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Interim report  
Fourth quarter and second half 2021



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## Letter from the CEO

# At the forefront of cancer innovation with a firm position in the US



Entering 2022, Lytix Biopharma has achieved one of its 2021 primary objectives by establishing a firm position in the US, the most important market for medical innovation. We have launched a clinical Phase II study in US on our lead cancer compound LTX-315 and started the recruitment of patients. In addition, our commercial partner Verrica Pharmaceuticals received clearance for their Investigational New Drug (IND) to initiate a Phase II study with LTX-315 in the US in patients with skin cancer, and they expect first patient early this year. LTX-315's clinical evaluation in two Phase II clinical trials at significant hospitals in the US demonstrates that Lytix now has transitioned from a discovery to a mature drug development company, with a technology platform offering a large commercial potential.

As part of our global expansion strategy, we have added new members to our staff and network in the US. Collaboration with academic partners is leading to new publications bringing attention to the superiority of our first-in-class in situ vaccination technology. By example, our excellent research collaborators at Weill Cornell Medicine in New York have documented that LTX-315 works in aggressive breast cancer models that are resistant to market approved immunotherapy.

We were very pleased when the U.S. Food and Drug Administration (FDA) accepted our partner Verrica Pharmaceutical's IND application in November, a major corporate milestone. Impressively, based upon significant preparation, Verrica announced that they expect to enroll the first patient in their Phase II study in the first quarter of 2022. They plan to treat patients with basal cell carcinoma - a skin cancer - with LTX-315. It is estimated that more than four million new patients in the US alone are burdened with this disease each year. As Verrica's product development program progresses and LTX-315 passes successfully through testing, Lytix is entitled to receive a total

of USD 111 million in milestone payments as well as royalties on product sales.

Importantly also, we recruited the first patient in our Phase II clinical study at MD Anderson Cancer Center in Houston, Texas. MD Anderson is one of the world's leading cancer hospitals, and the hospital where Nobel Prize winner Dr. Jim Allison works as a professor and chair of the department of immunology. Dr. Allison holds a position on Lytix Biopharma's advisory board and has contributed critically to the design and execution of our clinical study.

Cancer is a heterogeneous disease, and the need for effective immunotherapy that can meet this challenge remains urgent, as most patients do not respond to currently approved treatment regimens and checkpoint inhibitors. In the coming year, we are confident that we will add to our growing pipeline and library of robust clinical data supporting further late-stage development and commercial potential of Lytix' oncolytic molecules. All patients in our Phase II soft tissue sarcoma study at Herlev Hospital, Denmark, have completed treatment, and we look forward to presenting data from this study at an international cancer congress later this year. Though the ongoing COVID-19 pandemic has caused some disruption to our clinical trial activities, we are pleased to report that our newly launched Phase II trial, ATLAS-IT-05, is on track to complete enrollment by the end of 2022. In addition, we are mapping additional opportunities to expand our innovative pipeline of molecules. We are confident that our technology platform addresses the major challenge in immunotherapy and look forward to keeping the market updated on the path towards multiple significant inflection points.

**Øystein Rekdal**  
CEO Lytix Biopharma



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# Highlights and key figures

## Highlights from the fourth quarter and second half 2021

### Business and Partnership:

- Verrica Pharmaceuticals received approval from the U.S. Food and Drug Administration to initiate a Phase II study for LTX-315 in basal cell carcinoma (skin cancer). First patient enrolled in the study expected in the first quarter of 2022.

### Research and development:

- The first patient in the Phase II clinical trial (ATLAS-IT-05) started treatment at MD Anderson Cancer Center in Texas. This event marks an important milestone for Lytix. We expect the study will deliver additional key data in support of the solution Lytix' unique technology offers to cancer patients.

- Three new patents for LTX-315 have been granted, two in the US and one in the EU, strengthening the business case. Securing IP rights is critical for the protection of Lytix' technology platform and the long-term value generation.
- The LTX-315 study for soft tissue sarcoma at Herlev in Denmark (ATLAS-IT-04) is fully enrolled with the last patient completing treatment. The study explores the potential for the application of LTX-315 in a personalized adoptive T-cell therapy setting. Data from the study is being prepared for presentation at international cancer conferences.
- For LTX-401 – a second-generation molecule expanding the market to new indications - the preclinical preparations are progressing as planned to support submission of clinical trial application for Phase I study in 2022.

