Lytix Biopharma

Interim report

Second quarter and first half 2023

Letter from the CEO

Building the Phase II evidence base

Dear shareholders,

As a clinical-stage immune-oncology company, our mission is to use our drug candidates to kill cancer cells and kick start the immune system to address the unique and individual nature of a patient`s cancer. Looking at the first half of 2023, we are closer to achieving this mission.

Earlier this month, we were excited by the data presented by our partner, Verrica Pharmaceuticals Inc ("Verrica"), at the American Association of Dermatology Innovation Academy Conference, which shows that LTX-315 efficiently kills cancer cells and induces complete clearance of tumors in patients with basal cell carcinoma (BCC). Verrica reported that of the six patients with tumor lesions treated with the highest dose, complete tumor clearance was observed in four lesions, 95 per cent clearance in one lesion and 30 per cent clearance in one lesion. This is very encouraging data for the 3-4 million BCC patients and supports our efforts to advance LTX-315 as a non-surgical option for these patients. Based on the stronger than expected activity that were observed in the BCC patients, Verrica recently made the decision to expand Part 2 of their ongoing Phase 2 trial which they believe will accelerate the clinical development of LTX-315. We strongly believe Verrica's expertise in skin diseases and strong market orientation fits well with the enormous market potential for LTX-315 in BCC.

In the first half of 2023 we made substantial achievements in setting up new sites and recruiting more patients for ATLAS-IT-05. Thanks to the involvement and motivation of the investigation physicians, all patients have been recruited. We are very happy to see this important milestone reached.

ATLAS-IT-05 is a Phase II study evaluating the efficacy of LTX-315 in patients with malignant melanoma. The patients enrolled in the study have previously been through several other treatments and failed on check point inhibitor PD-1/PD-L1 treatment, making them a vulnerable and difficult to treat group as their immune systems are altered by the cancer and previous treatments. Thus, even a small number of responders in this group ensures proof of concept for LTX-315. We are looking forward to presenting the interim results at the upcoming European Society of Medical Oncology meeting in October.

Our clinical study in melanoma has generated a lot of interest from clinical melanoma experts globally. Reviewing and discussing different investigator initiatives we have decided to support an investigator led neoadjuvant study in melanoma patients led by Dr. Henrik Jespersen, Radiumhospitalet, Oslo University Hospital. This study is complementary to our ongoing melanoma study as it includes melanoma patients with an earlier stage disease and a healthier immune system. This will be the first time LTX-315 is tested in a neoadjuvant setting.

Overall, our expanded clinical program complementing our full clinical portfolio has been developed to deliver robust data, which we are confident will meet the highest standard of quality when it comes to clinical data readouts and validation of new technologies.

During the first half of 2023, our development program has matured and reached a point where the drug candidates now are recognized as a new treatment modality, with significant market potential. As we embark on the second half of the year, we are excited to deliver interim data and carry on this important work.

On behalf of everyone at Lytix, I also want to thank all our stakeholders who continue to support us on our journey. We look forward to updating you as we reach our next clinical milestone.

Øystein Rekdal
CEO and co-founder
Lytix Biopharma

Highlights and key figures

Highlights first half 2023

Partnership:

- Verrica Pharmaceutical's Phase II study with LTX-315
  - Verrica completed Part 1 of their ongoing Phase II study evaluating LTX-315 for the treatment of basal cell carcinoma (BCC). The encouraging clinical data shows that of the six patients with tumor lesions treated at the highest dose, complete clearance was observed in four lesions, 95 per cent clearance in one lesion and 30 per cent clearance in one lesion.
  - Based on the stronger than expected activity observed in patients receiving LTX-315 in Part 1, Verrica recently made the decision to expand Part 2 of the ongoing Phase II trial and to cancel a Part 3 of the trial. It is expected that this will accelerate Verrica's clinical development of LTX-315 completing the entire Phase II study in H1 2024.

Research and development:

- ATLAS-IT-05
  - In the first half of 2023 Lytix made substantial achievements in setting up new sites and recruiting more patients for ATLAS-IT-05 across the US and Europe.
  - Thanks to the involvement and motivation of the investigation physicians, all patients have been recruited. We are very happy to see this important milestone reached.
  - An abstract of interim results from the study has been approved for a poster presentation at the European Society for Medical Oncology (ESMO) Congress October 2023.
  - Provided the interim analysis shows encouraging efficacy results, an expansion of the study will be considered.
- Neoadjuvant study in earlier stage melanoma patients
  - The science behind LTX-315, the ATLAS-IT-05 study and clinical data to date has generated a lot of interest from clinicians reaching out Lytix to conduct clinical studies in various indications, and now Lytix has decided to support a first investigator led study at Oslo University Hospital, Radiumhospitalet. This will be a Phase II neoadjuvant study in melanoma patients to explore the clinical efficacy of LTX-315 in earlier stage melanoma. The study is expected to commence in H1 2024 and will enroll 27 patients.
- LTX-401
  - Given the positive feedback on ATLAS-IT-05, encouraging clinical data from Verrica, and increased interest from investigators, we are refocusing our resources by concentrating on generating additional clinical efficacy data with LTX-315 and for a period of time, postpone the start of the planned Phase I safety study with LTX-401.

