Lisata Therapeutics, Inc.

USA, Germany / Biotechnology
Nasdaq
Bloomberg: LSTA US
ISIN: US1280583022

Initiation of coverage

RATING	**BUY**
PRICE TARGET	**$ 15.00**
Return Potential	304.3%
Risk Rating	High

CERTEPETIDE – THE COMPANION OF CHOICE TO IMPROVE CANCER THERAPY

Lisata Therapeutics Inc (Lisata), previously Caladrius Biosciences and renamed after the merger with Cend Therapeutics in 2022, is a US clinical-stage pharmaceutical company focused on the development of innovative therapies for the treatment of advanced solid tumours and other serious diseases. Its lead drug candidate, certepetide, is a peptide with a dual mode of action which (1) enhances penetration of co-administered anti-cancer drugs into solid tumours and (2) modifies the tumour microenvironment (TME) by reducing immunosuppressive cell populations, such as regulatory T cells (Tregs), and increasing cytotoxic T cells. This modulation has the potential to enhance the efficacy of chemo- and immunotherapies and concurrently inhibit the progression of metastasis, making certepetide an ideal combination with standard cancer therapy. The drug candidate is in clinical development in seven trials for a number of indications: (1) 1st and 2nd line metastatic pancreatic ductal adenocarcinoma (mPDAC), (2) locally advanced non-resectable PDAC, (3) 1st and 2nd line cholangiocarcinoma, (4) 1st line glioblastoma multiforme and (5) pancreatic, colon and appendiceal cancer. In addition, Lisata has licensed the exclusive rights for certepetide in Greater China to Qilu Pharmaceuticals under a lucrative agreement with potential milestone payments of up to USD221m. Qilu conducted a phase 1b/2a study and is now carrying out a phase 2 study in the lead 1st line mPDAC indication. Lisata's own ongoing two-cohort ASCEND phase 2b study in 1st line mPDAC is expected to report results from the first cohort in January 2025 and from the second cohort by Q2/Q3 2025. We see 2025 as an exciting year for Lisata as we also expect results on the other ongoing trials of certepetide, which will likely act as a catalyst for the share price. Our sum-of-the-parts valuation model yields a price target of USD15.00. We initiate coverage of Lisata with a Buy recommendation.

Lisata has a solid total liquidity of USD35.9m as of Q3/24 with a cash runway through Q1/26 Lisata's financial leeway allows for the achievement of various development milestones for certepetide in 2025. Based on strong preclinical and initial clinical data we believe there is a good chance that certepetide's results reported in 2025 will be positive. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2021	2022	2023	2024E	2025E	2026E
Revenue ($ m)	0.0	0.0	0.0	0.0	0.0	0.0
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT ($ m)	-29.0	-57.6	-25.7	-24.1	-25.4	-26.0
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income ($ m)	-27.5	-54.2	-20.8	-21.3	-22.7	-23.8
EPS (diluted) ($)	-7.45	-10.47	-2.58	-2.53	-2.17	-0.96
DPS ($)	0.00	0.00	0.00	0.00	0.00	0.00
FCF ($ m)	-22.3	-24.8	-20.0	-19.5	-20.5	-21.6
Net gearing	-26.7%	-26.7%	-48.3%	-46.9%	-48.6%	-74.4%
Liquid assets ($ m)	95.0	69.2	50.5	31.0	20.4	8.7

RISKS

Risks include, but are not limited to development, regulatory, competition and financial risks.

COMPANY PROFILE

Originally founded in 1980, Lisata Therapeutics results from the acquisition of Cend Therapeutics by Caladrius Biosciences in 2022. Lisata is a leading US biotech company focused on the development of certepetide, a cyclic peptide shown to enhance the delivery of existing anti-cancer treatments. Certepetide is in clinical trials for various cancer indications, including mPDAC, which will report results throughout 2025.