- Lytix presented data at Society for Immunotherapy of Cancer (SITC) 2021 in US showing that LTX-315 provides strong therapeutic effects in a preclinical breast cancer model that is resistant to immune checkpoint inhibitors.

### Financial:

- Total operating expenses for the six months ended 31 December 2021 were related to increased R&D activities in connection to the ongoing ATLAS-IT-05 trial in the US, the ATLAS-IT-04 trial in Denmark as well as the progression of the preclinical development of LTX-401.
- Cash position at the end of the period was NOK 197.3 million compared to NOK 28.5 million as of 31 December 2020.

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

(in NOK thousands)	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
Total operating income	719	1 951	2 626	5 433	25 827	6 678
Total operating expense	(17 087)	(14 598)	(37 790)	(33 372)	(73 844)	(49 050)
<b>Loss from operations</b>	<b>(16 368)</b>	<b>(12 646)</b>	<b>(35 164)</b>	<b>(27 940)</b>	<b>(48 017)</b>	<b>(42 372)</b>
<b>Loss for the period</b>	<b>(16 395)</b>	<b>(12 491)</b>	<b>(35 301)</b>	<b>(27 669)</b>	<b>(48 049)</b>	<b>(42 088)</b>
Cash position at the end of the period	-	-	-	-	197 282	28 450
Trade and other receivables	-	-	-	-	5 680	4 168
<b>Total assets</b>	-	-	-	-	<b>202 962</b>	<b>32 617</b>
Total equity	-	-	-	-	189 624	19 889
Total liabilities	-	-	-	-	13 338	12 728
<b>Total equity and liabilities</b>	-	-	-	-	<b>202 962</b>	<b>32 617</b>

1) Interim figures are unaudited.



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# Review of the fourth quarter and second half year 2021

## Operational review

### PARTNERSHIPS

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

In November 2021, the U.S. Food and Drug Administration (FDA) accepted Verrica Pharmaceutical Inc's ("Verrica") (NASDAQ: VRCA) Investigational New Drug Application ("IND") for LTX-315 for the treatment of basal cell carcinoma. The collaboration with Verrica constitutes an essential part of Lytix' development program for LTX-315, and the FDA approval for the initiation of Verrica's Phase II study in basal cell carcinoma (BCC) adds extensive value to our development program. Verrica expects to initiate its Phase II trial of LTX-315 in the first quarter of 2022, and the study is expected to deliver a comprehensive amount of additional data in support for the therapeutic activity of LTX-315. The initiation of the study will trigger a milestone payment to Lytix.

With the Phase II study lined up to recruit patients from Q1 2022, Verrica has shown dedication to bring this novel immunotherapy forward to the clinic as a potential new non-surgical treatment for skin cancer. LTX-315 could be a remarkably innovative approach to skin cancer and represents a new paradigm beyond invasive surgery as the preferred treatment of BCC.

### RESEARCH AND DEVELOPMENT

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

Lytix opened a Phase II clinical trial in the US this summer, designed to assess the safety and efficacy of LTX-315 in solid tumors. In this clinical trial, LTX-315 will be evaluated in combination with the immune checkpoint inhibitor pembrolizumab (Keytruda®), which blocks tumor cells' ability to prevent the body's immune response. Results from earlier studies indicate that the combination of LTX-315 and pembrolizumab may work better than pembrolizumab alone. The aim of the trial is to document LTX-315's ability to enhance the number of cancer patients responding to checkpoint inhibitors.

The first patient started treatment at MD Anderson Cancer Center in December 2022. Treating the first patient marks an important milestone for Lytix along the path to demonstrate that Lytix' unique technology offers a solution to today's cancer treatment challenges, through activation of the body's own immune system.

The clinical trial is a multicenter study with MD Anderson Cancer Center in Texas as first site and Mount Sinai Hospital as the second site. Due to the COVID-19 pandemic's effect on number of patients available for clinical trials and the extreme competitive landscape, the company is searching for additional sites in the US and EU that will come online in 2022. In the pursuit for new sites, the search is only focused on hospitals with expertise within the field of intratumoral treatment. Expanding beyond the US transforms our clinical trial to a true global clinical trial.