Business and Financial:

- Dr Marie Roskrow was elected as the new Chair of the Board of Directors at the General Assembly. Dr Roskrow is a senior executive with vast international experience in both life sciences and investment banking. She holds a medical degree and a PhD in Immunology and serves as the Chair of several international biotechnology companies.
- Due to the significant increase in sites with an increase in number of patients recruited during the first six months of 2023 the direct R&D expenses increased to NOK 40.0 million from NOK 22.8 million for the same period in 2022.
- Expanding the ATLAS-IT-05 to Europe as well as increased efforts on the business development side, has increased other operating expenses to NOK 6.5 million from NOK 3.9 million.
- Lytix has delivered several presentations across international cancer immunotherapy conferences, including the New York Academy's Frontiers in Cancer Immunotherapy 2023 in New York, US, the Next-Gen Immuno-Oncology Conference in London and the Immuno UK 2023 conference. Lytix also presented at the ABG Sundal Collier Life Science Summit and Redeye Growth Day in Stockholm.

Key figures [1]

Amounts in NOK thousands	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	FY 2022
Total operating income	**449**	11 177	**824**	12 686	17 273
Total operating expense	**(34 607)**	(20 418)	**(59 454)**	(36 600)	(82 968)
Loss from operations	**(34 159)**	(9 241)	**(58 630)**	(23 914)	(65 695)
Loss for the period	**(31 435)**	(433)	**(51 109)**	(15 664)	(56 006)
Property, plant and equipment			**144**	132	124
Trade and other receivables			**5 959**	7 643	6 735
Short-term financial investments			**41 961**	-	50 606
Cash position at the end of the period	**-**	-	**58 257**	177 084	94 552
Total assets	**-**	-	**106 321**	184 858	152 017
Total equity	**-**	-	**86 122**	174 717	135 126
Total liabilities	**-**	-	**20 199**	10 141	16 891
Total equity and liabilities	**-**	-	**106 321**	184 858	152 017

1) Interim figures are unaudited.

Review of the first half year 2023

Operational review

PARTNERSHIPS

LTX-315 development in partnership with Verrica

Verrica Pharmaceuticals has completed treatment in Part 1 of its ongoing two-part Phase II study evaluating LTX-315 in basal cell carcinoma (BCC).

Part 1 enrolled 10 patients and demonstrated a favorable safety and tolerability profile with no reported serious adverse events. Of the six patients with tumor lesions treated at the highest dose, complete clinical and histologic clearance was observed in four lesions, 95 per cent clearance in one lesion and 30 per cent clearance in one lesion. These data were presented at the 2023 American Academy of Dermatology Association's Innovation Academy meeting.

Following the promising signs of efficacy in Part 1 of the study, Verrica has advanced into the second part. On April 12, 2023, Verrica announced that the first patient had been dosed. Part 2 of the Phase II trial is designed to further explore dosing regimens and identify an optimized dosing schedule of LTX-315 that will be used in the next stage of clinical development.

Based on the stronger- than-expected activity observed in patients receiving LTX-315, Verrica recently made the decision to expand Part 2 of the ongoing Phase II trial as the company expects this to accelerate the clinical development of LTX-315. BCC is usually treated with surgical intervention, which can be invasive, painful, disfiguring, and may require destruction of healthy tissue. LTX-315 represent a potentially non-surgical alternative for BCC patients. BCC is the most common skin cancer representing a large commercial potential for LTX-315. Approximately 3-4 million patients are diagnosed with BCC each year in the US.

ClinicalTrials.gov Identifier: NCT05188729

RESEARCH AND DEVELOPMENT

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

In ATLAS-IT-05, a Phase II study, LTX-315 is given to patients with advanced melanoma in combination with the immune checkpoint inhibitor pembrolizumab (Keytruda®), a market leading immunotherapeutic anti-PD-1 antibody. The study is running at several sites in the US and Europe, exploring the clinical effect of LTX-315 and Keytruda in patients who have previously failed treatment with anti-PD-1/PD-L1. The patients enrolled in the study have previously been through several other treatments and failed on check point inhibitor PD-1/PD-L1 treatment, making them a vulnerable and difficult to treat group as their immune systems are altered by the cancer and previous treatments. The primary objective is to document whether LTX-315 can induce responses in checkpoint inhibitor refractory malignant melanoma patients in combination with pembrolizumab. In the first half of 2023 we made substantial achievements in setting up new sites and recruiting more patients for ATLAS-IT-05. All ten sites listed below in Europe and the US are open and actively recruiting patients:

- M.D. Andersen Cancer Centre, US
- Mount Sinai Cancer Center, US
- UPMC Hillman Cancer Center, US
- Levine Cancer Center, US
- Akershus Universitetssykehus, Norway
- Radium Hospitalet, Norway
- Institute Gustave Roussy, France
- Hospices Civils de Lyon, France
- Centre Hospitalier Regional Université de Lille, France
- Clinica Universidad de Navarra, Spain

All of the ten sites are recognized for intratumoral immunotherapy expertise and are led by clinical teams with recognized expertise in melanoma.