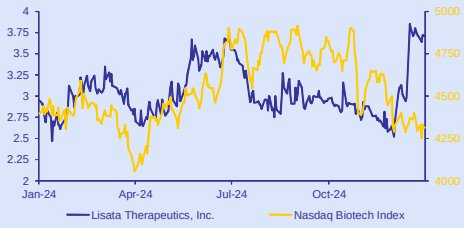
MARKET DATA

As of 17 Jan 2025

Closing Price	$ 3.71
Shares outstanding	8.32m
Market Capitalisation	$ 30.87m
52-week Range	$ 2.47 / 3.85
Avg. Volume (12 Months)	17,424

Multiples	2023	2024E	2025E
P/E	n.a.	n.a.	n.a.
EV/Sales	n.a.	n.a.	n.a.
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Sep 2024

Liquid Assets	$ 35.86m
Current Assets	$ 37.69m
Intangible Assets	$ 0.21m
Total Assets	$ 38.20m
Current Liabilities	$ 4.69m
Shareholders' Equity	$ 33.44m

SHAREHOLDERS

Erkki Ruoslahti	14.2%
BML Capital Management LLC	3.4%
David Mazzo	2.5%
Vanguard Global Advisers LLC	2.2%
Freefloat & others	77.6%

Analyst: Christian Orquera, Tel. +49 30 80 93 96 90

CONTENTS **PAGE**

INVESTMENT CASE

Proprietary Technology - CendR Platform and lead drug candidate certepetide promise to revolutionise treatments across oncology and other diseases characterised by complex biological barriers Lisata Therapeutics' (Lisata) main competitive edge lies in its proprietary drug candidate certepetide, developed through its CendR Platform® technology. Certepetide addresses a key challenge in oncology: improving targeted drug penetration of solid tumours, which account for the vast majority of cancer cases. Conventional cancer therapies often struggle to penetrate the dense tumour stroma, resulting in suboptimal efficacy. However, certepetide's unique dual mode of action also modifies the tumour microenvironment (TME), enhancing immune response through the increase of cytotoxic T cells and the reduction of immunosuppressive cell populations, such as regulatory T cells (Tregs). The drug candidate not only improves the efficacy of current treatments including chemotherapy and immunotherapy, but does so without any exacerbation of side effects from the co-administered cancer therapy. Lisata's primary focus for certepetide is on the clinical development of first-line treatment of advanced metastatic pancreatic ductal adenocarcinoma (mPDAC). In addition, the company is conducting clinical trials for certepetide in a variety of solid tumours. Of the seven total ongoing certepetide clinical trials, six are expected to report results in the course of 2025.

Strong partnerships validate the technology and leverage financial resources Lisata has closed two highly significant licensing partnerships with attractive conditions that validate certepetide: (1) Licensing agreement with heavyweight Qilu Pharmaceutical in China entailing exclusive rights to develop and commercialise the drug for the treatment of solid tumours in Greater China, including Taiwan, Hong Kong, and Macau. Lisata has received milestone payments of USD15m so far with the prospect of further payments of up to USD221m for various indications, dependent on reaching certain development and commercialisation milestones. (2) Global license agreement with Kuva Labs to develop advanced magnetic resonance (MR) imaging agents for the detection of solid tumour cancers based on certepetide. Kuva's NanoMark technology is designed to provide a targeted, non-radioactive imaging option with unparalleled contrast resolution, significantly advancing the early detection and diagnosis of solid tumours. The terms include a USD1m upfront license fee, USD19m in potential regulatory and commercial milestone payments, and royalties on future product sales.

Two separate open-label phase 1b/2a trials of certepetide + chemotherapy in mPDAC conducted in Australia and China showed significant efficacy improvement against chemotherapy alone Lisata conducted two independent open-label 1b/2a trials of certepetide at the recommended dose of 3.2 mg/kg (administered as a single intravenous push) in combination with standard of care (SOC) consisting of chemotherapeutic agents gemcitabine and nab-paclitaxel to assess the safety, tolerability, and preliminary efficacy of this combination therapy in first-line mPDAC. The first trial was conducted at 3 sites in Australia in 31 mPDAC patients (see Dean et al., 2022). The second trial in China had a similar design to the Australian trial and was conducted by the Chinese partner Qilu on 55 mPDAC patients. Both studies reported clear efficacy improvement in the key median overall survival (OS - usually the primary endpoint of pivotal studies) compared with historical efficacy in mPDAC trials of SOC administration, as described in the scientific literature (von Hoff et al., 2013, New England Journal of Medicine). The addition of certepetide to standard therapy improved median OS rates by 55% from 8.5 to 13.2 months in Australia and by 31% from 8.5 to 11.1 months in China. All other investigated efficacy endpoints such as progression-free survival (PFS), partial response (PR), disease control rate (DCR) and objective response rate (ORR) also showed a consistent improvement in both trials. These findings provided a strong foundation for the continued development of certepetide in later-phase clinical trials. The results were particularly promising given the aggressive nature of mPDAC and the limited success of current therapies.