MD Anderson is one of the world's leading cancer hospitals, and also the hospital where Nobel Prize winner Dr. Jim Allison works as a professor and chair of the department of immunology. Dr. Allison holds a position on Lytix Biopharma's advisory board. Enrolled patients will receive treatment with LTX-315 for up to five weeks. Pembrolizumab therapy will be administered with LTX-315 and then alone until progression or up to a maximum of 24 months. More information about the trial is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

*ClinicalTrials.gov Identifier: NCT04796194*

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

Lytix is currently finalizing a clinical trial at Herlev Hospital, Denmark, to assess the safety and efficacy of intratumoral administration of LTX-315 in combination with adoptive T-cell therapy in patients with advanced soft tissue sarcoma. The aim of this study is to reveal whether LTX-315's unique mechanism of action generates T cells that specifically recognize and kill the patient's tumor. Generation of such tumor antigen specific T cells will provide strong evidence of LTX-315's mode of action and strengthen its clinical potential.

Six patients have received LTX-315 treatment. Enrollment has been completed. Results are planned to be presented at an international cancer congress later this year.

*ClinicalTrials.gov Identifier: NCT03725605*



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### Key data presented at Society for Immunotherapy of Cancer (SITC) 2021

In November 2021, encouraging preclinical data from a study in triple negative breast cancer (TNBC) were presented at the Society for Immunotherapy of Cancer's 36th Annual Meeting (SITC 2021). The study was a collaborative research effort between Lytix and the excellent research groups of Drs. Lorenzo Galluzzi and Sandra Demaria at Weill Cornell Medicine in New York.

Among the different subtypes of breast cancer, TNBC is the most difficult to treat. The TNBC model that was used is resistant to checkpoint inhibitors and has several characteristics that resembles human TNBC.

An encouraging finding was that LTX-315 provided protection against metastatic lesions in the lungs when injected into breast tumors. Evenly important, this effect of LTX-315 was further improved when combined with checkpoint inhibitors. These results are congruent with and complementary to the findings documented in breast cancer patients, where tumors in the lung were reduced following LTX-315 treatment in breast lesions. The experimental analysis also gave further insight to how LTX-315 stimulates the immune system to control breast cancer progression.

These findings provide scientific rationale for the potential to combine LTX-315 with checkpoint inhibitors.

The detailed data presented at SITC can be reviewed from a scientific article in *OncoImmunology*, a leading journal within the cancer immunology field entitled.

## Financial review

### PROFIT AND LOSS

Total operating income for the six months ended 31 December 2021 amounted to NOK 2.6 million (NOK 5.4 million for the six months ended 31 December 2020). Operating income in the period was mainly related to government grants recognized in profit and loss. Other income for the second half of 2021 includes governmental grants of NOK 2.6 million (NOK 3.0 million).

Personnel expenses for the six months ended 31 December 2021 came in at NOK 14.3 million (NOK 16.7 million for the six months ended 31 December 2020). The decreased personnel expenses are explained by lower share-based payment expenses. Direct R&D expenses amounted to NOK 19.2 million for the six months ended 31 December 2021 (NOK 12.0 million for the six months ended 31 December 2020). Direct R&D expenses for the second half were related to increased activities in connection to the

### Intellectual property (IP) rights

Three new patents have been granted, two in the US and one in the EU. These patents are important milestones in the company's Intellectual Property (IP) strategy and further strengthens our business case. IP rights is critical for the protection of Lytix' technology platform and the long-term value generation of the company. The EU patent covers the use of LTX-315 in combination with a chemotherapeutic agent. The two new patents in the US covers the use of LTX-315 in combination with a chemotherapeutic agent and with the checkpoint inhibitor ipilimumab.

#### LTX-401

LTX-401 is a next generation oncolytic molecule for targeting deep-seated lesions such as liver cancer. This candidate drug expands the application of our in situ vaccination technology to several additional major cancer indications. LTX-401 is currently going through a preclinical program at Aptuit in Italy for assessment of all requirements needed for starting human clinical trials. The program is expected to finish in the first half of 2022. Favorable safety data received so far confirms the suitability of LTX-401 injections in deep-seated lesions. Lytix is heading for submission of clinical trial application late this year for a Phase I study to be performed in Europe.