Thanks to the involvement and motivation of the investigation physicians, all patients have been recruited. This is a very important milestone.

In July 2023, Lytix announced that an abstract with interim clinical data from the ATLAS-IT-05 study had been accepted for a presentation at ESMO 2023. The interim efficacy and safety data will be presented by the top recruiting investigator of the trial, Professor Stéphane Dalle (Centre Hospitalier Universitaire de Lyon, France) in a poster session.

ClinicalTrials.gov Identifier: NCT04796194

Neoadjuvant setting

Neoadjuvant immunotherapy refers to the administration of immunotherapy treatments before radiation or surgery and is expected to play an increasingly significant role in future cancer treatment strategies.

Neoadjuvant therapy is relevant for earlier stage patients and is delivered with the goal of the primary immunotherapy treatment having a stronger effect if it is given at an earlier stage of the disease.

To explore the clinical benefits provided by LTX-315 in earlier stage melanoma patients, Lytix has decided to initiate an investigator led neoadjuvant study in melanoma patients at Oslo University Hospital, Radiumhospitalet.

Using LTX-315 as a neoadjuvant immunotherapy can lead to the shrinkage of tumors, making them more amenable to surgical removal, but additionally LTX-315 will expose the tumor antigens and release critical immune-stimulating substances leading to increased activation of tumor-specific immune cells and potentially systemic anti-tumor responses. The planned neoadjuvant study is expected to commence in H1 2024 and will enroll 27 patients.

This study will be led by Dr. Henrik Jespersen, MD PhD and Head of Melanoma Oncology, Department of Oncology, Oslo University Hospital and Lytix will support the study by providing the necessary LTX-315 for the treatment of the patients.

LTX-401

Preparations for a clinical trial application (CTA) for a Phase I study with LTX-401 have been completed, but the company has decided to temporarily postpone the CTA submission. Because of the positive feedback on ATLAS-IT-05, encouraging clinical data from Verrica, and increased interest from investigators, we are refocusing our resources by concentrating on generating additional clinical efficacy data with LTX-315 and for a period of time, postpone the start of the planned Phase I safety study with LTX-401.

BUSINESS

At the annual general meeting in April 2023, Dr Marie Roskrow was elected as Chair of the Board of Directors. Dr Marie Roskrow is a senior executive with vast international experience in life sciences and investment banking. She holds a medical degree and a PhD in Immunology and serves as the Chair of several international biotechnology companies.

In May 2023, Øystein Rekdal, PhD, was invited by the New York Academy of Sciences to discuss how tumor-directed strategies enable superior immune-stimulation of 'cold' non-infiltrated tumors, in a joint presentation with Lorenzo Galluzzi, PhD, Weill Cornell Medicine, at the 'Frontiers in Cancer Immunotherapy 2023' conference, which took place in New York. In his presentation, Rekdal focused on the efficacy data achieved in human clinical trials performed with LTX-315 and how oncolytic molecules can address the challenge represented by the modest activity of immune checkpoint inhibitors (ICIs) in patients with immunologically 'cold' tumors.

During the period, Lytix was also invited to give plenary lectures at the Immuno UK 2023 Conference and at Next-Gen Immuno-Oncology Conference, both in London, presenting our novel technology platform.

Financial review

PROFIT AND LOSS

Revenue for the six months ended 30 Jun 2023 amounted to NOK 74 thousand and is related to the supply of LTX-315 to Verrica Pharmaceuticals. Other operating income for the first half of 2023 amounted to NOK 0.8 million down from NOK 12.7 million for the first half of 2022. Operating income in the period was mainly related to government grants of NOK 0.8 million. In 2022, Lytix received a milestone payment of NOK 9.6 million from Verrica Pharmaceuticals.

Personnel expenses for the first half of 2023 came in at NOK 12.8 million (NOK 9.9 million for the first half of 2022). The increased personnel expenses are mainly explained by higher share-based payment expenses in 2023.

Direct R&D expenses amounted to NOK 40.0 million for the first half (NOK 22.8 million for the same period in 2022). The increased direct R&D expenses for the first half is a result of ATLAS-IT-05 running at full speed across ten sites in the US and Europe. In addition, other operating expenses increased to NOK 6.5 million (NOK 3.9 million). The increase in other operating expense is resulting from the higher activity level in R&D as well as business development. Loss from operations for the first half of 2023 amounted to NOK 58.6 million (NOK 23.9 million).