Ongoing two-cohort, placebo-controlled ASCEND phase 2b trial of certepetide in combination with chemotherapy as a first-line treatment of mPDAC in Australia and New Zealand (n=155) Lisata, in collaboration with the Australasian Gastrointestinal Trials Group (AGITG), is conducting a two-cohort phase 2b study in mPDAC in Australia and New Zealand evaluating the efficacy, safety, and tolerability of certepetide at a dose of 3.2 mg/kg (either as a single administration or as two administrations) in combination with standard-of-care (SoC) chemotherapy (gemcitabine+nab-paclitaxel). The second cohort has a modified dosing regimen in which the second intravenous dose of certepetide is administered four hours after the initial dose. This design will provide critical insights into the most effective dosing strategy for the pivotal phase 3 clinical trials. Due to the additional certepetide exposure which may potentially enhance chemotherapeutic agent penetration into tumour cells, we see a possibility that this cohort could improve efficacy even further. Enrolment was completed in December 2023. Top-line data from an interim analysis of the 95 patients assigned to the first cohort of the study will be presented at the American Society of Clinical Oncology Gastrointestinal (ASCO-GI) Cancers Symposium in San Francisco, CA on 23-25 January 2025 (https://conferences.asco.org/gi/program). The full dataset of all 155 patients, including both cohorts from the trial, will be made available by mid-2025, which could enable the start of a phase 3 trial in 2026.

Qilu is also conducting a first-line mPDAC phase 2 trial in China (n=120) Qilu's double-blind, placebo-controlled, randomised, multi-centre trial evaluating the efficacy and safety of certepetide administered at a 3.2 mg/kg dose as a single IV push in combination with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel and placebo as first-line treatment in 120 patients with mPDAC is also underway. The first patient was enrolled in April 2024 and publication of preliminary ORR data is anticipated for Q3 2025.

mPDAC and solid tumours are growing markets with high unmet medical need The solid tumour market was valued at USD170.3bn in 2023 and is expected to grow at a CAGR of 7.45% to hit USD375.4bn by 2034. In 2022, there were 20m new cancer cases globally, resulting in 10m deaths, with over 90% of these cancers classified as solid tumours. Looking ahead to 2050, the number of new cancer cases is projected to rise by 77% to 35m, while cancer-related deaths are expected to reach 18.5m. PDAC alone is expected to become the second leading cause of cancer-related deaths by 2030, and only 3% of patients survive five years after diagnosis (International Agency for Research on Cancer – IARC- and Globocan, 2020; National Institutes of Health, UEG Public Affairs). Certepetide's potential to improve these outcomes in combination with standard treatments, makes Lisata's platform highly attractive.

Lisata shares are undervalued in our view. We initiate coverage with a price target of USD15.00 and a Buy recommendation Our proprietary risk-adjusted sum-of-the-parts valuation model suggests fair value for Lisata of USD15.00 per share. We believe that the preliminary results from the first cohort of the ongoing phase 2b trial of certepetide + chemotherapy in mPDAC in Australia, due in January 2025, could mark the start of a rerating of the stock. We also expect positive news on the achievement of further important development milestones in the numerous ongoing clinical trials for various solid-tumour indications due over the course of 2025 to act as strong catalysts for the stock. We believe that investors have not yet recognised the enormous potential of the anti-cancer drug candidate certepetide, which could improve the treatment of solid tumours.

SWOT ANALYSIS

STRENGTHS

- **Proprietary certepetide technology** Lisata's proprietary certepetide technology, which is based on the CendR Platform®, provides a cutting-edge approach to improving the targeting and penetration of anti-cancer drugs in solid tumours. This technology positions Lisata as a leader in the highly specialized field of tumour microenvironment modification, allowing for enhanced drug delivery and immune response.