#### LTX-122

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

ongoing ATLAS-IT-05 trial in the US, the ATLAS-IT-04 trial in Denmark as well as the progression of the preclinical development of LTX-401. Furthermore, other operating expenses decreased to NOK 4.2 million (NOK 4.6 million). Loss from operations for the second half of 2021 amounted to NOK 35.2 million (NOK 27.9 million).

### Cash flow

Cash flow from operating activities amounted to positive NOK 126.3 million for the six months ended 31 December 2021 compared to negative NOK 13.8 million for the six months ended 31 December 2020. The positive cash flow from operating activities is explained by the proceeds from the private placement in June not being settled by 30 June 2021. Lytix received the proceeds in Q3 2021. There were no cash flows from financing activ-



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ities for the six months ended 31 December 2021. Cash and cash equivalents at the end of the reporting period amounted to NOK 197.3 million compared to NOK 28.5 million at 31 December 2020 and NOK 71.0 million at 30 June 2021.

#### Statement of financial position / balance sheet

On 14 June 2021, the company listed its shares at Euronext Growth in Oslo. The listing followed the successful completion of a private placement and a national offering together raising NOK 225 million in new equity. Hence, total assets on 31 December 2021 were NOK 202.9 million compared to NOK 32.6 million on 31 December 2020 and NOK 233.7 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. As part of this process, in situ vaccination results in an efficient

## Product 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 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 100's 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 adjunct to cell therapy.

### IN SITU VACCINATION

#### – delivering immunotherapy straight into the tumor

In situ vaccination stimulates a patient's immune system by injecting drugs with the ability to kill cancer cells straight into the tumor environment. Lytix Biopharma 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 without pre-identifying the antigens, which in turn can save considerable costs and valuable time.

release of tumor neoantigens (mutated proteins) and immune activating molecules. This unique way of killing 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).

They 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.

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 high unmet medical need.

LTX-401 is a second-generation candidate drug with improved properties; it is smaller and thus can be administered at higher doses than LTX-315 and used for treatment of tumors seated deep in the body. The plan is to forward LTX-401 into a human clinical trial in 2023.



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Product candidate	Combination partner	Population	Preclinical	Phase I	Phase II	Phase III	Collaborators
LTX-315	Atlas-IT-05 Pembrolizumab (Keytruda®)	Patient progressed on checkpoint inhibitors	→				THE UNIVERSITY OF TEXAS MDAnderson Cancer Center
	Monotherapy	Basal cell carcinoma	→				VERRICA PHARMACEUTICALS Reinventing Skin Science
	Atlas-IT-04 Adoptive T cell therapy	Advanced soft tissue sarcoma	→				REGION H Herlev Hospital
LTX-401	Monotherapy	Live cancer	→			aptuit	
LTX-122	Adoptive T cell therapy	Dog lymphoma	→			Aurelius BIOTHERAPEUTICS	
<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, B et al. 2017).

The preclinical findings conveying the rationale for 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 the 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 contributes 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 is administered in combination with adoptive T-cell 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 clinical response. The study is now finalized, and the results are under preparation for a presentation within 1H 2022.

### LTX-401

LTX-401 is a small molecule that has a potential for the treatment of deep-seated tumors such as hepatocellular carcinoma



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(liver cancer) and liver metastases. In several experimental models, LTX-401 induces complete regression after intratumoral injection with a 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 is now progressing through a preclinical program towards a first clinical study expected to be performed in 2023.

#### 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

### VERRICA PHARMACEUTICALS INC

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 world-wide license to develop and commercialize LTX-315 for all 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 111m as signing fee and 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. 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% 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 T-cell transfer to treat dog lymphoma.

## The type and location of the business

Lytix Biopharma AS is a company whose business consists of research and development work in bio-technology. The company was established in 2003 and is located in Oslo, Norway.

Lytix' strategy involves developing projects through Phase II, and subsequently collaborate with partners for late-stage development and commercialization. The company considers retaining commercial rights in selected geographical areas and considers strategic partnerships, at any point in time if appropriate and in the best interest of Lytix.

