ACT to generate a high number of tumor-specific T cells.

Based on the positive Phase II results, Lytx will further analyze the commercial potential of oncolytic molecules in combination with ACTs, a field of cancer research and development showing exponential growth.

In April, we were pleased to announce that our partner, Verrica Pharmaceuticals, had recruited and dosed the first patient in its Phase II study evaluating Lytx' LTX-315 in basal cell carcinoma patients. This specific skin cancer is one of the most common diagnoses, representing a significant market potential for LTX-315. We expect their commitment to this study to result in continued investments on their behalf and look forward to conveying news from this study to our shareholders as Verrica presents them.

This milestone also triggered a USD 1 million payment to Lytx, adding to our cash runway.

In the period, we also expanded the reach of our Phase II study in malignant melanoma to Europe to advance patient recruitment. We expect to soon receive regulatory approval for this expansion, which will pave the way for new sites across three European countries this fall.

Lytx encountered some delays in patient recruitment associated with COVID-19 and the strategic refocus on malignant melanoma. With increased capacity to enroll patients into this study, we aim



to complete enrollment early next year and to meet the study's primary endpoint by demonstrating LTX-315's ability to increase the number of patients responding to immunotherapy. Whilst we work towards this milestone, we are confident that we will continue to attract the attention of potential partners interested in exploring the commercial potential of LTX-315 within metastatic cancer.

In addition to advancing our lead asset, preparations are underway for the first Phase I clinical study evaluating our second-generation molecule, LTX-401. This oncolytic molecule has shown unique properties making it ideal for the treatment of deep-seated cancers such as liver cancer. The preclinical program for LTX-401 will be completed by the end of 2022, preparing LTX-401 for a clinical Phase I study.

As a clinical stage company, clinical data is the most important area for value creation. Most of our resources are therefore invested directly into clinical trials, which ultimately help shape and support the power of our unique technology platform and product candidates.

We are also excited to have strengthened the team by having Jacqueline Earabino step into the role as Head of Clinical Operations supporting our clinical trial activities.

I am also pleased to report that our efforts are supported by solid financials, allowing us to continue all ongoing activities.

In closing, the first six months of the year have been exciting and are a good demonstration of how we work to progress our unique pipeline of oncolytic molecules. We look forward to announcing further updates as we advance our assets in clinical development.

**Øystein Rekdal**  
CEO Lytx Biopharma

# Highlights and key figures

## Highlights first half 2022

### Business and Partnership:

- In April, Verrica Pharmaceuticals dosed the first patient in its Phase II study evaluating LTX-315 in basal cell carcinoma (BCC), triggering an initial milestone payment to Lytix.
- On 1 June, Lytix hosted its first Capital Markets Day (CMD) as a listed company. The event honed in on the collaboration with Verrica, which also presented key information from its Phase II clinical trial evaluating intratumoral treatment of BCC.
- During the first six months of the year, Lytix presented clinical data across several internationally recognized science and investor conferences, including the American Society of Clinical Oncology Annual Meeting (ASCO) in June, the Next-Gen Immuno-Oncology Conference London in March and the Next-Gen Immuno-Oncology Conference in Boston in June.

### Research and development:

- Data from the Phase II ATLAS-IT-04 trial evaluating LTX-315 in sarcoma patients demonstrated proof-of-concept by showing that the compound improved the outcome of adoptive cell transfer treatment. The results were presented at ASCO in June and showed that LTX-315 stabilized the disease in patients with progressive metastatic soft tissue sarcoma.
- Regulatory process is ongoing to expand the site network for the ATLAS-IT-05 study to highly recognized sites with intratumoral immunotherapy expertise in three European countries.
- The preclinical safety testing for LTX-401 has been completed demonstrating a favorable safety profile. Preparations for a Phase I clinical study are progressing according to plan.
- Jacqueline Earabino joined Lytix as Head of Clinical Operations to strengthen Lytix' clinical team.

### Financial:

- In April, Lytix received a USD 1 million milestone payment from Verrica following first patient dosed in its Phase II study of LTX-315 for the treatment of basal cell carcinoma.
- Total operating expenses for the six months ended 30 June 2022 ended at NOK 36.6 million, which is in line with last year's figures of NOK 36.1 million. Compared to the six months ended 30 June 2021, there has been an increase in activities in connection to the ongoing ATLAS-IT-05 trial in the US and the preclinical development of LTX-401. In parallel, personnel expenses and other operating expenses have decreased. Cash position at the end of the period was NOK 177.1 million compared with NOK 71.0 million as of 30 June 2021.

## Key figures<sup>1</sup>

Amounts in NOK thousands	Q2 2022	Q2 2021	H1 2022	H1 2021	FY 2021
Total operating income	10 427	1 640	11 936	23 201	25 827
Total operating expense	(20 418)	(14 041)	(36 600)	(36 054)	(73 844)
<b>Loss from operations</b>	<b>(9 991)</b>	<b>(12 401)</b>	<b>(24 664)</b>	<b>(12 853)</b>	<b>(48 017)</b>
<b>Loss for the period</b>	<b>(1 183)</b>	<b>(12 392)</b>	<b>(16 414)</b>	<b>(12 748)</b>	<b>(48 049)</b>
Property, plant and equipment	-	-	132	-	-
Cash position at the end of the period	-	-	177 084	70 950	197 282
Trade and other receivables	-	-	6 893	162 792	5 680
<b>Total assets</b>	<b>-</b>	<b>-</b>	<b>184 108</b>	<b>233 742</b>	<b>202 962</b>
Total equity	-	-	173 967	223 030	189 624
Total liabilities	-	-	10 141	10 712	13 338
<b>Total equity and liabilities</b>	<b>-</b>	<b>-</b>	<b>184 108</b>	<b>233 742</b>	<b>202 962</b>

1) Interim figures are unaudited.

# Review of the first half year 2022

## Operational review

### PARTNERSHIPS

#### LTX-315 development in partnership with Verrica

The first patient in Verrica Pharmaceutical's Phase II study investigating LTX-315 in BCC was dosed on 4 April. This achievement triggered a milestone payment of USD 1 million to Lytx. Approximately 66 patients with BCC will be enrolled in the study.