Net financial items contributed positively to the net result with NOK 7.5 million in the first half of 2023 (NOK 8.3 million). Lytix has decided to hedge part of its expected USD cost related to the ATLAS-IT-05 study and the financial income for the first half of 2023 stems from a conversion of that USD cash position into NOK as of 30 June 2023.

CASH FLOW

Cash flow from operating activities amounted to negative NOK 46.2 million in the first half of 2023, compared with negative NOK 20.2 million for the first half of 2022.

Cash flow from investing activities in the first half of 2023 amounted to NOK 9.9 million and is mainly related to the sale of a part of a short-term financial asset.

Cash flow from financing activities for the first half of 2023 amounted to NOK 0.0 million compared to NOK 0.1 million for the same period last year which was related to the exercise of warrants.

Cash and cash equivalents at the end of the reporting period amounted to NOK 58.3 million, compared with NOK 94.5 million at 31 December 2022 and NOK 177.1 million at 30 June 2022.

At the end of the period, cash plus short-term financial investments amounted to NOK 100.2 million, compared to NOK 145.2 million as of 31 December 2022 and NOK 177.1 million at 30 June 2022.

Statement of financial position / balance sheet

Total assets on 30 June 2023 were NOK 106.3 million, compared with NOK 152.0 million on 31 December 2022 and NOK 184.9 million at 30 June 2022.

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 novel molecules derived from naturally occurring host defense peptides. These have the potential to address the main challenge in current cancer therapy; tumor heterogeneity, which increases therapy resistance and risk of cancer recurrence.

Delivering immunotherapy straight into the tumor

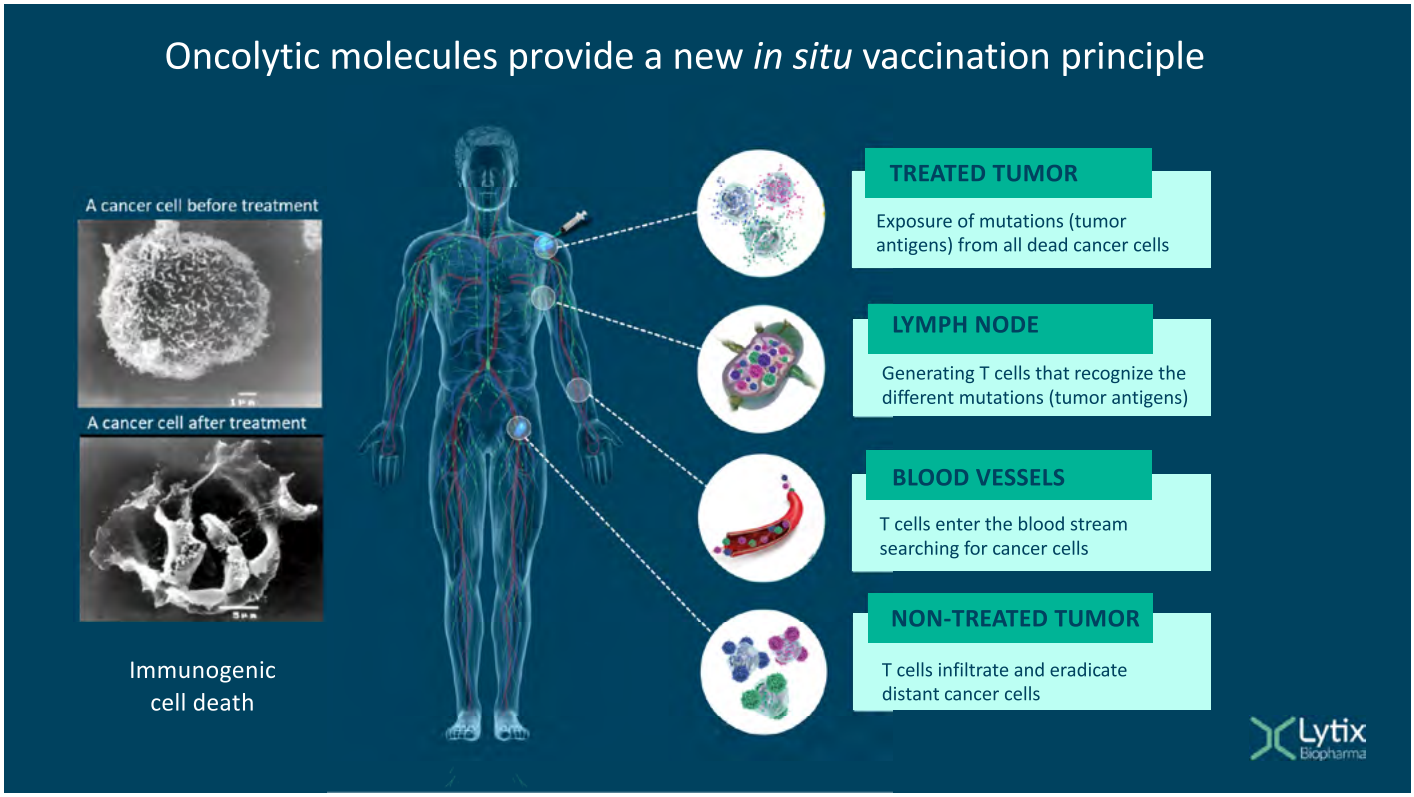
Lytix Biopharma's unique technology platform potentiates a patient's immune system by injecting drugs with the ability to kill cancer cells straight into the tumor environment. This approach generates an immune response against a broad antigen repertoire targeting the tumors without pre-identifying the antigens, which in turn can save considerable costs and valuable time.