#### GOING CONCERN

These interim financial statements have been prepared under the assumption that the company will continue as a going concern. The going concern basis of presentation assumes that the company will be able to meet its obligations and continue its operations for the foreseeable future and be able to realize its assets and discharge its liabilities and commitments in the normal course of business. The company's ability to continue as a going concern depends on its ability to obtain additional equity financing. The company has funded its operations primarily by shares issuances.



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#### REPORT ON THE INTERIM ACCOUNTS

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 December 2021 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 at 31 December 2021. 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.

#### FINANCIAL RISKS

The company has no interest-bearing debt. Bank deposits are exposed to market fluctuations in interest rates, which affects financial income. Currency risk is limited to fluctuations in currencies relating to partners and vendors abroad. The credit risk is limited as revenues are minimal exclusive of public grants.

#### NON-FINANCIAL RISKS

##### Technology risk

The company's lead product candidate, LTX-315, is still at an early stage (Phase II) and the clinical studies may not prove to be successful.

##### 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.

#### POST-BALANCE SHEET EVENTS

In fiscal year 2021, the company is dealing with the consequences of the COVID-19 virus. Government measures to curb the virus have affected economic activity. The company considers this to be an event after the balance sheet date that does not provide any further information about the actual situation on the balance sheet date. Several measures have been taken to limit the effects of the COVID-19 virus, such as safety and health measures for all employees (such as social distancing and working from home). Lytix will continue to follow government policies and advice while doing its best to continue operations in the best possible and safest way without compromising the health of company staff members. These measures are reason for the board of directors to rely on the sustainable continuation of the business activities so that the financial statements are prepared on a going concern basis.

#### WORKING ENVIRONMENT, EQUAL OPPORTUNITY, AND DISCRIMINATION

The board considers that the working environment in the company is good. No special measures have been implemented in this connection. The employees of the business have not suffered accidents or injury in connection with their work. Total sick leave over the accounting period has been of a modest number.

Lytix Biopharma AS has a goal to be a workplace where there is full equality of opportunity between men and women and has established a personnel policy that is considered to be gender neutral in all areas.

#### ENVIRONMENT REPORTING

Lytix strives to minimize its environmental footprint. All company activities are subject to strict requirements in terms of quality, safety and impacts on personal health and the environment. Lytix' operations do not directly pollute or harm the external environment more than what is considered normal for this industry. The environmental footprint stems mainly from the resources consumed in office spaces as well as indirect business activities such as travel and supply chain operations. All production and distribution activities are outsourced.



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#### RESEARCH AND DEVELOPMENT ACTIVITIES

Expenditure on research and development activities is recognized as an expense in the period in which it is incurred. Internal research and development expenses related to the company's development of products are recognized in the income statement in the year incurred unless it meets the asset recognition criteria Intangible Assets. An internally generated asset arising from the research and development phase of an R&D project is recognized if, and only if, all the following has been demonstrated:

- Technical feasibility of completing the intangible asset so that it will be available for use or sale
- The intention to complete the intangible asset and use or sell it
- The ability to use or sell the intangible asset

- How the intangible asset will generate probable future economic benefits
- The availability of adequate technical, financial, and other resources to complete the development and use or sell the intangible asset
- The ability to measure reliably the expenditure attributable to the intangible asset during its development

Uncertainties related to the regulatory approval process and results from ongoing clinical trials generally indicate that the criteria are not met until the time when marketing authorization is obtained from relevant regulatory authorities. The company has currently no development expenditure that qualifies for recognition as an intangible asset.

Oslo 16 February 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



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## Interim statement of profit or loss<sup>1</sup>