*ClinicalTrials.gov Identifier: NCT05188729*

### RESEARCH AND DEVELOPMENT

#### ATLAS-IT-04 trial (LTX-315 in combination with adoptive therapy in advanced soft tissue sarcoma)

##### Key data presented at ASCO 2022

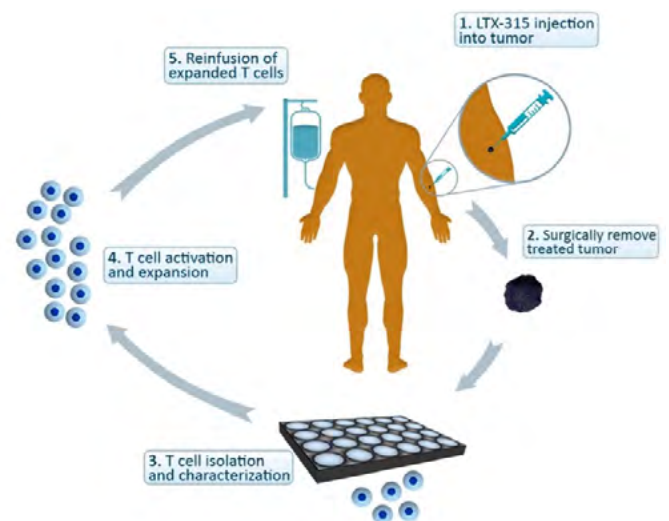
Lytx Biopharma has finalized a clinical Phase II trial together with Herlev Hospital in Denmark to assess the safety and efficacy of intratumoral administration of LTX-315 in combination with Adoptive Cell Therapy (ACT). The study showed that a combination of LTX-315 and ACT has the potential to improve clinical outcome in solid cancers with low numbers of T cells (cold tumors) where ACT alone may not be effective. The combination of LTX-315 and ACT has large commercial potential in several cancer indications that are less T-cell infiltrated.

The study was conducted in patients with progressive metastatic soft tissue sarcoma (STS). STS is a rare and heterogenous group of tumors, and current therapy is often ineffective for patients with metastatic disease. Median survival at time of diagnosis is one year. To improve outcomes, novel therapeutic approaches are needed.

ACT is a process where the patient's T cells are isolated from the tumor, before growing them in large numbers in the laboratory and then given back to the patient. The intention is to generate large numbers of the patient's own cancer specific T cells that can attack the cancer.

In the ATLAS-IT-04 study, LTX-315 in combination with ACT demonstrated a clinical benefit in patients who had mostly a progressive disease at the start of treatment. Three out of the four patients that received full treatment (receiving LTX-315 and ACT) obtained stabilization of the disease which in one patient persisted for 26 weeks. In addition, it was documented that LTX-315 is able to generate neoantigen specific T cells which proves that LTX-315 generate T cells that are able to specifically target the cancer cells.

ACT using T cells from the patient's tumor has been shown to be capable of generating durable clinical responses in patients with melanoma but has so far not been tested in patients with STS. STS patients, in contrast to melanoma patients are generally more challenging to treat with immune based therapies as their tumors are less infiltrated with T cells (cold tumors). LTX-315 was evaluated in the ATLAS-IT-04 trial to increase the possibility for clinical benefit boosting the number of tumor specific T cells available for ACT.



*The clinical treatment schedule included injection of LTX-315 into a tumor (step 1), followed by excision of the tumor (step 2), isolation and expansion of T cells (step 3 and 4) subsequently to be returned into the patient (step 5).*

The key finding from the study was that LTX-315 was able to generate a diverse pool of T cells which were able to be expanded with ACT and showed efficacy in delaying progression of STS. LTX-315 was well tolerated and no safety concerns were raised by combining LTX-315 with ACT. The laboratory analysis documented that LTX-315 generated T cells that recognized several tumor antigens and induced effects on tumor cells from the same patient. Although few patients were enrolled in the ATLAS-IT-04 trial, the results from the study document LTX-315's potential to generate multiple novel tumor-specific T-cell clones that can be expanded to billions before being reinfused to the patients. Lytx plans to start discussions with potential partners with a commercial interest in adoptive cell therapy.

*ClinicalTrials.gov Identifier: NCT03725605*



### ATLAS-IT-05 trial (LTX-315 in combination with pembrolizumab in patients with advanced solid tumors)

In this ongoing Phase II trial, the combination of LTX-315 and pembrolizumab is being evaluated in patients with advanced melanoma refractory to anti-PD-1/PDL-1 therapy. Sites are currently open in the US and recruitment is ongoing. To mitigate recruitment challenges due to COVID-19, which continues to impact site resources, the study will be expanded to sites in Europe. A regulatory application was submitted in Europe in the second quarter of 2022. Due to the impact of COVID-19 and the time taken to strategically optimize the study, it is now anticipated that the study will complete enrollment in early 2023. In addition, CRO resources have been optimized and the CRO Voisin Consulting Life Sciences (VCLS) was contracted to assist the EU regulatory application process. The clinical team has also been strengthened by hiring Jackie Earabino as Head of Clinical Operations.

*ClinicalTrials.gov Identifier: NCT04796194*

### Intellectual property (IP) rights

#### Granted patent Family in Australia

Lytix has been granted the first patent from its «T cell clonality» patent family in Australia (AU2017214321B2). The patent covers tumor-infiltrating T cells isolated from tumors of patients that have been treated with oncolytic molecules such as LTX-315, and the therapeutic use of such T cells, which recognize different tumor antigens, in tumor treatment, e.g., treatment by autologous T cell therapy.

## Financial review

### PROFIT AND LOSS

Total operating income for the six months ended 30 June 2022 amounted to NOK 11.9 million (NOK 23.2 million for the six months ended 30 June 2021). Operating income in the period was mainly related to a milestone payment of NOK 9.6 million following the license agreement with Verrica Pharmaceuticals. Other income for the first half of 2022 includes governmental grants of NOK 2.3 million (NOK 3.7 million). Personnel expenses for the six months ended 30 June 2022 came in at NOK 9.9 million (NOK 17.3 million for the six months ended 30 June 2021). The decreased personnel expenses are mainly explained by an extraordinary bonus in 2021, as well as lower share-based payment expenses in 2022.

Direct R&D expenses amounted to NOK 22.8 million for the six months ended 30 June 2022 (NOK 9.6 million for the six months ended 30 June 2021). Direct R&D expenses for the first half were related to increased activities in connection to the ongoing ATLAS-IT-05 trial in the US, and the ATLAS-IT-04 trial in Denmark as well as the progression of the preclinical development

Lytix has already established an expanding patent portfolio consisting of several patent families in the field of oncolytic molecules and related therapies covering key markets throughout the world.

### LTX-401

In experimental cancer models, Lytix' next-generation oncolytic molecule, LTX-401, has demonstrated a commercial potential for deep-seated tumors such as primary liver cancer and colorectal cancer that has spread to the liver as well as several additional major cancer indications located in other internal organs. In addition to demonstrating promising anticancer efficacy, a preclinical safety program required for entering human clinical trials has been completed concluding that LTX-401 has a favorable safety profile.