- **Strategic partnerships** Lisata has established valuable partnerships, particularly with Qilu Pharmaceutical, which has exclusive development and commercialisation rights for certepetide in key Asian markets. This partnership not only strengthens Lisata's financial position through milestone payments but also reduces development costs and risks in those regions. We also note the global license agreement with Kuva Labs to develop advanced magnetic resonance (MR) imaging agents for the detection of solid tumour cancers based on certepetide. Kuva's NanoMark technology is designed to provide a targeted, non-radioactive imaging option with unparalleled contrast resolution, significantly advancing the early detection and diagnosis of solid tumours.

- **Solid financial position** The company has a solid financial foundation, with USD35.9m in cash and short-term investments and no debt as of 30 September 2024. These funds will enable Lisata to support its clinical development programmes through critical milestones in 2025. We estimate that the cash will last into ~Q1 2026.

WEAKNESSES

- **Early-stage pipeline** While certepetide shows promise, Lisata remains in the clinical-stage of development, and its lead compounds have not yet been commercialised. This exposes the company to significant risks, including the possibility of clinical trial failures or delays, which could affect future growth prospects.

- **Small size compared with large competitors active in the solid tumour market** With a market cap of ~USD25m, Lisata is small compared to peers such as Eli Lilly, Ipsen, Merrimack Pharmaceutials, Halozyme Therapeutics and Medac, or the big immuno-oncology players such as Bristol Myers (Juno Theraputics), Roche (Spark Therapeutics), Merck & Co, AstraZeneca, Novartis, Gilead Sciences (Kite Pharma) and Iovance Biotherapeutics.

- **Dependence on external partnerships** Lisata's reliance on external partners, particularly for development and commercialisation in international markets, means it has limited control over these processes.

OPPORTUNITIES

- **Growing global demand for cancer therapies** With over 90% of global cancer cases being solid tumours, Lisata's focus on treating these types of cancers offers significant market potential. The company is well-positioned to capitalise on the increasing demand for more effective treatments, particularly for difficult-to-treat cancers such as pancreatic and liver cancer.

- **Designation by state agencies** Certepetide's Fast Track designation, Rare Pediatric Disease designation and Orphan Drug designations from the FDA and EMA provide accelerated regulatory pathways and potential financial incentives. This can expedite the development and commercialisation of certepetide, allowing Lisata to bring its treatments to market more quickly while benefiting from exclusivity, tax credit and business-related benefits.

- **Market potential expansion for certepetide in other cancer indications** Lisata is currently focusing most of its resources on certepetide's lead mPDAC indication. Certepetide is in phase 1-2 clinical development in further attractive cancer indications such as 1st and 2nd line cholangiocarcinoma, 1st line glioblastoma multiforme, pancreatic, colon and appendiceal cancer. These new indications hold out the prospect of significant additional market potential.

- **Expansion into emerging markets** Through its partnership with Qilu Pharmaceutical, Lisata has the opportunity to extend certepetide's reach into the Chinese market, one of the largest for cancer therapies. The potential for additional partnerships in other regions, such as Latin America or Africa, presents further growth opportunities for the company.

THREATS

- **Regulatory and clinical risks** The success of Lisata's pipeline is highly dependent on the outcomes of ongoing clinical trials and the approval of regulatory agencies. Any delays, negative trial results, or stringent regulatory hurdles could significantly impact the company's timeline and financial performance.

- **Strong competition in oncology** The oncology market is highly competitive, with numerous companies developing similar therapies targeting solid tumours. Larger, more established pharmaceutical companies with greater resources may pose a threat to Lisata's ability to secure market share, even if its treatments are successful.

- **Reimbursement and pricing challenges** Even if certepetide successfully gains regulatory approvals, securing favourable reimbursement rates from insurance companies and healthcare systems can be challenging. The pricing of oncology drugs is often scrutinised, and Lisata may face pushback from payers on pricing, or restrictions on patient access.

