Lytix Biopharma

Interim report

Fourth quarter and second half 2022

Letter from the CEO

Steady progress towards improving cancer treatment outcomes

Cancers are highly complex and dynamic diseases requiring innovative multimodal treatment approaches.

At Lytix, we are dedicated to solving some of the major hurdles of cancer treatment and working towards more successful treatment outcomes for more patients. The discovery of immune checkpoint inhibitors represents a significant breakthrough in the treatment of cancer patients. We are now in a position where we can boost the patient's own immune system and help the immune system identify and destroy cancerous cells. This has been an incredible development, but still, only a limited portion of cancer patients experience the curing effect of today´s immunotherapy.

So, where do we go from here? Our ambition is to be part of tomorrow's established cancer treatments by overcoming one of the major hurdles in immunotherapy – tumor heterogeneity. This phenomenon describes the fact that solid tumors mutate from a single mutated cell through a series of mutations and cell divisions, resulting in many different subpopulations of cancer cells with distinct mutations. Some of these cancer subclones are often resistant to current cancer therapies, making it very difficult to cure the cancer patient.

Lytix is meeting this challenge head-on. Our oncolytic molecules have been proven to kill all types of mutated cancer cells, including cancer cells that have been resistant to conventional treatment, such as chemotherapy and radiotherapy. Our ambition is clear; we want to overcome tumor heterogeneity and increase the number of patients responding to immunotherapy.

In the closing quarter of 2022, we were pleased to announce that we had expanded our ATLAS-IT-05 study in the US to three European countries. Enrolling patients across two continents, this Phase II combination study is evaluating our lead asset, LTX-315, in combination with immune checkpoint inhibitor (ICI) pembrolizumab in advanced melanoma and is now available to patients in Norway, Spain, France and the US. We have previously experienced recruitment delays due to COVID-19, but with the expansion of the study to six additional sites, recruitment has picked up and we are expecting to see patient recruitment completed by mid-2023.

Our partner, Verrica Pharmaceuticals, is showing good progress with their three-part Phase II trial evaluating LTX-315 in basal cell carcinoma. Verrica recently completed treatment in Part 1 of their Phase II study, and we are pleased to note that no safety issues were reported and that they were seeing a consistent response of clinical tumor necrosis at higher levels of dosing.

In November, we were invited by the Society for Immunotherapy of Cancer's (SITC) 2022 Annual Meeting in the US to present compelling new data describing how treatment with LTX-315 activates specific immune cells that are critical for proper priming of tumor-specific T cells.

In 2022, we completed the pre-clinical program for our second-generation compound, LTX-401, which has demonstrated promising results for deep-seated cancer lesions such as liver or colorectal cancer metastases. These cancer types represent a substantial unmet medical need, with liver cancer being one of the deadliest types of cancer worldwide. Liver cancer is characterised by a high degree of tumor heterogeneity, meaning it does not respond well to immunotherapy and checkpoint inhibitors. As a result, patients face few treatment options that demonstrate limited clinical benefit. We are preparing this asset for a Phase I study and plan to submit a CTA to regulatory authorities H2 2023 for approval to initiate the study. This will represent a significant milestone for Lytix as a company, validating the broad applicability of our technology platform and the ability of the team to deliver promising compounds suited for different types of cancers.

We are excited to receive results from the different clinical development programs for our molecules. Our molecules have a unique dual mode of action and can kill cancer cells in a way that activates a broad T-cell response that has the potential to target all cancer cells within heterogeneous tumors and thereby increasing the number of patients responding to immunotherapy.

The past year has represented several challenges for the biotech industry, which has been impacted by steep economic downturns and a challenging funding climate. Biotech companies have also experienced the continued impact of COVID-19, which has hampered patient enrollment in clinical trials. At Lytix, we are pleased to have a sufficient cash runway that will see us through 2023 and into 2024. This is due to our continued efforts to run a lean and effective organisation, which will not be significantly expanded during 2023.

Reflecting on the last 12 months, I would like to thank the Lytix team for their continued hard work and our shareholders for their continued support. Together, we are getting closer to making our molecules part of tomorrow's cancer treatment.

Looking at 2023, we have an exciting year ahead with several ongoing R&D activities. We are pleased with the progress we have made in 2022 and look forward to continuing to report on our development programs in the months to come.

Øystein Rekdal
CEO of Lytix Biopharma

Highlights and key figures

Highlights second half 2022

Business and Partnership:

- Verrica Pharmaceuticals recently completed treatment in Part 1 of their ongoing Phase II study evaluating LTX-315 in basal cell carcinoma. Part 1 has enrolled 10 patients and demonstrated a favorable safety and tolerability profile with no reported serious adverse events. Patients receiving the higher range of dosing experienced a consistent response of clinical tumor necrosis.
- Lytix Biopharma appointed Stephen Worsley as Chief Business Officer as part of the company's strong focus on exploring commercial opportunities for its drug candidates. Stephen brings a great track record of successful deals in oncology on assets in development and is now introducing Lytix assets to key opinion leaders and companies within the industry.