At present, Lytix is performing preclinical development activities needed for submitting a clinical trial application for a Phase I trial.

### LTX-122

LTX-122 is in a preclinical development program as part of the strategic partnership with Aurelius Biotherapeutics, a US-based veterinary company. Aurelius aim to use LTX-122 together with their own adoptive cell transfer technology to develop a treatment for B-cell lymphoma in dogs.

of LTX-401. Furthermore, other operating expenses decreased to NOK 3.9 million (NOK 9.2 million). Loss from operations for the first half of 2022 amounted to NOK 24.7 million (NOK 12.9 million).

Net financial items contributed positively to the net result with NOK 8.3 million in the first half of 2022 (NOK 0.1 million). Lytix has decided to hedge part of its expected USD cost related to the ATLAS-IT-05 study in the US and the financial income for the first half of 2022 stems from a conversion of that USD cash position into NOK as of 30 June 2022.

### Cash flow

Cash flow from operating activities amounted to negative NOK 20.2 million for the six months ended 30 June 2022 compared with negative NOK 171.2 million for the six months ended 30 June 2021. The large negative cash flow from operating activities in 2021 was related to the settlement of the capital raised in the IPO. Lytix received the Proceeds in the third quarter of

2021. Cash flow from financing activities for the six months ended 30 June 2022 amounted to NOK 0.1 million and is related to the exercise of warrants. Cash and cash equivalents at the end of the reporting period amounted to NOK 177.1 million compared with NOK 197.3 million at 31 December 2021 and NOK 71.0 million at 30 June 2021.

## Platform technology

Lytix' technology platform is based on more than 30 years of preclinical and clinical research and originates from UiT, The Arctic University of Norway, Tromsø. The company has successfully generated highly active oncolytic molecules from naturally occurring host defense peptides. These have the potential to address the main challenge to deal efficiently with cancer; the heterogeneity of the tumor, enabling the cancerous cells to escape various targeting therapies.

When Lytix' improved molecules are injected straight into solid tumors, they activate the patient's own immune system and enable killer T cells to recognize and eliminate cancer cells. This process results in an efficient release of tumor neoantigens (mutated proteins) and immune activating molecules. This unique way of eliminating cancer cells results in potent activation of the patient's immune system, with subsequent infiltration of T cells into the tumor. The oncolytic molecule's unique mode of action results in a significant increase of infiltration of immune cells into the injected tumor and is usually designated to make cold (no or few T cells) tumors hot (presence of T cells).

The oncolytic molecules are therefore also ideal for combination with other types of immune therapies where the lack of immune cells in the patients' tumors is one of the major hurdles for these therapies to be effective.

In a GlobalData survey<sup>1</sup>, physicians ranked tumor heterogeneity as the most challenging aspect of optimizing immuno-oncology (IO). Tumor heterogeneity introduces significant challenges in

### Statement of financial position / balance sheet

Total assets on 30 June 2022 were NOK 184.1 million compared with NOK 203.0 million on 31 December 2021 and NOK 233.7 million at 30 June 2021.

### DELIVERING IMMUNOTHERAPY STRAIGHT INTO THE TUMOR

Lytix Biopharma's unique technology platform potentiates a patient's immune system by injecting drugs with the ability to kill cancer cells straight into the tumor environment. Lytix has applied this approach with its first-in-class oncolytic molecules, representing an alternative and unique approach to cancer vaccination. Importantly, this approach generates an immune response against a broad antigen repertoire targeting the heterogenous tumors without pre-identifying the antigens, which in turn can save considerable costs and valuable time.

cancer therapy and is the main cause of treatment failure, drug resistance, relapse and recurrence. Lytix' oncolytic molecules uniquely address heterogeneity by being able to recognize and target the different cancer subclones in a heterogenous tumor, including both drug sensitive and resistant cancer cells.

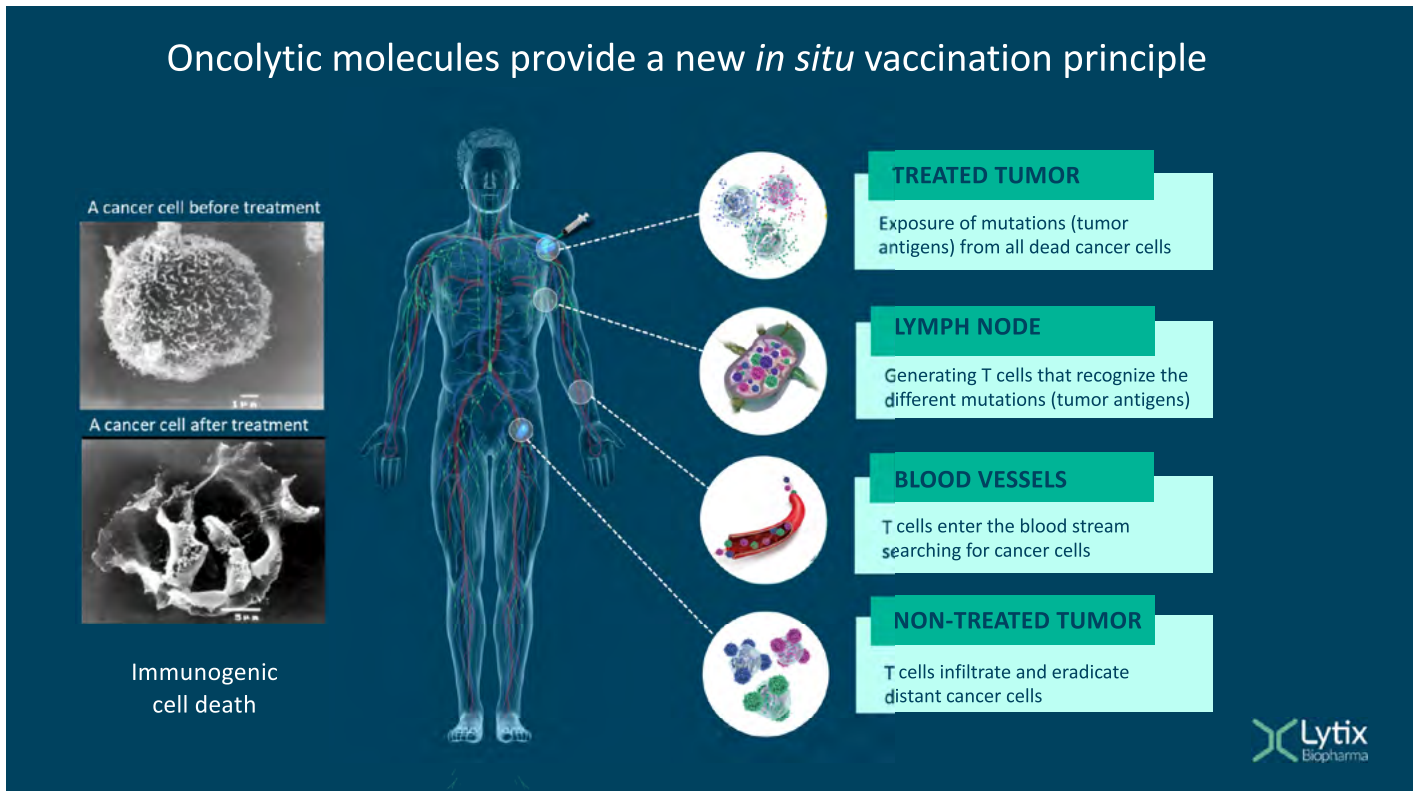
Oncology is the largest pharmaceutical market by revenue. Oncology therapeutics represented USD 143 billion in sales in 2019 (~20 per cent of global pharmaceutical sales)<sup>2</sup>. To capture a larger market share, parallel development across multiple indications increases the value of an individual asset and makes deal-making more likely. Unmet need remains high, and the mar-