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

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

Heterogeneity is considered one of the greatest challenges in cancer treatment for the following reasons:

1. **Treatment resistance:** Different cell populations within a tumor may develop distinct genetic alterations, making them resistant to specific treatments. While one population of cells may respond well to a particular therapy, another population may continue to grow and evade treatment. This can lead to treatment failure and disease recurrence and an even harder to treat disease.
2. **Metastasis:** Heterogeneity can contribute to the spread of cancer to other parts of the body. Certain subpopulations of cells within a tumor may acquire genetic changes that enhance their ability to invade nearby tissues and spread to distant sites. These cells can give rise to new tumors at different locations and contribute to disease progression.
3. **Personalized medicine challenges:** Tumor heterogeneity poses challenges for the development of effective personalized cancer treatments. It is difficult to target all the diverse cell populations within a tumor with a single targeted therapy. Additionally, the genetic changes observed in a tumor at one point in time may evolve over the course of treatment, leading to further heterogeneity and therapy resistance.
4. **Diagnostic and prognostic implications:** Tumor heterogeneity can complicate accurate diagnosis and prognosis. Biopsies or genetic testing from a limited area within a tumor may not capture the full genetic landscape, potentially leading to incomplete or misleading information about the tumor characteristics and behavior.



Oncolytic molecules

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

In a GlobalData survey[1], physicians ranked tumor heterogeneity as the most challenging aspect of optimizing IO therapy. Tumor heterogeneity introduces significant challenges in cancer therapy and is the main cause of treatment failure, drug resistance, relapse and recurrence. Lytix' oncolytic molecules uniquely address heterogeneity by being able to recognize and target the different cancer subclones in a heterogenous tumor, including both drug sensitive and resistant cancer cells.

Oncology is the largest pharmaceutical market by revenue. Oncology therapeutics represented USD 143 billion in sales in 2019 (~20 per cent of global pharmaceutical sales)[2]. 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 medical need remains critical, and the market is expected to reach USD 250 billion by 2024[3]. 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.

Lytix' oncolytic molecules have the potential to claim a unique position within immuno-oncology, 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, creating significant patient impact as well as value for Lytix.

1 *Source: GlobalData High-Prescriber Survey (December 2020)*
2 *Source: McKinsey analysis of EvaluatePharma (July 2020)*
3 *Source: McKinsey analysis of EvaluatePharma (July 2020)*

Product candidates and portfolio

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

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

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

After the recent completion of the ATLAS-IT-04 study in adoptive 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 initiated at MD Anderson Cancer Centre in the US is planned to include 20 patients with metastatic melanoma, a patient population with a high unmet medical need.

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

Product candidate	Combination partner	Population	Discovery	Preclinical	Phase I	Phase II	Phase III
LTX-315	**Atlas-IT-05** Pembrolizumab (Keytruda®)	Melanoma patients progressed on checkpoint inhibitors					
	Verrica Pharmaceuticals Monotherapy	Basal cell carcinoma					
	Atlas-IT-06 NeoLIPA	Neoadjuvant resctable melanoma patients					
	Atlas-IT-04 Adoptive T-cell therapy	Advanced soft tissue sarcoma		COMPLETED			
LTX-401	Monotherapy	Solid tumors (deep seated lesions)					
Undisclosed chemistry		Solid tumors					

A unique technology platform	Oncolytic molecules inspired by nature	*In situ* vaccination platform
	Based on the concepts of naturally occuring host defense peptides, scientifically improved for cancer therapy.	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 (Sveinbjørnsson et al. 2017).

The preclinical findings conveying the rationale for the therapeutic use of LTX-315 in humans have been confirmed in clinical trials. LTX-315 has undergone a comprehensive Phase I clinical trial in heavily pretreated patients. In this clinical trial, one of the key features of LTX-315 treatment, to promote T-cell infiltration into tumors, was evident in cancer patients. LTX-315 was shown to be a potent drug with the ability to also create systemic effects based on local injection of tumors. In this trial, LTX-315 was either given as monotherapy or in combination with a checkpoint inhibitor to patients with transdermally accessible tumors. The trial has shown that LTX-315 has an acceptable safety profile without any added safety concerns when given in combination with a checkpoint inhibitor. The scientific foundation has been laid to claim that LTX-315 is clinically active and 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 the clinical response. The study is finalized, and the results were presented at ASCO in June 2022.