Resarch and development:

- Following approval of the clinical trial application (CTA) for ATLAS-IT-05 in Europe in Q3 2022, the Phase II study in the US has expanded to an additional three has expanded to an additional three European countries, Norway, France and Spain. All sites are open and recruiting patients with the aim of completing enrollment by mid-2023.
- Activities are ongoing to prepare for a regulatory submission, which is required to start a Phase I study with LTX-401.
- The Clinical Study Report for ATLAS-IT-04 has been completed. ATLAS-IT-04 showed encouraging data demonstrating that LTX-315 improved the outcome of adoptive cell transfer treatment, stabilising the disease in patients with progressive metastatic soft tissue sarcoma.
- Compelling data from Lytix' collaboration with research groups at National Cancer Institute and Weill Cornell Medicine were presented at the Society for Immuno-therapy of Cancer (SITC) Annual Meeting.

Financial:

- Total operating expenses for the six months ended 31 December 2022 ended at NOK 46.4 million compared to NOK 37.8 million in the same period in 2021. Compared to the six months ended 31 December 2021, there has been an increase in activities in connection to the ongoing ATLAS-IT-05 trial in the US and EU and the preclinical development of LTX-401. The important expansion of ATLAS-IT-05 to the EU has been driving costs during this period. In parallel, personnel expenses have decreased.
- Cash position at the end of the period was NOK 94.6 million compared with NOK 197.3 million as of 31 December 2021. In addition to the cash position, Lytix has NOK 50.6 million placed in a liquidity fund as of 31 December 2022. In total Lytix has NOK 145.2 in cash and short-term financial investments at the end of the year.

Key figures[1]

Amounts in NOK thousands	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Total operating income	**1 615**	719	**4 587**	2 626	**17 273**	25 827
Total operating expense	**(25 453)**	(17 087)	**(46 368)**	(37 790)	**(82 968)**	(73 844)
Loss from operations	**(23 837)**	(16 368)	**(41 781)**	(35 164)	**(65 695)**	(48 017)
Loss for the period	**(29 195)**	(16 395)	**(40 343)**	(35 301)	**(56 006)**	(48 049)
Property, plant and equipment					**124**	-
Trade and other receivables					**6 735**	5 680
Short-term financial investments					**50 606**	-
Cash position at the end of the period					**94 552**	197 282
Total assets					**152 017**	202 962
Total equity					**135 126**	189 624
Total liabilities					**16 891**	13 338
Total equities and liabilities					**152 017**	202 962

1) Interim figures are unaudited.

Review of the second half year 2022

Operational review

BUSINESS AND PARTNERSHIPS

LTX-315 development in partnership with Verrica

Verrica continued to progress its Phase II clinical trial of LTX-315 (VP-315), a potentially first-in-class oncolytic peptide immunotherapy, for the treatment of basal cell carcinoma. The Phase II trial is a three-part, open-label, multicenter, dose-escalation, proof-of-concept study with a safety run-in designed to assess the safety, pharmacokinetics and efficacy of LTX-315 when administered intratumorally to adults with biopsy-proven basal cell carcinoma.

Recently, Verrica completed treatment in Part 1 with 10 patients enrolled and a favorable safety and tolerability profile with no reported serious adverse events. The patients receiving the higher range of dosing experienced a consistent response of clinical tumor necrosis. Part 2 of the Phase II trial is expected to begin in the second quarter of 2023 and will further explore dosing regimens to allow Verrica to identify the recommended dose for Part 3 of the study, which is expected to start in the second half of 2023.

ClinicalTrials.gov Identifier: NCT05188729

RESEARCH AND DEVELOPMENT

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

In Q4 2022, Lytix Biopharma finalised the Clinical Study Report (CSR), which compiles all results of the Phase II ATLAS-IT-04 study. The CSR is a central document in the drug development and regulatory submission process. The report includes the scientific rationale for the study design methods and conduct of the study, individual patient data and details of analytical methods. Data from the ATLAS-IT-04 trial evaluating LTX-315 in sarcoma patients demonstrated that the compound could improve the outcome of adoptive cell transfer treatment in sarcoma patients. The results were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June and showed that LTX-315 stabilised the disease in heavily pre-treated patients with progressive metastatic soft tissue sarcoma for up to 26 weeks.

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. The MD Anderson Cancer Centre and Icahn School of Medicine at Mount Sinai are currently open in the US and recruitment is ongoing. Two additional sites in the US are in the process of opening and the study has been expanded to sites in Europe where recruitment is ongoing. In Norway, sites have opened at the Oslo University Hospital, Radiumhospitalet (Dr. Marta Nyakas) and Akershus University Hospital (Dr. Belal Aljabri). Three sites have opened in France at Hospital Lyon Sud (Dr. Stephane Dalle), Gustave Roussy Cancer Campus (Dr. Caroline Robert) and Centre Hospitalier Regional Universitaire De Lille (Dr. Laurent Mortier). Moreover, one site is opened in Spain at Clínica Universidad de Navarra (Dr. Miguel Sanmamed).

The expansion of the site network will drive enrollment towards completion and extend the clinical impact field for LTX-315. The European branch of the study is performed at highly recognised sites with intratumoral immunotherapy expertise, led by melanoma experts at each site. It will follow the same protocol as in the US and recruitment is expected to be completed by by mid-2023.