Amounts in NOK thousands	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
Revenue	-	-	-	-	17	3
Other operating income	719	1 951	2 626	5 433	25 810	6 675
<b>Total operating income</b>	<b>719</b>	<b>1 951</b>	<b>2 626</b>	<b>5 433</b>	<b>25 827</b>	<b>6 678</b>
Payroll and related expenses	(8 701)	(5 561)	(14 309)	(16 735)	(31 605)	(23 416)
Direct R&D expenses	(6 161)	(7 102)	(19 248)	(12 048)	(28 817)	(16 008)
Other expenses	(2 225)	(1 934)	(4 233)	(4 589)	(13 421)	(9 626)
<b>Total operating expenses</b>	<b>(17 087)</b>	<b>(14 598)</b>	<b>(37 790)</b>	<b>(33 372)</b>	<b>(73 844)</b>	<b>(49 050)</b>
<b>Loss from operations</b>	<b>(16 368)</b>	<b>(12 646)</b>	<b>(35 164)</b>	<b>(27 940)</b>	<b>(48 017)</b>	<b>(42 372)</b>
<b>Net financial items</b>	<b>(27)</b>	<b>155</b>	<b>(137)</b>	<b>271</b>	<b>(32)</b>	<b>284</b>
<b>Loss before tax</b>	<b>(16 395)</b>	<b>(12 491)</b>	<b>(35 301)</b>	<b>(27 669)</b>	<b>(48 049)</b>	<b>(42 088)</b>
Tax expense	-	-	-	-	-	-
<b>Loss for the period</b>	<b>(16 395)</b>	<b>(12 491)</b>	<b>(35 301)</b>	<b>(27 669)</b>	<b>(48 049)</b>	<b>(42 088)</b>

<sup>1)</sup> Interim figures are unaudited.



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## Interim statement of financial position<sup>1</sup>

Amounts in NOK thousands	30.06.2021	30.09.2021	31.12.2021	31.12.2020
<b>Assets</b>				
<b>Current Assets</b>				
Trade and other receivables	162 792	4 957	5 680	4 168
Cash and cash equivalents	70 950	209 177	197 282	28 450
<b>Total current assets</b>	<b>233 742</b>	<b>214 134</b>	<b>202 962</b>	<b>32 617</b>
<b>Total assets</b>	<b>233 742</b>	<b>214 134</b>	<b>202 962</b>	<b>32 617</b>
<b>Shareholder's equity and liabilities</b>				
<b>Issued capital and reserves</b>				
Share capital	3 874	3 874	3 874	2 623
Share premium reserve	219 156	201 436	185 750	17 266
<b>Total equity</b>	<b>223 030</b>	<b>205 310</b>	<b>189 624</b>	<b>19 889</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade payables	2 775	1 366	1 476	3 284
Other current liabilities	7 937	7 458	11 862	9 444
<b>Total current liabilities</b>	<b>10 712</b>	<b>8 825</b>	<b>13 338</b>	<b>12 728</b>
<b>Total liabilities</b>	<b>10 712</b>	<b>8 825</b>	<b>13 338</b>	<b>12 728</b>
<b>Total equity and liabilities</b>	<b>223 742</b>	<b>214 134</b>	<b>202 962</b>	<b>32 617</b>

1) Interim figures are unaudited.



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## Interim statement of cash flows<sup>1</sup>

<i>Amounts in NOK thousands</i>	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
<b>Cash flows from operating activities</b>						
Loss for the period	(16 395)	(12 491)	(35 301)	(27 669)	(48 049)	(42 088)
<b>Adjustments for:</b>						
Share-based payment expense	709	748	1 894	7 695	4 055	8 397
Increased/decreased in trade and other receivables	(723)	1 504	157 112	1 291	(1 513)	471
Increased/decreased in trade and other payables	4 514	4 157	2 626	4 853	610	8 874
<b>Cash generated from operations</b>	<b>(11 896)</b>	<b>(6 083)</b>	<b>126 332</b>	<b>(13 830)</b>	<b>(44 896)</b>	<b>(24 347)</b>
Income tax paid	-	-	-	-	-	-
<b>Net cash flows from operations</b>	<b>(11 896)</b>	<b>(6 083)</b>	<b>126 332</b>	<b>(13 830)</b>	<b>(44 896)</b>	<b>(24 347)</b>
<b>Financing activities</b>						
Proceeds from share issue	-	-	-	-	213 728	40 000
<b>Net cash from/(used in) financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>213 728</b>	<b>40 000</b>
Net increase in cash and cash equivalents	(11 896)	(6 083)	126 332	(13 830)	168 832	15 653
Cash and cash equivalents at the beginning of the period	209 177	34 532	70 950	42 279	28 450	12 796
<b>Cash and cash equivalents at the end of the period</b>	<b>197 282</b>	<b>28 450</b>	<b>197 282</b>	<b>28 450</b>	<b>197 282</b>	<b>28 450</b>

1) Interim figures are unaudited.



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

### Accounting principles

The 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 2020 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% 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.

<sup>1)</sup> Interim figures are unaudited.