### ONCOLYTIC MOLECULES

- Demonstrates a dual mode of action as they
  - *directly induce immunogenic cell death of tumor cells*
  - *activate antigen presenting cells to generate tumor specific T cells*
- Harness the solid tumor as a source of antigens
- Generate systemic and lasting anti-tumor immunity
- Induce a switch from an immuno-suppressive environment towards an immuno-stimulatory environment enriched for activated cytotoxic cells

<sup>1</sup> Source: GlobalData High-Prescriber Survey (December 2020)

<sup>2</sup> Source: McKinsey analysis of EvaluatePharma (July 2020)



ket is expected to reach USD 250 billion by 2024<sup>3</sup>. The key driver behind this future growth is expected to be immuno-oncology combination therapies. Lytix’ oncolytic molecules are synergistic and complementary to other immuno-oncology therapies with the potential to create new treatment paradigms.

By addressing the main challenge across a wide section of cancer indications as well as being able to combine with many other immuno-oncology therapies, Lytix’ oncolytic molecules have the potential to claim a unique position within immuno-oncology, creating significant patient impact as well as value for Lytix.

## Product candidates and portfolio

Lytix Biopharma’s unique technology platform has the capacity to deliver several molecules within the class of amphipathic membranolytic drugs. These are aimed at improving the lives of patients across many cancer types where tumors are accessible for intratumoral injections.

This *in situ* vaccination technology platform offers a whole range of product opportunities. Out of hundreds of candidates, only a few oncolytic molecules have passed through the rigorous testing before being amphipathic molecules with oncolytic properties.

The developmental program progresses the oncolytic molecules both as monotherapy, as a combination partner with checkpoint inhibitors and as an adjunct to cell therapy.

After the recent completion of the ATLAS-IT-04 study in adoptive therapy, LTX-315 is now being evaluated in two different Phase II trials, both as monotherapy and as combination therapy with the checkpoint inhibitors pembrolizumab.

Lytix’ ATLAS-IT-05 clinical trial with LTX-315 initiated at MD Anderson Cancer Centre in the US is planned to include 20 patients with metastatic melanoma, a patient population with a high unmet medical need.

LTX-401 is a second-generation candidate drug; it is a small molecule and thus can be administered at higher doses than LTX-315 and used for the treatment of tumors seated deep in the body. The next step is to evaluate LTX-401 in a human clinical trial.

<sup>3</sup> Source: McKinsey analysis of EvaluatePharma (July 2020)

Product candidate	Combination partner	Population	Preclinical	Phase I	Phase II	Phase III	Collaborations	
LTX-315	Atlas-IT-05 Pembrolizumab (Keytruda®)	Patient progressed on checkpoint inhibitors	→					
	Verrica Pharmaceuticals Monotherapy	Basal cell carcinoma	→					
	Atlas-IT-04 Adoptive T-cell therapy	Advanced soft tissue sarcoma	→					
LTX-401	Monotherapy	Liver cancer	→					
LTX-122	Adoptive T-cell therapy	Dog lymphoma	→					
<b>A unique technology platform</b>	<b>Inspired by nature</b> Based on the scientific concepts of naturally occurring host defense proteins, scientifically improved for cancer therapy.			<b>In situ vaccination platform</b> Candidate drugs to be directly injected into solid tumors priming the immune system for potent activation.				

## Product candidates

### LTX-315

LTX-315, the lead candidate of Lytix Biopharma is a 9 amino acid peptide developed from bovine lactoferricin. It is a first-in-class oncolytic molecule that is developed for intratumoral injections. Preclinical studies have demonstrated that treatment of solid tumors with LTX-315 results in growth inhibition, complete regression, and long-lasting tumor specific immune protection. These studies also demonstrate that the treatment results in a significant increase of the number of tumor-infiltrating T cells in the tumor micro-environment (Sveinbjörnsson et al. 2017).

The preclinical findings conveying the rationale for the therapeutic use of LTX-315 in humans have been confirmed in clinical trials. LTX-315 has undergone a comprehensive Phase I clinical trial in heavily pretreated patients. In this clinical trial, one of the key features of LTX-315 treatment, to promote T-cell infiltration into tumors, was evident in cancer patients. LTX-315 was shown to be a potent drug with the ability to also create systemic effects based on local injection of tumors. In this trial, LTX-315 was either given as monotherapy or in combination with a checkpoint inhibitor to patients with transdermally accessible tumors. The trial has shown that LTX-315 has an acceptable safety profile without any added safety concerns when given in combination with a checkpoint inhibitor. The scientific foundation has been laid to claim that LTX-315 is clinically active and contrib-

utes to immune-mediated anticancer activity (Spicer et al. 2018/ Spicer et al. 2021). Based on the data from the Phase I clinical trial, the dosing regimen of LTX-315 has been assessed and optimized for the ATLAS-IT-05 study.

LTX-315’s ability to induce T-cell infiltration into tumors can be further exploited in adoptive cell therapy. This kind of therapy implies the isolation of T cells from the tumor, expansion in the laboratory and transfer back to the patient to improve the immune response against the tumor. The ATLAS-IT-04 study at Herlev Hospital Denmark was set up to evaluate the potential of LTX-315 to enhance the number of T cells prior to isolation and expansion of the T cells to billions. The T cells were then given back to the patient. In this study, LTX-315 was administered in combination with adoptive therapy in advanced soft tissue sarcoma patients. During the study an extensive immune profile was measured to characterize the immune status and nature of immune response together with monitoring the clinical response. The study is now finalized, and the results were presented at ASCO in June 2022.