LTX-401

LTX-401 is a small molecule that has the potential to treat deep-seated tumors such as hepatocellular carcinoma (liver cancer) and liver metastases. In several experimental models, LTX-401 induces complete regression after intratumoral injection with subsequent development of systemic immune protection. LTX-401 has shown increased efficacy when combined with checkpoint inhibitors and has demonstrated significant effects in experimental liver cancer models. LTX-401 has been through a preclinical safety program to enable the initiation of the first clinical trial at a later stage.

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

Verrica Pharmaceuticals is a Nasdaq-listed dermatology therapeutics company developing medications for skin diseases requiring medical interventions, and it is headquartered in West Chester, Pennsylvania. In August 2020, Lytix announced that it entered into a license agreement providing Verrica Pharmaceuticals with a worldwide license to develop and commercialize LTX-315 for some malignant and pre-malignant dermatological indications. 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 the manufacturing of the LTX-315 drug product, while Lytix retains responsibility for the manufacturing of the active pharmaceutical ingredient (API). Under the license agreement, Lytix may receive aggregate payments of more than USD 111 million as a signing fee and upon achievement of certain clinical, regulatory and sales milestones as well as tiered royalty payments in the double-digit teens.

Verrica intends to initially focus on basal cell and squamous cell carcinoma as the lead indications for development for LTX-315. In November 2021, Verrica received IND approval from the US FDA to initiate a Phase II clinical trial in basal cell carcinoma, and the first patient was recruited to the study in April 2022. Data from Part 1 of this study were presented in August 2023, showing complete clearance of basal cell carcinoma lesions in four out of six patients and 95 and 30 per cent reductions in the

remaining two. Verrica also communicated that their Phase II study is expected to complete four months earlier than anticipated, during the first half of 2024.

The American Cancer Society has estimated that about 5.4 million basal cell carcinoma (BCC) and squamous cell carcinomas (SCC) are diagnosed in the US annually. With about 80 per cent of these skin cancers being BCC there is a significant potential for new treatment options.

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 commercialized.

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

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

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

NON-FINANCIAL RISKS

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

Technology risk

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

Competitive technology

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

Market risks

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

Outlook

Lytix is well positioned to advance and develop its clinical stage assets. In the period, the company initiated a regulatory process to set up additional test sites in Europe to accelerate its ongoing Phase II trial evaluating LTX-315 in patients with advanced melanoma. Recruitment was completed during the second quarter of 2023. Additionally, and in support of increased commercial and planned clinical trial activities, the company continues to make strategic hires to strengthen the overall team.
The company remains well funded and will continue to regularly assess its financial position to ensure that it has the necessary funds to develop its pipeline.

Responsibility statement

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

The board stated that the interim accounts represent a true and fair view of the company's financial position on June 30, 2023. 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 31 August 2023
The board of directors and the chief executive officer of Lytix Biopharma AS

Marie Roskrow
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*	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Revenue	*1, 3*	**74**	-	**74**	-	**1 409**
Other operating income	*2, 3*	**375**	11 177	**750**	12 686	**15 864**
Total operating income		**449**	11 177	**824**	12 686	**17 273**
Payroll and related expenses	*4*	**(7 549)**	(6 175)	**(12 837)**	(9 875)	**(21 133)**
Depreciation and amortization expenses	*5*	**(14)**	(6)	**(28)**	(6)	**(30)**
Direct R&D expenses		**(24 632)**	(12 055)	**(40 041)**	(22 780)	**(50 974)**
Other operating expenses		**(2 413)**	(2 182)	**(6 546)**	(3 939)	**(10 832)**
Total operating expenses		**(34 607)**	(20 418)	**(59 454)**	(36 600)	**(82 968)**
Loss from operations		**(34 159)**	(9 241)	**(58 630)**	(23 914)	**(65 695)**
Net financial items	*6*	**2 723**	8 808	**7 521**	8 250	**9 689**
Loss before tax		**(31 435)**	(433)	**(51 109)**	(15 664)	**(56 006)**
Tax expense		**-**	-	**-**	-	**-**
Loss for the period		**(31 435)**	(433)	**(51 109)**	(15 664)	**(56 006)**

1) Interim figures are unaudited.