ClinicalTrials.gov Identifier: NCT04796194

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 activities needed to submit a clinical trial application for a Phase I trial. This includes work related to the development and manufacture of the investigational LTX-401 product, medical writing of the clinical trial protocol, Investigator brochure, IMPD (investigational medicinal product dossier) and other regulatory documents and activities related to the set-up of the clinical trial.

Financial review

PROFIT AND LOSS

Total operating income for the six months ended 31 December 2022 amounted to NOK 4.6 million (NOK 2.6 million for the six months ended 31 December 2021). Operating income in the period was mainly related to governmental grants of NOK 3.2 million (NOK 2.6 million), as well as revenue of NOK 1.4 million following the license agreement with Verrica Pharmaceuticals. This revenue is for sale of LTX 315 to Verrica for use in Verrica's development program. Personnel expenses for the six months ended 31 December 2022 came in at NOK 11.3 million (NOK 14.3 million for the six months ended 31 December 2021). The decrease in personnel expenses is mainly explained by lower bonus accruals and lower share-based payment expenses in 2022.

Direct R&D expenses amounted to NOK 28.2 million for the six months ended 31 December 2022 (NOK 19.2 million for the six months ended 31 December 2021). Direct R&D expenses for the second half were related to increased activities in connection to the ongoing ATLAS-IT-05 trial in the US and EU and the preclinical development of LTX-401. The important expansion of ATLAS-IT-05 to the EU has been driving costs. Furthermore, other operating expenses increased to NOK 6.9 million (NOK 4.2 million). Loss from operations for the second half of 2022 amounted to NOK 41.8 million (NOK 35.2 million).

Net financial items contributed positively to the net result with NOK 1.4 million in the second half of 2022 (negative NOK 0.1 million for the second half of 2021). Lytix has decided to hedge part of its expected USD cost related to the ATLAS-IT-05 study in the US and the net financial income for the second half of 2022 is mainly explained by the net currency gain from that USD cash position.

Cash flow

Cash flow from operating activities amounted to negative NOK 31.9 million for the six months ended 31 December 2022 compared with positive NOK 126.3 million for the six months ended 31 December 2021. The large positive cash flow from operating activities in 2021 was related to the settlement of the capital raised in the IPO. The IPO took place in the first half of 2021, while Lytix received the Proceeds in the second half of 2021. Cash flow from investing activities for the six months ended 31 December 2022 amounted to negative NOK 50.6 million, explained by a portion of the cash position being placed in a liquidity fund. Cash and cash equivalents at the end of the reporting period amounted to NOK 94.6 million compared with NOK 197.3 million as of 31 December 2021 and NOK 177.1 million as of 30 June 2022.

Statement of financial position / balance sheet

Total assets as of 31 December 2022 were NOK 152.0 million compared with NOK 203.0 million on 31 December 2021 and NOK 184.9 million as of 30 June 2022. Total current liabilities as of 31 December 2022 amounted to NOK 16.9 million compared to NOK 10.1 million as of 30 June 2022. Total equity decreased by NOK 39.6 million to NOK 135.1 million as of 31 December 2022 compared to NOK 174.7 million as of 30 June 2022.

Platform technology

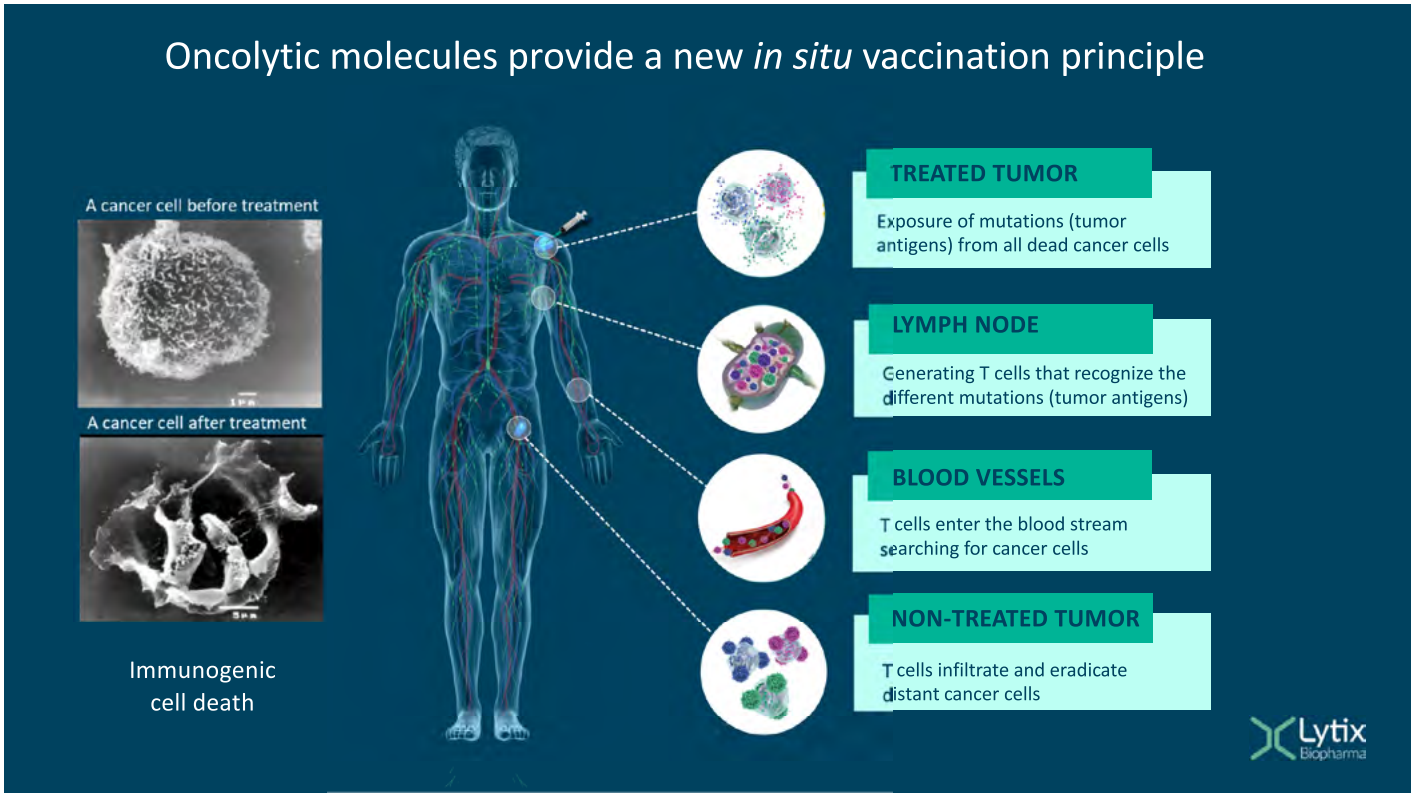
Lytix' technology platform has successfully generated highly active oncolytic molecules from naturally occurring host defense peptides. These have the potential to address the main challenge to dealing efficiently with cancer; the heterogeneity of the tumor, which enables the cancerous cells to be resistant to treatment by escaping various targeting therapies.