### LTX-401

LTX-401 is a small molecule that has the potential to treat deep-seated tumors such as hepatocellular carcinoma (liver cancer)



and liver metastases. In several experimental models, LTX-401 induces complete regression after intratumoral injection with subsequent development of systemic immune protection. LTX-401 has shown increased efficacy when combined with checkpoint inhibitors and has demonstrated significant effects in experimental liver cancer models. LTX-401 has been through a preclinical safety program to enable the initiation of the first clinical trial.

### **LTX-122**

LTX-122 is an oncolytic peptide that consists of 12 naturally occurring amino acids. In preclinical research the peptide proved to have high activity and selectivity against B-cell lymphoma.

In a lymphoma mouse model intratumoral administration resulted in full regression and protective immunity. The peptide was developed in a collaboration between Lytix Biopharma and the University of Tromsø (UiT). Lytix has entered a license agreement with UiT that grants Lytix rights to further develop and commercialize LTX-122.

### **UNDISCLOSED**

Lytix is pursuing several new opportunities, all of them based on the *in situ* vaccination technology platform that delivered LTX-315 and LTX-401. Further information on these will be provided as they advance from early stage of development.

## **Partnerships**

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### **VERRICA PHARMACEUTICALS**

Verrica is a Nasdaq-listed dermatology therapeutics company developing medications for skin diseases requiring medical interventions, and it is headquartered in West Chester, Pennsylvania. In August 2020, Lytix announced that it entered into a license agreement providing Verrica Pharmaceuticals with a worldwide license to develop and commercialize LTX-315 for some malignant and pre-malignant dermatological indications (skin cancer). Lytix maintains all rights to the use of LTX-315 in patients with metastatic melanoma and metastatic Merkel cell carcinoma. Verrica will assume responsibility for manufacturing of the LTX-315 drug product, while Lytix retains responsibility for manufacturing of the active pharmaceutical ingredient (API). Under the license agreement, Lytix may receive aggregate payments of more than USD 110 million upon achievements of certain clinical, regulatory and sales milestones as well as tiered royalty payments in the double-digit teens.

Verrica intends to focus initially on basal cell and squamous cell carcinoma as the lead indications for development for LTX-315. In November, Verrica received US IND approval to initiate a

Phase II clinical trial in basal cell carcinoma, and the first patient was recruited to the study in April 2022. The American Cancer Society has estimated that about 5.4 million basal cell carcinoma (BCC) and squamous cell carcinomas (SCC) are diagnosed in the US annually. With about 80 per cent of these skin cancers being BCC there is a significant potential for new treatment options.

### **AURELIUS BIOTHERAPEUTICS LLC**

In March 2021, Lytix announced it had entered into a strategic partnership with Aurelius Biotherapeutics whereas Aurelius will investigate and develop LTX-122 for the veterinary medicine market. The partnership is arranged with an option period where Aurelius has initiated further feasibility studies on LTX-122 together with their own technology, which is based on adoptive cell transfer to treat dog lymphoma.

LTX-122 has been developed in collaboration with UiT. Lytix has an exclusive license agreement with UiT to further develop and commercialize LTX-122.

## Risks and uncertainties

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Lytix is a pure research and development company which means that the company is accumulating financial losses. Operating losses are expected to continue during the development phases of the company's products, and other than potential development milestone payments from the licensing agreement with Verrica, potentially cash generating operations are not expected until one or more of the company's products are commercialized.

The company has no interest-bearing debt. Bank deposits are exposed to market fluctuations in interest rates, which affects financial income. Lytix is on a regular basis transacting in various currencies other than the functional currency (NOK). This implies that the company is exposed to currency fluctuations. Transactions related to the ATLAS-IT-05 study are mainly denominated in USD, and Lytix has consequently placed a significant part of its cash position in USD to hedge part of the foreign currency risk. The credit risk is limited as revenues are minimal exclusive of public grants.

The company controls its cash flow from both long- and short-term perspectives through rolling cash forecasts. The company has no loan agreements involving covenants or other financial instruments or requirements.

Funding of ongoing operations is, and will be for some time, depending on external sources, mainly equity contributions. There is an inherent risk around future financing of the company, depending upon the company's own performance and on the financial market conditions. Acceptable sources of funding may not be available when needed or may not be available on acceptable terms. The company's ability to obtain capital or financing will depend in part upon prevailing market conditions as well as conditions of its business and its operating results, and those factors may affect its efforts to arrange additional financing on satisfactory terms.

## Outlook

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Lytix is well positioned to advance and develop its clinical trial assets. In the period, the company initiated a regulatory process to set up additional test sites in Europe to support its ongoing Phase II trial evaluating LTX-315 in patients with advanced solid tumors. Recruitment is expected to expand and advance into early 2023. Additionally, and in support of increased commer-

### NON-FINANCIAL RISKS

Lytix' activity is the development of pharmaceutical medications. Research and development up to approved registration is subject to considerable risk and is a capital-intensive process. Lytix' candidates for cancer medications and technology platform are dependent on research and development and go through several stages before commercialization and risk of failure is generally inherent throughout the process.

#### Technology risk

The company's lead product candidates are still at an early stage and the preclinical and clinical studies may not prove to be successful. Furthermore, the product candidates are dependent on continued research and development which may be delayed and/or incur higher costs than currently expected.

#### Competitive technology

Immunotherapy and other cancer therapeutics industries are in general highly competitive and dynamic, and as such a high-risk business.

#### Market risks

The financial success of the company will require beneficiary partner agreements as well as obtaining market access and reimbursement/pricing at attractive levels. There can be no guarantee that the company's product(s) will meet these requirements. The company will need approvals from the European Medicines Agency (EMA) to market products in Europe and from the U.S. Food and Drug Administration (FDA) to market its products in the US, as well as equivalent regulatory authorities in other foreign jurisdictions to commercialize in those regions.

cial and planned clinical trial activities, the company continues to make strategic hires to strengthen the overall team.

The company remains well funded and will continue to regularly assess its financial position to ensure that it has the necessary funds to develop its pipeline.

## Responsibility statement

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The board is not aware of any matters that are important for an assessment of the company's position and results that are not set out in the interim accounts. Similarly, no matters have occurred after June 30, 2022, that in the opinion of the board are material to an assessment of the accounts.