Condensed interim statement of financial position[1]

Amounts in NOK thousands	*Notes*	**30.06.2023**	30.06.2022	**31.12.2022**
ASSETS				
Non-current assets				
Property, plant and equipment		**144**	132	**124**
Total non-current assets		**144**	132	**124**
Current assets				
Trade and other receivables	*8*	**5 959**	**7 643**	**6 735**
Short-term financial investments		**41 961**	-	**50 606**
Cash and cash equivalents	*9*	**58 257**	177 084	**94 552**
Total current assets		**106 177**	184 727	**151 893**
Total assets		**106 321**	184 858	**152 017**
Shareholder's equity and liabilities				
Issued capital and reserves				
Share capital	*10*	**4 007**	4 007	**4 007**
Share premium reserve	*10*	**82 115**	170 710	**131 119**
Total equity		**86 112**	174 717	**135 126**
LIABILITIES				
Current liabilities				
Trade payables		**5 889**	2 557	**6 997**
Other current liabilities		**14 310**	7 585	**6 894**
Total current liabilities		**20 199**	10 141	**16 891**
Total liabilities		**20 199**	10 141	**16 891**
Total equity and liabilities		**106 321**	184 858	**152 017**

1) Interim figures are unaudited.

Condensed interim statement of cash flows[1]

Amounts in NOK thousands	*Notes*	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Cash flows from operating activities						
Loss for the period		**(31 435)**	(433)	**(51 109)**	(15 664)	**(56 006)**
Adjustments for:						
Depreciation and amortization expenses		**14**	6	**28**	6	**30**
Share-based payment expense		**1 086**	344	**2 104**	624	**1 376**
Interest received		**(660)**	-	**(1 344)**	-	
Increase/decrease in trade and other receivables		**1 114**	(401)	**776**	(1 963)	**(1 055)**
Increase/decrease in trade and other payables		**3 101**	(2 994)	**3 308**	(3 197)	**3 553**
Cash generated from operations		**(26 779)**	(3 479)	**(46 235)**	(20 193)	**(52 102)**
Income tax paid		**-**	-	**-**	-	**-**
Net cash flows from operations		**(26 779)**	(3 479)	**(46 235)**	(20 193)	**(52 102)**
Investing activities						
Investments in tangible assets		**(32)**	(102)	**(49)**	(137)	**(154)**
Interest received		**660**	-	**1 344**	-	
Increase/decrease in other investments		**9 352**	-	**8 645**	-	**(50 606)**
Net cash from/(used) in investing activities		**9 980**	(102)	**9 940**	(137)	**(50 761)**
Financing activities						
Proceeds from share issue		**-**	-	**-**	133	**133**
Net cash from/(used) in financing activities		**-**	-	**-**	133	**133**
Net increase in cash and cash equivalents		**(16 800)**	(3 582)	**(36 295)**	(20 198)	**(102 730)**
Cash and cash equivalents at the beginning of the period		**75 057**	180 666	**94 552**	197 282	**197 282**
Cash and cash equivalents at the end of the period		**58 257**	177 084	**58 257**	177 084	**94 552**

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

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

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

Intangible assets
Expenditure on own Research and Development are expensed as and when they incur. Expenses for other intangible assets are reflected in the balance sheet providing a future financial benefit relating to the development of an identifiable intangible asset can be identified and the cost can be measured reliably. Otherwise, such expenditure is expensed as and when incurred. Capitalized development costs are amortized linearly over the asset's expected useful life.

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

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

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

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

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

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

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

1) Interim figures are unaudited.

NOTE 1 REVENUE

Amounts in NOK thousands	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Revenue	**74**	-	**74**	-	**1 409**
Other	**-**	-	**-**	-	**-**
Total Revenue	**74**	-	**74**	-	**1 409**

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	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Other operating Income					
Government grants recognized in profit and loss	**375**	1 555	**750**	3 064	**6 242**
Other	**-**	9 622	**-**	9 622	**9 622**
Other operating Income	**375**	11 177	**750**	12 686	**15 864**

Government grants recognized 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 are not be reconcilable with the 2022 H1 report without adjusting for this error.

NOTE 3 GEOGRAPHICAL DISTRIBUTION INCOME

Amounts in NOK thousands	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Geographical distribution					
Norway	**375**	1 555	**750**	3 064	**6 242**
US	**74**	9 622	**74**	9 622	**11 031**
Total operating income	**449**	11 177	**824**	12 686	**17 273**

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

NOTE 4 PAYROLL AND RELATED EXPENSES

Amounts in NOK thousands	**Q2 2023**	Q2 2022	**H1 2023**	H1 2022	**FY 2022**
Payroll and related expenses, including directors, comprise					
Wages and salaries	**3 538**	4 352	**6 988**	7 818	15 814
Defined contribution pension const	**300**	194	**571**	403	820
Share-based payment expense	**1 086**	344	**2 104**	624	1 376
Social security contributions	**918**	830	**1 439**	538	1 597
Other personnel costs	**1 706**	455	**1 735**	492	1 526
Total payroll and related expenses	**7 549**	6 175	**12 837**	9 875	21 133

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 5 PROPERTY, PLANT AND EQUIPMENT