Lytix' oncolytic molecules kill cancer cells in a unique way resulting in an efficient release of tumor neoantigens (mutated proteins) and immune activating molecules. This process results in the activation of the patient's own killer T cells which will enter into circulation and search for and kill cancer cells.

The oncolytic molecules are 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.

GENERATING A SYSTEMIC AND LASTING ANTI-TUMOR IMMUNITY

Oncolytic molecules work by inducing immunogenic cell death of cancerous cells and by activating antigen presenting cells to generate tumor specific T cells. When these molecules are injected straight into the tumor environment, they potentiate the patient's immune system. Lytix' approach represents an alternative and unique treatment approach to cancer vaccination. So far, data has demonstrated that Lytix' molecules can generate a systemic and lasting anti-tumor immunity.



In a GlobalData survey , physicians ranked tumor heterogeneity as the most challenging aspect of optimising IO therapy. Tumor heterogeneity introduces significant challenges in cancer therapy and is the main cause of treatment failure, drug resistance, relapse and recurrence.

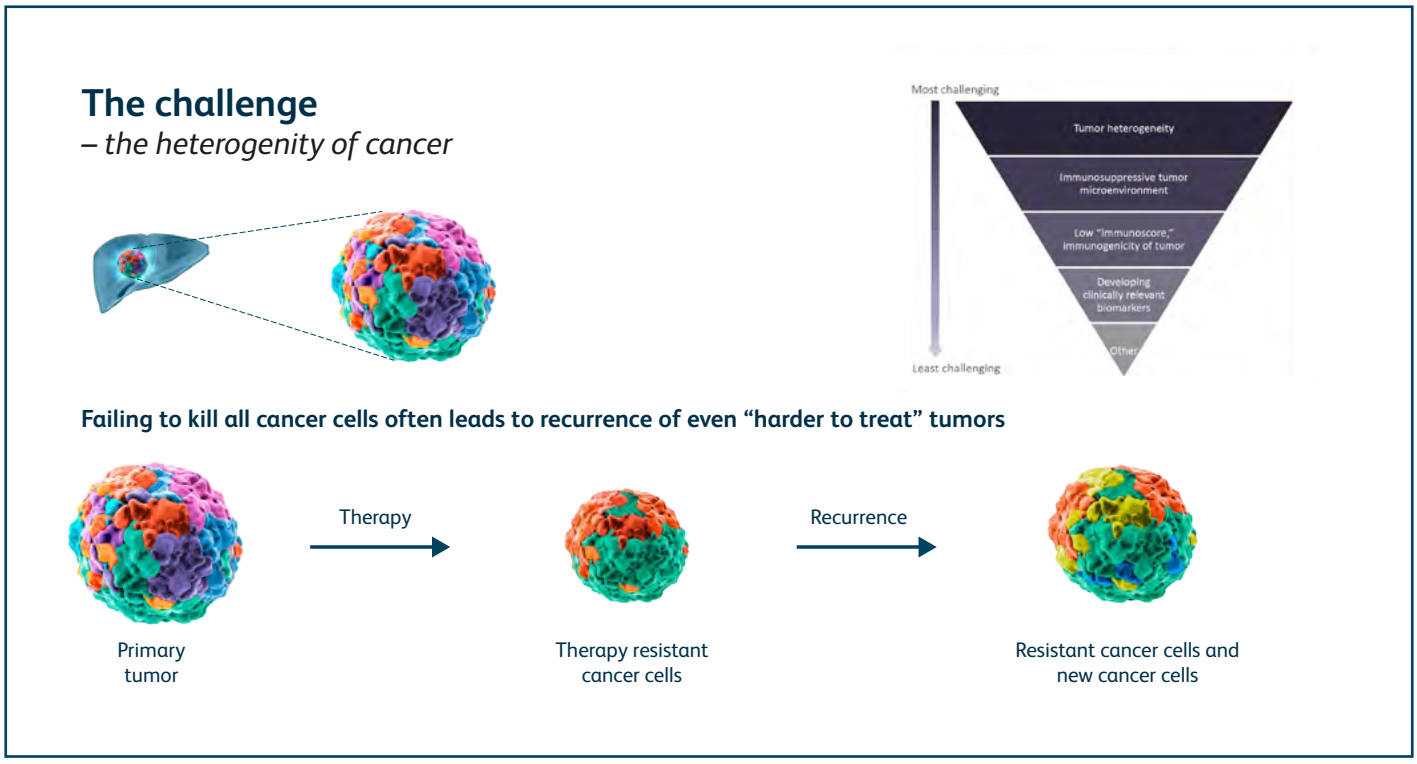


Illustration 1: *Tumor heterogeneity is the major driver of resistance to all forms of cancer therapy, including immunotherapy.*

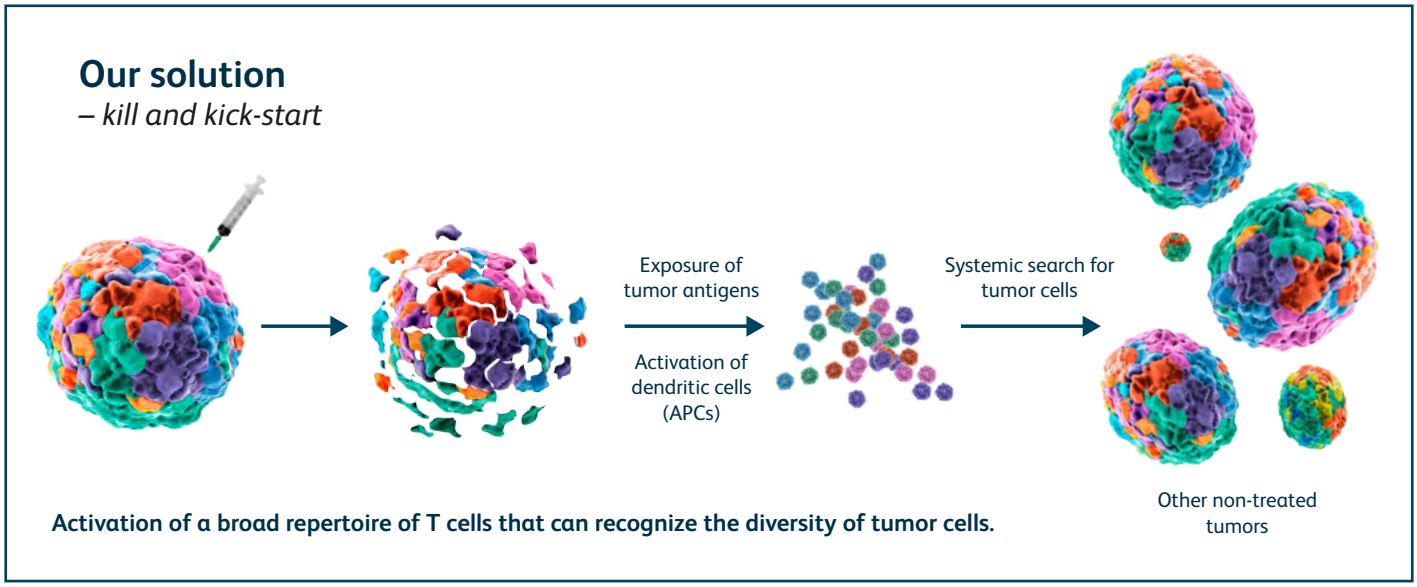


Illustration 2: *Lytix' oncolytic molecules uniquely address heterogeneity by being able to recognise and target the different cancer subclones in a heterogenous tumor, including both drug sensitive and resistant cancer cells.*

Oncology is the largest pharmaceutical market by revenue. Oncology therapeutics represented USD 184 billion in sales in 2021 (~20 per cent of global pharmaceutical sales).[1] To capture a larger market share, parallel development across multiple indications increases the value of an individual asset and makes deal-making more likely. The unmet need remains high, and the market is expected to reach USD 269 billion by 2025.[2] 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 *in situ* vaccination technology platform offers a whole range of product opportunities and has the capacity to improve the lives of patients across many cancer types.

The developmental program is progressing the oncolytic molecules both as a 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 T-cell therapy, LTX-315 is now being evaluated in two different Phase II trials, both as monotherapy and as combination therapy with the checkpoint inhibitor pembrolizumab.

Lytix' ATLAS-IT-05 clinical trial with LTX-315 was initiated at the MD Anderson Cancer Centre in the US and recently expanded to six sites in Europe. It is planned to enroll 20 patients with metastatic melanoma into the study, a patient population with a significant 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 Phase I human clinical trial.