The board stated that the interim accounts represent a true and fair view of the company's financial position on June 30, 2022. According to the Norwegian Accounting Act §3-3 (a), the board of directors confirmed that the financial statements have been prepared under the assumption of going concern and that the grounds for this assumption exist.

*Oslo 24 August 2022*

*The board of directors and the chief executive officer of Lytix Biopharma AS*

**Gert W. Munthe**  
*Chair of the board*

**Brynjar Forbergskog**  
*Director*

**Evelina Vågesjö**  
*Director*

**Jayson Rieger**  
*Director*

**Kjetil Hestdal**  
*Director*

**Marie-Louise Fjällskog**  
*Director*

**Øystein Rekdal**  
*Chief executive officer*

# Financial statements

## Condensed interim statement of profit or loss<sup>1</sup>

<i>Amounts in NOK thousands</i>	<i>Notes</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
Revenue	1	-	-	-	17	17
Other operating income	2	10 427	1 640	11 936	23 184	25 810
<b>Total operating income</b>	3	<b>10 427</b>	<b>1 640</b>	<b>11 936</b>	<b>23 201</b>	<b>25 827</b>
Payroll and related expenses	5	(6 175)	(3 462)	(9 875)	(17 296)	(31 605)
Depreciation and amortization expenses	6	(6)	-	(6)	-	-
Direct R&D expenses		(12 055)	(4 692)	(22 780)	(9 569)	(28 817)
Other operating expenses	4	(2 182)	(5 887)	(3 939)	(9 188)	(13 421)
<b>Total operating expenses</b>		<b>(20 418)</b>	<b>(14 041)</b>	<b>(36 600)</b>	<b>(36 054)</b>	<b>(73 844)</b>
<b>Loss from operations</b>		<b>(9 991)</b>	<b>(12 401)</b>	<b>(24 664)</b>	<b>(12 853)</b>	<b>(48 017)</b>
<b>Net financial items</b>	9	<b>8 808</b>	<b>9</b>	<b>8 250</b>	<b>105</b>	<b>(32)</b>
<b>Loss before tax</b>		<b>(1 183)</b>	<b>(12 392)</b>	<b>(16 414)</b>	<b>(12 748)</b>	<b>(48 049)</b>
Tax expense		-	-	-	-	-
<b>Loss for the period</b>		<b>(1 183)</b>	<b>(12 392)</b>	<b>(16 414)</b>	<b>(12 748)</b>	<b>(48 049)</b>

1) Interim figures are unaudited.



## Condensed interim statement of financial position<sup>1</sup>

<i>Amounts in NOK thousands</i>	<i>Notes</i>	<b>30.06.2022</b>	30.06.2021	<b>31.12.2021</b>
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment	6	132	-	-
Other receivables		-	-	-
<b>Total non-current assets</b>		<b>132</b>	-	-
<b>Current assets</b>				
Trade and other receivables	10	6 893	162 792	5 680
Cash and cash equivalents	8, 9	177 084	70 950	197 282
<b>Total current assets</b>		<b>183 977</b>	233 742	<b>202 962</b>
<b>Total assets</b>		<b>184 108</b>	233 742	<b>202 962</b>
<b>Shareholder's equity and liabilities</b>				
<b>Issued capital and reserves</b>				
Share capital	11	4 007	3 874	3 874
Share premium reserve	11	169 960	219 156	185 750
<b>Total equity</b>		<b>173 967</b>	223 030	<b>189 624</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade payables		2 557	2 775	1 476
Other current liabilities		7 585	7 937	11 862
<b>Total current liabilities</b>		<b>10 141</b>	10 712	<b>13 338</b>
<b>Total liabilities</b>		<b>10 141</b>	10 712	<b>13 338</b>
<b>Total equity and liabilities</b>		<b>184 108</b>	233 742	<b>202 962</b>

1) Interim figures are unaudited.

## Condensed interim statement of cash flows<sup>1</sup>

<i>Amounts in NOK thousands</i>	<i>Notes</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
<b>Cash flows from operating activities</b>						
Loss for the period		<b>(1 183)</b>	<b>(12 392)</b>	<b>(16 414)</b>	<b>(12 748)</b>	<b>(48 049)</b>
<b>Adjustments for:</b>						
Depreciation and amortization expenses	6	<b>6</b>	-	<b>6</b>	-	-
Share-based payment expense		<b>344</b>	993	<b>624</b>	2 161	<b>4 055</b>
Increase/decrease in trade and other receivables		<b>349</b>	(156 602)	<b>(1 213)</b>	(158 624)	<b>(1 513)</b>
Increase/decrease in trade and other payables		<b>(2 994)</b>	2 641	<b>(3 197)</b>	(2 016)	<b>610</b>
<b>Cash generated from operations</b>		<b>(3 479)</b>	<b>(165 361)</b>	<b>(20 193)</b>	<b>(171 228)</b>	<b>(44 896)</b>
Income tax paid		-	-	-	-	-
<b>Net cash flows from operations</b>		<b>(3 479)</b>	<b>(165 361)</b>	<b>(20 193)</b>	<b>(171 228)</b>	<b>(44 896)</b>
<b>Investing activities</b>						
Investments in tangible assets	6	<b>(102)</b>	-	<b>(137)</b>	-	-
<b>Net cash from/(used) in investing activities</b>		<b>(102)</b>	-	<b>(137)</b>	-	-
<b>Financing activities</b>						
Proceeds from share issue		-	213 728	<b>133</b>	213 728	<b>213 728</b>
<b>Net cash from/(used) in financing activities</b>		-	213 728	<b>133</b>	213 728	<b>213 728</b>
Net increase in cash and cash equivalents		<b>(3 582)</b>	48 368	<b>(20 198)</b>	42 500	<b>168 832</b>
Cash and cash equivalents at the beginning of the period		<b>180 666</b>	22 582	<b>197 282</b>	28 450	<b>28 450</b>
<b>Cash and cash equivalents at the end of the period</b>		<b>177 084</b>	70 950	<b>177 084</b>	70 950	<b>197 282</b>

1) Interim figures are unaudited.

## Notes to the financial statements<sup>1</sup>

### Accounting principles

The condensed interim financial statements have been prepared in accordance with the recognition and measurement criteria in accordance with the Norwegian Accounting Act and generally accepted accounting principles in Norway. The interim financial statements should be read in conjunction with the company's annual financial statements for 2021 as they do not include all the information required for a complete set of financial statements in accordance with the Norwegian accounting act. The interim financial statements are presented in NOK, which is also the company's functional currency. Amounts are rounded to the nearest thousand unless otherwise stated. The interim financial statements are unaudited.