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## NOTE 1 REVENUE

<i>Amounts in NOK thousands</i>	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
<b>Revenue</b>						
Other income	-	-	-	-	17	3
<b>Total Revenue</b>	-	-	-	-	17	3

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>	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
<b>Other operating income</b>						
Government grants recognized in profit and loss	719	1 860	2 626	3 012	6 332	4 071
Other	-	91	-	2 412	19 478	2 604
<b>Other operating income</b>	719	1 951	2 626	5 433	25 810	6 675

## NOTE 3 PAYROLL AND RELATED EXPENSES

<i>Amounts in NOK thousands</i>	Q4 2021	Q4 2020	2H 2021	2H 2020	FY 2021	FY 2020
<b>Payroll and related expenses, including directors, comprise</b>						
Wages and salaries	7 016	3 924	10 591	6 600	24 381	10 952
Defined contribution pension const	211	159	422	260	789	463
Share-based payment expense	709	853	1 894	8 799	4 055	8 397
Social security contributions	562	578	1 005	993	1 864	2 874
Other personnel costs	203	47	397	104	517	730
<b>Total payroll and related expenses</b>	8 701	5 561	14 309	16 735	31 605	23 416

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 4 INTANGIBLE ASSETS

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

## NOTE 5 CASH AND CASH EQUIVALENTS

<i>Amounts in NOK thousands</i>	30.06.2021	30.09.2021	31.12.2021	31.12.2020
<b>Cash and cash equivalents</b>				
Employee withholding tax	1 304	1 178	1 411	1 299
Variable rate bank accounts	69 646	207 999	195 871	27 150
<b>Total Cash and cash equivalents</b>	70 950	209 177	197 282	28 450



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## NOTE 6 TRADE AND OTHER RECEIVABLES

<i>Amounts in NOK thousands</i>	30.06.2021	30.09.2021	31.12.2021	31.12.2020
<b>Trade and other receivables</b>				
Trade receivables	-	-	-	-
Governmental grants	6 120	4 105	4 824	3 168
VAT	519	88	309	463
Prepayments	639	764	548	536
Other receivables	155 514	-	-	-
<b>Total trade and other receivables</b>	<b>162 792</b>	<b>4 957</b>	<b>5 680</b>	<b>4 168</b>

## NOTE 7 EQUITY AND SHARE CAPITAL

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

<i>Amounts in NOK thousands</i>	Share capital	Share premium reserve	Total equity
<b>Balance at 1 January 2020</b>	2 289	11 291	13 580
<b>Income for the period</b>			
Loss for the period	-	(42 088)	(42 088)
<b>Total income for the period</b>	-	(42 088)	(42 088)
Registration of share issue 16 March 2020	292	34 708	35 000
Registration of share issue 16 April 2020	42	4 958	5 000
Share based payment	-	8 397	8 397
<b>Total contributions by and distributions to owners</b>	<b>333</b>	<b>48 064</b>	<b>48 397</b>
<b>Balance at 31 December 2020</b>	<b>2 623</b>	<b>17 266</b>	<b>19 889</b>

Share capital at 31 December 2021 is NOK 3 873 901.3 (31 December 2020: NOK 2 622 712), being 38 739 013 ordinary shares at a nominal value of NOK 0.1. All shares carry equal voting rights.



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

	31.12.2021	31.12.2020
Ordinary shares at 1 January	26 227 120	22 893 784
Capital increase 16 March 2020 <sup>1)</sup>	-	2 916 667
Capital increase 16 April 2020 <sup>2)</sup>	-	416 669
Capital increase 10 June 2021 <sup>3)</sup>	3 234 116	-
Capital increase 11 June 2021 <sup>4)</sup>	9 277 777	-
Ordinary shares per 30 June 2020 / 31 December 2020	38 739 013	26 227 120

1) In February 2020, 2 916 667 shares were subscribed for in a private placement among existing shareholders at a share price of NOK 12 for total gross proceeds of NOK 35 million. The share issue was approved by the board of directors in the meeting held on 18 February 2020 under the existing authorization from the General Meeting dated 12 June 2019. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on 16 March 2020.