1 *IQVIA Research, 2023*
2 *IQVIA Research, 2023*

Product candidate	Description	Indication	Discovery	Preclinical	Phase I	Phase II	Phase III
LTX-315	**Atlas-IT-05** Pembrolizumab (Keytruda®)	Melanoma patients progressed on checkpoint inhibitors					
	Phase II by Verrica Pharmaceuticals (monotherapy)	Basal cell carcinoma					
	Atlas-IT-04 Adoptive cell therapy	Advanced soft tissue sacroma			COMPLETED		
LTX-401	Monotherapy	Liver cancer					
LTX-122	Adoptive cell therapy	Dog lymphoma					
Undisclosed	Undisclosed	Not applicable					
A unique technology platform	**Inspired by nature** Based on the scientific concepts of naturally occuring host defense peptides, scientifically improved for cancer therapy.			***In situ* vaccination platform** 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 developed for intratumoral injections. Pre-clinical 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 in the number of tumor-infiltrating T cells in the tumor micro-environment (Sveinbjørnsson et al. 2017).

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. LTX-315 was either given as a monotherapy or in combination with a checkpoint inhibitor to patients with transdermal accessible tumors. The trial showed 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 optimised 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 T-cell therapy in advanced soft tissue sarcoma patients. During the study, an extensive

immune profile was measured to characterise the immune status and nature of the immune response together with monitoring the clinical response. 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. The non-clinical development is completed and the asset is currently being prepared for a Phase I clinical trial.

LTX-122

LTX-122 is an oncolytic molecule that consists of 12 naturally occurring amino acids. In pre-clinical research, the peptide proved to have high activity and selectivity against B-cell lymphoma. In a pre-clinical lymphoma study, 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 commercialise LTX-122 and the molecule has been out-licensed to Aurelius Biotherapeutics for veterinary cancer.

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 development.

Partnerships

VERRICA PHARMACEUTICALS

Verrica Pharmaceuticals is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. In August 2020, Lytix announced that it entered into a license agreement providing Verrica Pharmaceuticals with a worldwide license to develop and commercialise 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 111 million 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 on basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) as the lead indications for development for LTX-315. In November 2021, 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 BCC and SCC patients are diagnosed in the US annually. With about 80 per cent of these skin cancers being BCC there is a significant commercial potential for new treatment options.

AURELIUS BIOTHERAPEUTICS LLC

In March 2021, Lytix announced it had entered into a strategic partnership with Aurelius Biotherapeutics, whereby 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.

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

Risks and uncertainties

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 commercialised.

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 vari-

ous 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.

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 commercialisation 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 therapeutic 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 commercialise in those regions.

Outlook

Lytix remains well positioned to advance and develop its clinical trial assets and technology platform. In the period, Lytix received regulatory approval to set up additional test sites in Europe to support its ongoing Phase II trial evaluating LTX-315 in patients with advanced solid tumors. Six sites have opened across Norway, France and Spain and recruitment is expected to be completed by by mid-2023. Lytix is also working to initiate a Phase I trial with its second-generation molecule for deep-seated cancer lesions, LTX-401. The company looks forward to the progression of Verrica's Phase II study in basal cell carcinoma. It is anticipated that Verrica will begin Part 2 of the study in the second quarter of 2023. This part will further explore dosing regimens to allow Verrica to identify the recommended dose for Part 3 of the study, which is expected to start in the second half of 2023. Financially, the company has a sufficient cash runway that will see it through 2023 and into 2024 as it continues to regularly assess the financial position to ensure that it has the necessary funds to support new and future activities.

Responsibility statement

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 31 December 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 31 December 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 15 February 2023
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[1]

Amounts in NOK thousands	*Notes*	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Revenue	*1, 3*	**-**	-	**1 409**	-	**1 409**	17
Other operating income	*2, 3*	**1 615**	719	**3 178**	2 626	**15 864**	25 810
Total operating income		**1 615**	719	**4 587**	2 626	**17 273**	25 827
Payroll and related expenses	*5*	**(6 163)**	(8 701)	**(11 253)**	(14 309)	**(21 133)**	(31 605)
Depreciation and amortisation expenses	*6*	**(13)**	-	**(24)**	-	**(30)**	-
Direct R&D expenses		**(14 847)**	(6 161)	**(28 194)**	(19 248)	**(50 974)**	(28 817)
Other operating expenses	*4*	**(4 430)**	(2 225)	**(6 897)**	(4 233)	**(10 832)**	(13 421)
Total operating expenses		**(25 453)**	(17 087)	**(46 368)**	(37 790)	**(82 968)**	(73 844)
Loss from operations		**(23 837)**	(16 368)	**(41 781)**	(35 164)	**(65 695)**	(48 017)
Net financial items	*9*	**(5 357)**	(27)	**1 439**	(137)	**9 689**	(32)
Loss before tax		**(29 195)**	(16 395)	**(40 343)**	(35 301)	**(56 006)**	(48 049)
Tax expense		**-**	-	**-**	-	**-**	-
Loss for the period		**(29 195)**	(16 395)	**(40 343)**	(35 301)	**(56 006)**	(48 049)

1) Interim figures are unaudited.