### Use of estimates

The preparation of accounts in accordance with the recognition- and measurement criteria in accordance with the Norwegian Accounting Act requires the use of estimates. It also requires management to exercise judgment in applying the company's accounting policies. The areas where significant judgments and estimates have been made in preparing the financial statements and their effect are disclosed in the following notes.

### Revenue

Revenue comprises the fair value of any consideration received or due consideration for the sale of services in regular business activities. Revenue is presented net of value added tax provided the amount of revenue can be measured reliably and it is probable that the company will receive any considerations. The company's products are still in the research and development phase, and it has no revenue from sales of products yet.

Revenues for services are recognized when the services are performed, and the company has a right to payment.

The company's revenue is not significantly affected by seasonality or other variations throughout the reporting period.

### Classification and assessment of balance sheet items

Assets intended for long term ownership or use are classified as fixed assets. Assets relating to the operating cycle have been classified as current assets. Other receivables are classified as current assets if they are to be repaid within one year after the transaction date. Similar criteria apply to liabilities. First year's instalment on long term liabilities and long-term receivables are, however, not classified as short-term liabilities and current assets.

### Intangible assets

Expenditure on own Research and Development are expensed as and when they incur. Expenses for other intangible assets are reflected

in the balance sheet providing a future financial benefit relating to the development of an identifiable intangible asset can be identified and the cost can be measured reliably. Otherwise, such expenditure is expensed as and when incurred. Capitalized development costs are amortized linearly over the asset's expected useful life.

### Receivables

Accounts receivables and other receivables are recorded in the balance sheet at face value after deduction of provisions for expected loss. Provisions for losses are made on the basis of individual assessments of the individual receivables.

Additionally, for accounts receivables, an unspecified provision is made to cover expected losses.

### Defined contribution plan

With a defined contribution plan the company pays contributions to an insurance company. After the contribution has been made the company has no further commitment to pay. The contribution is recognized as payroll expenses. Prepaid contributions are reflected as an asset (pension fund) to the degree the contribution can be refunded or will reduce future payments.

### Tax

The tax charge in the income statement includes both payable taxes for the period and changes in deferred tax. Deferred tax is calculated at 22 per cent on the basis of the temporary differences that exist between accounting and tax values, as well as any possible taxable loss carried forwards at the end of the accounting year. Tax enhancing or tax reducing temporary differences, which are reversed or may be reversed in the same period, have been offset and netted.

The disclosure of deferred tax benefits on net tax reducing differences which have not been eliminated, and tax losses varied forward losses, is based on estimated future earnings. Deferred tax benefits are not shown in the balance sheet.

### Forward contracts

Assets/liabilities secured through forward contracts are reflected in the balance sheet at forward exchange rate, except for the interest rate element which is accrued and classified as interest income / expense.

### Cash flow statement

The cash flow statement has been prepared according to the indirect method. Cash and cash equivalents include cash, bank deposits, and other short-term investments which immediately and with minimal exchange risk can be converted into known cash amounts, with due date less than three months from purchase date.

1) Interim figures are unaudited.

**NOTE 1 REVENUE**

<i>Amounts in NOK thousands</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
<b>Revenue</b>					
Other income	-	-	-	17	17
<b>Total Revenue</b>	-	-	-	17	17

The company's products are still in the research and development phase, and there is no revenue from sales of products yet.

**NOTE 2 OTHER OPERATING INCOME**

<i>Amounts in NOK thousands</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
<b>Other operating income</b>					
Government grants recognized in profit and loss	805	1 546	2 314	3 706	6 332
Other	9 622	94	9 622	19 478	19 478
<b>Other operating income</b>	<b>10 427</b>	<b>1 640</b>	<b>11 936</b>	<b>23 184</b>	<b>25 810</b>

**NOTE 3 GEOGRAPHICAL DISTRIBUTION INCOME**

<i>Amounts in NOK thousands</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
<b>Geographical distribution</b>					
Norway	805	1 640	2 314	3 910	6 537
US	9 622	-	9 622	19 290	19 290
<b>Total operating income</b>	<b>10 427</b>	<b>1 640</b>	<b>11 936</b>	<b>23 201</b>	<b>25 827</b>

**NOTE 4 TRANSACTIONS WITH RELATED PARTIES**

<i>Amounts in NOK thousands</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
North Murray AS (Gert W. Munthe)	-	-	-	150	150

Transactions with related parties consist of invoiced fee for consultancy services.

**NOTE 5 PAYROLL AND RELATED EXPENSES**

<i>Amounts in NOK thousands</i>	<b>Q2 2022</b>	<b>Q2 2021</b>	<b>H1 2022</b>	<b>H1 2021</b>	<b>FY 2021</b>
<b>Payroll and related expenses, including directors, comprise</b>					
Wages and salaries	4 352	2 872	7 818	13 790	24 381
Defined contribution pension const	194	192	403	364	789
Share-based payment expense	344	993	624	2 161	4 055
Social security contributions	830	(707)	538	859	1 864
Other personnel costs	455	112	492	122	517
<b>Total payroll and related expenses</b>	<b>6 175</b>	<b>3 462</b>	<b>9 875</b>	<b>17 296</b>	<b>31 605</b>

Lytix Biopharma AS is required to have a pension scheme in accordance with the Norwegian law of mandatory occupational pension. The company's pension scheme fulfils the requirements of the law.



**NOTE 6** PROPERTY, PLANT AND EQUIPMENT

<i>Amounts in NOK thousands</i>	Machinery and equipment	Total 2022	Machinery and equipment	Total 2021
Carrying amount 1 January	-	-	-	-
Additions	137	137	-	-
Depreciation	(6)	(6)	-	-
<b>Carrying value 30 June</b>	<b>132</b>	<b>132</b>	-	-
As of 1 January				
Acquisition cost	-	-	-	-
Accumulated depreciation and write-downs	-	-	-	-
<b>Carrying amount 1 January</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
As of 30 June				
Acquisition cost	137	137	-	-
Accumulated depreciation and write-downs	(6)	(6)	-	-
<b>Carrying amount 30 June</b>	<b>132</b>	<b>132</b>	<b>-</b>	<b>-</b>

**NOTE 7** INTANGIBLE ASSETS

The company has no intangible assets as all ongoing projects have been classified as research.