2) In March 2020, 416 669 shares were subscribed for in a private placement among existing shareholders at a share price of NOK 12 for total gross proceeds of NOK 5 million. The share issue was approved by the board of directors in the meeting held on 17 March 2020 under the existing authorization from the General Meeting dated 12 June 2019. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on 16 April 2020.

3) 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.

4) 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.

PBM LYT Holdings, LLC ("PBM LYT"), an affiliate of PBM Capital Group, LLC ("PBM"), pre-committed for NOK 42.5 million in the private placement conditional upon the company issuing to PBM LYT a number of warrants equal to 56.3 per cent of the number of shares subscribed for by PBM LYT in the private placement. Each warrant has a duration of 12 months and shall give the right upon exercise to subscribe for one share in the company at a subscription price of NOK 0.10 any time after the date falling 90 days after the company's

first trading day on Euronext Growth. The decision to offer PBM LYT to subscribe for warrants was based on the belief that the precommitment by PBM LYT in the private placement, was of crucial importance for the successful completion of the private placement, and thus the financing of the Companies activities. Further, the company held the opinion that PBM LYT, as a shareholder in the company, would provide additional value to the company given their broad contact network in the United States.



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#### Top 20 shareholders as of 31 December 2021:

No.	Shareholder	No. of shares	Percentage share of total no. of shares
1	Taj Holding AS	5 440 850	14.0%
2	Jakob Hatteland Holding AS	3 000 000	7.7%
3	North Murray AS	2 810 359	7.3%
4	PBM Lyt Holdings, LLC	2 361 111	6.1%
5	3T Produkter Holding AS	1 808 764	4.7%
6	Brødrene Karlsen Holding AS	1 709 274	4.4%
7	Care Holding AS	1 608 080	4.2%
8	Picasso Kapital AS	1 122 860	2.9%
9	Per Strand Eiendom AS	1 024 128	1.9%
10	Mikael Lønn	741 967	1.9%
11	Danske Bank A/S	685 184	1.8%
12	Lysnes Invest AS	615 654	1.6%
13	Kvasshøgdi AS	604 727	1.6%
14	Norinnova Invest AS	557 510	1.4%
15	Hifo Invest AS	555 555	1.4%
16	Saturn Invest AS	555 555	1.4%
17	Jahatt AS	500 000	1.3%
18	Hopen Invest AS	481 117	1.2%
19	Svenska Handelsbanken AB	420 423	1.1%
20	Belvedere AS	281 856	0.7%
<b>Total number of shares for top 20 shareholders</b>		<b>26 884 974</b>	<b>69.4%</b>
<b>Total number of shares for the other shareholders</b>		<b>11 854 039</b>	<b>30.6%</b>
<b>Total number of shares</b>		<b>38 739 013</b>	<b>100.0%</b>

#### NOTE 8 EVENTS AFTER THE REPORT DATE

In fiscal year 2021, the company is dealing with the consequences of the COVID-19 virus. Government measures to curb the virus have affected economic activity. The company considers this to be an event after the balance sheet date that does not provide any further information about the actual situation on the balance sheet date. We have taken several measures to limit the effects of the COVID-19 virus, such as safety and health measures for our people (such as social distancing and working from home). We will continue

to follow government policies and advice while doing our best to continue our operations in the best possible and safest way without compromising the health of our people. These measures, with the continued financial support of the company, are reason for the board of directors to rely on the sustainable continuation of the business activities so that the financial statements are prepared on a going concern basis.





## MENU:

### **Letter from the CEO**

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### **Highlights and key figures**

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Highlights from the fourth quarter and second half 2021

### **Review of the fourth quarter 2021**

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Operational review  
Financial review  
Platform technology  
Product portfolio  
Product candidates  
Partnerships  
The type and location of the business

### **Financial statements**

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Interim statement of profit or loss  
Interim statement of financial position  
Interim statement of cash flows

### **Notes to the financial statements**

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Note 1 Revenue  
Note 2 Other operating income  
Note 3 Payroll and related expenses  
Note 4 Intangible assets  
Note 5 Cash and cash equivalents  
Note 6 Trade and other receivables  
Note 7 Equity and share capital  
Note 8 Events after the report date

### **Contact information**

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

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

**Media enquiries:**  
[oystein.rekdal@lytixbiopharma.com](mailto:oystein.rekdal@lytixbiopharma.com)

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

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