Amounts in NOK thousands	Machinery and equipment	**Total 2023**	Machinery and equipment	Total 2022
Carrying amount January 1	124	124	-	-
Additions	49	**49**	154	154
Depreciation	(28)	**(28)**	(30)	(30)
Carrying value June 30 / December 31	144	**144**	124	124
As of January 1				
Acquisition cost	154	**154**	-	-
Accumulated depreciation and write-downs	(30)	**(30)**	-	-
Carrying amount January 1	124	**124**	-	-
As of June 30 / December 31				
Acquisition cost	203	**203**	154	154
Accumulated depreciation and write-downs	(59)	**(59)**	(30)	(30)
Carrying amount June 30 / December 31	144	**144**	124	124

NOTE 6 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 first half of 2023, net financial income came in at NOK 7,5 million. The increase in net financial income is mainly a result of a conversion of the USD cash position into NOK.

NOTE 7 INTANGIBLE ASSETS

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

NOTE 8 TRADE AND OTHER RECEIVABLES

Amounts in NOK thousands	**30.06.2023**	30.06.2022	**31.12.2022**
Trade and other receivables			
Trade receivables	**74**	-	-
Governmental grants	**4 750**	7 072	5 500
VAT	**604**	274	498
Prepayments	**531**	297	737
Other receivables	**-**	-	-
Total trade and other receivables	**5 959**	7 643	6 735

NOTE 9 CASH AND CASH EQUIVALENTS

Amounts in NOK thousands	**30.06.2023**	30.06.2022	**31.12.2022**
Cash and cash equivalents			
Employee withholding tax	2 366	2 416	**1 373**
Variable rate bank accounts	55 890	174 668	**93 179**
Total Cash and cash equivalents	58 257	177 084	**94 552**

At the end of the period cash plus short-term financial investments was NOK 100.2 million compared to NOK 177.1 million as of 31 March 2022 and NOK 145.2 as of 31 December 2022.

NOTE 10 EQUITY AND SHARE CAPITAL

Amounts in NOK thousands	Share capital	Share premium reserve	**Total equity**
Balance on January 1, 2023	4 007	131 119	**135 126**
Income for the period			
Loss for the period	-	(51 109)	**(51 109)**
Total income for the period	-	(51 109)	**(51 109)**
Share based payment	-	2 104	**2 104**
Total contributions by and distributions to owners	-	2 104	**2 104**
Balance on June 30, 2023	4 007	82 115	**86 122**

Amounts in NOK thousands	Share capital	Share premium reserve	**Total equity**
Balance on January 1, 2022	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 April 20, 2022	133	-	**133**
Share based payment	-	1 376	**1 376**
Total contributions by and distributions to owners	133	1 376	**1 509**
Balance on December 31, 2022	4 007	131 119	**135 126**

Share capital on June 30, 2023, is NOK 4 006 831.9 (December 31, 2022: NOK 4 006 831.9), being 40 068 319 ordinary shares at a nominal value of NOK 0.1. All shares carry equal voting rights.

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

	30.06.2023	31.12.2022
Ordinary shares on January 1,	**38 739 013**	26 227 120
Capital increase April 20, 2022[1)]	**1 329 306**	-
Ordinary shares per 30 June 2023 / 31 December 2022	**40 068 319**	38 739 013

1) On March 15, 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 June 7, 2021, with a subscription price per share of NOK 0.1 and with an expiry date of June 6, 2022. The contribution was confirmed and registered in the Norwegian Register of Business Enterprises on April 20, 2022.

Top 20 shareholders at 31 June 2023

No.	Shareholder	No. of shares	Percentage share of total no. of shares
1	Citibank, N.A.	3 691 267	9.21%
2	Jakob Hatteland Holding AS	3 000 000	7.49%
3	North Murray AS	2 803 345	7.00%
4	Taj Holding AS	1 834 702	4.58%
5	Waatvika AS	1 808 764	4.51%
6	Lyr Invest AS	1 770 925	4.42%
7	Brødrene Karlsen Holding AS	1 709 274	4.27%
8	Care Holding AS	1 208 080	3.02%
9	Ynni Invest AS	1 202 049	3.00%
10	Picasso Kapital AS	1 122 860	2.80%
11	Per Strand Eiendom AS	1 024 128	2.56%
12	Skandinaviska Enskilda Banken AB	869 372	2.17%
13	LTH Invest AS	801 366	2.00%
14	Lysnes Invest AS	615 654	1.54%
15	Kvasshøgdi AS	604 727	1.51%
16	Belvedere AS	569 591	1.42%
17	Norinnova Invest AS	557 510	1.39%
18	Hifo Invest AS	555 555	1.39%
19	Saturn Invest AS	555 555	1.39%
20	Jahatt AS	500 000	1.25%
	Total number of shares for top 20 shareholders	26 804 724	66.90%
	Total number of shares for the other shareholders	13 263 595	33.10%
	Total number of shares	40 068 319	100.00%

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