**NOTE 8** CASH AND CASH EQUIVALENTS

<i>Amounts in NOK thousands</i>	30.06.2022	30.06.2021	31.12.2021
<b>Cash and cash equivalents</b>			
Employee withholding tax	2 416	1 304	1 411
Variable rate bank accounts	174 668	69 646	195 871
<b>Total Cash and cash equivalents</b>	<b>177 084</b>	<b>70 950</b>	<b>197 282</b>

**NOTE 9** FOREIGN CURRENCY RISK

Lytx Biopharma AS is on a regular basis transacting in various currencies other than the functional currency (NOK). This implies that the company is exposed to currency fluctuations. Transactions related to the ATLAS-IT-05 study are mainly denominated in USD, and Lytx has consequently placed a significant part of its cash

position in USD to hedge part of the foreign currency risk. For the six months ended June 30, 2022, net financial income came in at NOK 8.3 million. The increase in net financial income is mainly a result of a conversion of the USD cash position into NOK.

**NOTE 10** TRADE AND OTHER RECEIVABLES

<i>Amounts in NOK thousands</i>	30.06.2022	30.06.2021	31.12.2021
<b>Trade and other receivables</b>			
Trade receivables	-	-	-
Governmental grants	6 322	6 120	4 824
VAT	274	519	309
Prepayments	297	639	548
Other receivables	-	155 514	-
<b>Total trade and other receivables</b>	<b>6 893</b>	<b>162 792</b>	<b>5 680</b>

**NOTE 11 EQUITY AND SHARE CAPITAL**

<i>Amounts in NOK thousands</i>	Share capital	Share premium reserve	Total equity
<b>Balance at 1 January 2022</b>	3 874	185 750	<b>189 624</b>
<b>Income for the period</b>			
Loss for the period	-	(16 414)	<b>(16 414)</b>
<b>Total income for the period</b>	-	(16 414)	<b>(16 414)</b>
Registration of share issue 20 April 2022	133		<b>133</b>
Share based payment		624	<b>624</b>
<b>Total contributions by and distributions to owners</b>	133	624	<b>757</b>
<b>Balance at 30 June 2022</b>	4 007	169 960	<b>173 967</b>

<i>Amounts in NOK thousands</i>	Share capital	Share premium reserve	Total equity
<b>Balance on January 1, 2021</b>	2 623	17 266	<b>19 889</b>
<b>Income for the period</b>			
Loss for the period	-	(48 049)	<b>(48 049)</b>
<b>Total income for the period</b>	-	(48 049)	<b>(48 049)</b>
Registration of share issue June 10, 2021	323	57 891	<b>58 214</b>
Registration of share issue June 11, 2021	928	166 072	<b>167 000</b>
Transaction cost	-	(11 486)	<b>(11 486)</b>
Share based payment	-	4 055	<b>4 055</b>
<b>Total contributions by and distributions to owners</b>	1 251	216 532	<b>217 783</b>
<b>Balance on December 31, 2021</b>	3 874	185 750	<b>189 624</b>

Share capital on 30 June 2022 is NOK 4 006 831.9 (31 December 2021: NOK 3 783 901), being 40 068 319 ordinary shares at a nominal value of NOK 0.1. All shares carry equal voting rights.

## Change in the number of shares during the period was as follows:

	30.06.2022	31.12.2021
Ordinary shares on 1 January	38 739 013	26 227 120
Capital increase 10 June 2021 <sup>1)</sup>	-	3 234 116
Capital increase 11 June 2021 <sup>2)</sup>	-	9 277 777
Capital increase 20 April 2022 <sup>3)</sup>	1 329 306	-
<b>Ordinary shares at 30 June 2022 / 31 December 2021</b>	<b>40 068 319</b>	<b>38 739 013</b>

1) In May 2021, 3 234 116 shares were subscribed for in a national placement among existing shareholders and selected potential investors at a share price of NOK 18 for total gross proceeds of NOK 58 million. The share issue was approved by the Annual General Meeting held on 7 June 2021. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on 10 June 2021.

2) In June 2021, 9 277 777 shares were subscribed for in a private placement among existing shareholders and selected potential investors at a share price of NOK 18 for total gross proceeds of NOK 167 million. The issuance of 9 277 777 new shares in the private placement was completed by the General Meeting issuing 9 000 000 new shares at the Annual General Meeting held 7 June 2021, and by the board of directors issuing 277 777 new shares at the meeting held on 8 June 2021 under the authorization from the General Meeting dated 7 June 2021. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on 11 June 2021.

3) On 15 March 2022, Lytix announced that PBM LYT, an affiliate of PBM Capital Group, LLC, exercised 1 329 306 warrants giving rights to 1 329 306 shares. Reference is made to the warrants issued by the Company's General Meeting on 7 June 2021, with a subscription price per share of NOK 0.1 and with an expiry date of 6 June 2022. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on 20 April 2022.

## Top 20 shareholders at 31 June 2022

No.	Shareholder	No. of shares	Percentage share of total no. of shares
1	TAJ Holding AS	5 440 850	13.6%
2	Citibank, N.A.	3 691 267	9.2%
3	Jakob Hatteland Holding AS	3 000 000	7.5%
4	North Murray AS	2 810 359	7.0%
5	3T Produkter Holding AS	1 808 764	4.5%
6	Brødrene Karlsen Holding AS	1 709 274	4.3%
7	Care Holding AS	1 608 080	4.0%
8	Picasso Kapital AS	1 122 860	2.8%
9	Per Strand Eiendom AS	1 024 128	2.6%
10	Skandinaviska Enskilda Banken AB	869 372	2.2%
11	Lysnes Invest AS	615 654	1.5%
12	Kvasshøgdi AS	604 727	1.5%
13	Norinnova Invest AS	557 510	1.4%
14	HIFO Invest AS	555 555	1.4%
15	Saturn Invest AS	555 555	1.4%
16	Jahatt AS	500 000	1.2%
17	Hopen Invest AS	481 117	1.1%
18	Svenska Handelsbanken AB	423 823	0.8%
19	Belvedere AS	331 856	0.8%
20	Union Bancaire Privee, UBP SA	313 283	0.8%
	<b>Total number of shares for top 20 shareholders</b>	<b>28 024 034</b>	<b>69.9%</b>
	<b>Total number of shares for the other shareholders</b>	<b>12 044 285</b>	<b>30.1%</b>
	<b>Total number of shares</b>	<b>40 068 319</b>	<b>100.0%</b>



**Lytix Biopharma AS**  
Sandakerveien 138  
NO-0484 Oslo  
Norway

**Investor relations and media:**  
[ole.peter.nordby@lytixbiopharma.com](mailto:ole.peter.nordby@lytixbiopharma.com)

**Business development:**  
[bd@lytixbiopharma.com](mailto:bd@lytixbiopharma.com)

**General enquiries:**  
[post@lytixbiopharma.com](mailto:post@lytixbiopharma.com)

[www.lytixbiopharma.com](http://www.lytixbiopharma.com)