Condensed interim statement of financial position[1]

Amounts in NOK thousands	*Notes*	**31.03.2022**	30.06.2022	30.09.2022	**31.12.2022**	31.12.2021
Assets						
Non-current assets						
Property, plant and equipment	*6*	**35**	132	137	**124**	-
Other receivables		**-**	-	-	**-**	-
Total non-current assets		**35**	132	137	**124**	-
Current assets						
Trade and other receivables	*10*	**7 242**	7 643	5 656	**6 735**	5 680
Short-term financial investments		**-**	-	49 909	**50 606**	-
Cash and cash equivalents	*8, 9*	**180 666**	177 084	121 671	**94 552**	197 282
Total current assets		**187 907**	184 727	177 237	**151 893**	202 962
Total assets		**187 942**	184 858	177 374	**152 017**	202 962
Shareholder's equity and liabilities						
Issued capital and reserves						
Share capital	*11*	**3 874**	4 007	4 007	**4 007**	3 874
Share premium reserve	*11*	**170 933**	170 710	159 876	**131 119**	185 750
Total equity		**174 807**	174 717	163 883	**135 126**	189 624
Liabilities						
Current liabilities						
Trade payables		**3 920**	2 557	6 426	**6 997**	1 476
Other current liabilities		**9 216**	7 585	7 065	**9 894**	11 862
Total current liabilities		**13 135**	10 141	13 491	**16 891**	13 338
Total liabilities		**13 135**	10 141	13 491	**16 891**	13 338
Total equity and liabilities		**187 942**	184 858	177 374	**152 017**	202 962

1) Interim figures are unaudited.

Condensed interim statement of cash flows[1]

Amounts in NOK thousands	*Notes*	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2021**	FY 2021
Cash flows from operating activities							
Loss for the period		**(29 195)**	(16 395)	**(40 343)**	(35 301)	**(56 006)**	(48 049)
Adjustments for:							
Depreciation and amortisation expenses	*6*	**13**	-	**24**	-	**30**	-
Share-based payment expense	*5*	**438**	709	**751**	1 894	**1 376**	4 055
Increase/decrease in trade and other receivables	*10*	**(1 079)**	(723)	**908**	157 112	**(1 055)**	(1 513)
Increase/decrease in trade and other payables		**3 400**	4 514	**6 750**	2 626	**3 553**	610
Cash generated from operations		**(26 422)**	(11 896)	**(31 909)**	126 332	**(52 102)**	(44 896)
Income tax paid		**-**	-	**-**	-	**-**	-
Net cash flows from operations		**(26 422)**	(11 896)	**(31 909)**	126 332	**(52 102)**	(44 896)
Investing activities							
Investments in tangible assets		**-**	-	**(17)**	-	**(154)**	-
Increase/decrease in other investments		**(697)**	-	**(50 606)**	-	**(50 606)**	-
Net cash from/(used) in investing activities		**(697)**	-	**(50 623)**	-	**(50 761)**	-
Financing activities							
Proceeds from share issue		**-**	-	**-**	-	**133**	213 728
Net cash from/(used) in financing activities		**-**	-	**-**	-	**133**	213 728
Net increase in cash and cash equivalents		**(27 120)**	(11 896)	**(82 532)**	126 332	**(102 730)**	168 832
Cash and cash equivalents at the beginning of the period		**121 671**	209 177	**177 084**	70 950	**197 282**	28 450
Cash and cash equivalents at the end of the period		**94 552**	197 282	**94 552**	197 282	**94 552**	197 282

1) Interim figures are unaudited.

Notes to the financial statements[1]

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 recognised 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. Capitalised development costs are amortised 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 recognised 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.

1) Interim figures are unaudited.

NOTE 1 REVENUE

Amounts in NOK thousands	**Q4 2022**	Q42 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Revenue	**-**	-	**1 409**	-	**1 409**	-
Other income	**-**	-	**-**	-	**-**	17
Total Revenue	**-**	-	**1 409**	-	**1 409**	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

Amounts in NOK thousands	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Other operating income						
Government grants recognised in profit and loss	**1 615**	719	**3 178**	2 626	**6 242**	6 332
Other	**-**	-	**-**	-	**9 622**	19 478
Other operating income	**1 615**	719	**3 178**	2 626	**15 864**	25 810

Government grants recognised in profit and loss, part of Other operating Income, for Q2 2022 was reported at NOK 805 thousand which was NOK 750 thousand lower than actual. The correct amount is NOK 1 555 thousand. The figures in this report are correct, but the YTD figures will therefore not be reconcilable with the H1 report without adjusting for this error.

NOTE 3 GEOGRAPHICAL DISTRIBUTION INCOME

Amounts in NOK thousands	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Geographical distribution						
Norway	**1 615**	719	**3 178**	2 626	**6 242**	6 537
US	**-**	-	**1 409**	-	**11 031**	19 290
Total operating income	**1 615**	719	**4 587**	2 626	**17 273**	25 827

Lytix has only one operating segment, which is research and development.

NOTE 4 TRANSACTIONS WITH RELATED PARTIES

Amounts in NOK thousands	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2021**	FY 2021
North Murray AS (Gert W. Munthe)	-	-	-	-	**-**	150

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

NOTE 5 PAYROLL AND RELATED EXPENSES

Amounts in NOK thousands	**Q4 2022**	Q4 2021	**H2 2022**	H2 2021	**FY 2022**	FY 2021
Payroll and related expenses, including directors, comprise						
Wages and salaries	**4 486**	7 016	**7 818**	10 591	15 814	24 381
Defined contribution pension const	**219**	211	**403**	422	820	789
Share-based payment expense	**438**	709	**624**	1 894	1 376	4 055
Social security contributions	**565**	562	**538**	1 005	1 597	1 864
Other personnel costs	**455**	203	**496**	397	1 526	517
Total payroll and related expenses	**6 163**	8 701	**9 880**	14 309	21 133	31 605

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

Amounts in NOK thousands	Machinery and equipment	**Total 2022**	Machinery and equipment	Total 2021
Carrying amount 1 January	-	-	-	-
Additions	154	**154**	-	-
Depreciation	(30)	**(30)**	-	-
Carrying value 31 December	124	**124**	-	-
As of 1 January				
Acquisition cost	-	**-**	-	-
Accumulated depreciation and write-downs	-	**-**	-	-
Carrying amount 1 January	-	**-**	-	-
As of 31 December				
Acquisition cost	154	**154**	-	-
Accumulated depreciation and write-downs	(30)	**(30)**	-	-
Carrying amount 31 December	124	**124**	-	-

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

Amounts in NOK thousands	30.06.2022	30.09.2021	**31.12.2022**	31.12.2021
Cash and cash equivalents				
Employee withholding tax	2 416	1 142	**1 373**	1 411
Variable rate bank accounts	174 668	120 529	**93 179**	195 871
Total Cash and cash equivalents	177 084	121 671	**94 552**	197 282

NOTE 9 FOREIGN CURRENCY RISK

Lytix 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 Lytix has consequently placed a significant part of its cash position in USD to hedge part of the foreign currency risk.

For the second half of 2022, net financial income came in at NOK 1.4 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

Amounts in NOK thousands	30.06.2022	30.09.2021	**31.12.2022**	31.12.2021
Trade and other receivables				
Trade receivables	-	830	**-**	-
Governmental grants	7 072	3 885	**5 500**	4 824
VAT	274	79	**498**	309
Prepayments	297	862	**737**	548
Other receivables	-	-	**-**	-
Total trade and other receivables	7 643	5 656	**6 735**	5 680

NOTE 11 EQUITY AND SHARE CAPITAL

Amounts in NOK thousands	Share capital	Share premium reserve	**Total equity**
Balance at 1 January 1	3 874	185 750	**189 624**
Income for the period			
Loss for the period	-	(56 006)	**(56 006)**
Total income for the period	-	(56 006)	**(56 006)**
Registration of share issue 20 April 2022	133	-	**133**
Share based payment		1 376	**624**
Total contributions by and distributions to owners	133	624	**757**
Balance at 31 December	4 007	131 119	**135 126**

Amounts in NOK thousands	Share capital	Share premium reserve	**Total equity**
Balance at 1 January 2021	2 623	17 266	**19 889**
Income for the period			
Loss for the period	-	(48 049)	**(48 049)**
Total income for the period	-	(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**
Total contributions by and distributions to owners	1 251	216 532	**217 783**
Balance at 31 December 2021	3 874	185 750	**189 624**

Share capital at 31 December 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.

	31.12.2022	31.12.2021
Ordinary shares on 1 January	**38 739 013**	26 227 120
Capital increase 10 June 2021 [1)]		3 234 116
Capital increase 11 June 2021 [2)]		9 277 777
Capital increase 20 April 2022 [3)]	**1 329 306**	
Ordinary shares per 31 December 2022 / 31 December 2021	**40 068 319**	38 739 013

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 authorisation 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	13.58%
2	Citibank, N.A.	3 691 267	9.21%
3	Jakob Hatteland Holding AS	3 000 000	7.49%
4	North Murray AS	2 968 878	7.41%
5	3T Produkter Holding As	1 808 764	4.51%
6	Brødrene Karlsen Holding As	1 709 274	4.27%
7	Care Holding AS	1 608 080	4.01%
8	Picasso Kapital AS	1 122 860	2.80%
9	Per Strand Eiendom AS	1 024 128	2.56%
10	Skandinaviska Enskilda Banken AB	869 372	2.17%
11	Lysnes Invest AS	615 654	1.54%
12	Kvasshøgdi AS	604 727	1.51%
13	Norinnova Invest AS	557 510	1.39%
14	Hifo Invest AS	555 555	1.39%
15	Saturn Invest AS	555 555	1.39%
16	Jahatt AS	500 000	1.25%
17	Hopen Invest AS	481 117	1.20%
18	Belvedere AS	331 856	0.83%
19	Harila Invest AS	275 680	0.69%
20	Nordnet Bank AB	261 736	0.65%
	Total number of shares for top 20 shareholders	27 982 863	69.84%
	Total number of shares for the other shareholders	12 085 456	30.16%
	Total number of shares	40 068 319	100.0%

Lytix Biopharma AS
Sandakerveien 138
NO-0484 Oslo
Norway

Investor relations and media:
ole.peter.nordby@lytixbiopharma.com

Business development:
bd@lytixbiopharma.com

General enquiries:
post@lytixbiopharma.com

www.lytixbiopharma.com