VALUATION

"SUM-OF-THE-PARTS" VALUATION MODEL

Biotechnology valuation is notoriously difficult since there is high risk in R&D pipeline development, which leads to uncertainty in projecting cash flows. We have assessed Lisata's fair value based on a sum-of-the-parts methodology. We believe this is the most appropriate valuation method for Lisata because it reflects the implicit risk-adjusted value of every drug candidate in its R&D pipeline. Development risks, including clinical and regulatory risks, are taken into account as are market size and the expected timing of cash flows post-approval for each project.

We have used a risk-adjusted NPV model for the lead drug candidate certepetide in the following indications: (1) first-line metastatic pancreatic ductal adenocarcinoma - mPDAC; (2) first-line mPDAC in partnership with Qilu for China; (3) first- and second-line cholangiocarcinoma – CCA; (4) glioblastoma multiforme – GBM; and (5) colon (CN) & appendiceal cancer (AL). We believe that other preclinical indications are also promising, such as endometriosis or melanoma. However, due to their earlier preclinical stage, we consider them as upside to our valuation. During the forecasting process, we adjust our sales estimates and resulting cash flows for success probabilities to obtain risk-adjusted expected values. We base our probability coefficients on statistical sector studies, such as the Tufts CSDD, and on our own estimates.

Additionally, using First Berlin methodology, which takes into account company-specific risk factors, we have derived a cost of equity (COE) of 16% for Lisata. Based on a debt ratio of 0%, we arrive at a WACC of 16%, which we have used to discount projected cash flows. Including projected proforma net cash of USD81.0m, we value Lisata at USD288.7m, which implies a fair value of USD15.00 (€14.60) per share on a proforma fully diluted basis. Using our ten-factor risk analysis, we set a High risk rating for Lisata. The main risk factors that we have identified are development, regulatory, competition and financing.

Table 1: "Sum-of-the-parts" valuation model

Compound	Project[1]	Present Value	Patient Pop (K)	Treatment Cost (USD)	Market Size (USDM)	Market Share (%)	Peak Sales (USDM)	PACME Margin[2] (%)	Discount Factor (%)	Patent Life[3] (years)	Time to Market (years)
Certepetide	mPDAC - US	USD 86.6M	33K	120,000	3,960.0M	10%	532.2M	22%	16.0%	12	6
Certepetide	mPDAC - EU	USD 70.3M	50K	80,000	4,000.0M	10%	497.3M	22%	16.0%	12	6
Certepetide	mPDAC - China	USD 49.8M	57K	70,000	3,990.0M	10%	568.9M	13%	16.0%	12	6
Certepetide	CCA - US & EU	USD 23.2M	17K	90,000	1,530.0M	15%	327.2M	22%	16.0%	12	6
Certepetide	GBM - US & EU	USD 34.5M	25K	90,000	2,250.0M	15%	467.2M	22%	16.0%	12	6
Certepetide	CN & AL - US & EU	USD 25.4M	450K	90,000	40,500.0M	2%	1,194.6M	22%	16.0%	12	8
PACME PV		USD 289.7M			56,230.0M		3,587.4M				
Costs PV[4]		USD 95.7M									
NPV		USD 194.0M									
Milestones PV		USD 13.8M									
Net cash (proforma)		USD 80.9M									
Fair Value		USD 288.7M									
Share Count (proforma)		19,187K									
Price Target		USD 15.00									
Price Target		EUR 14.60	(based on EUR-USD exchange rate of 1.03)								

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining market exclusivity after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

ESTIMATED PRICE FOR CERTEPETIDE

Peer drugs and certepetide's potential pricing Pricing of comparable oncology drugs such as checkpoint inhibitors with a US average of USD 144k p.a. (source: Guirguis et al., 2021) suggests that a sales price of USD120k per patient per year should be achievable for certepetide in the US given that drug prices have shown an upward trend since 2021. Price levels in Europe are generally 20-30% and in China even up to 40% lower than in the US, depending on the drug and indication. We have therefore assumed pricing of USD80k (-33%) for the European and USD 70k (-42%) for the Chinese markets. Our price estimate implies a slight discount to the peer drugs which will in our view promote the achievement of faster reimbursement and market penetration. For some indications we have assumed a combined average price for the US+Europe in our NPV calculation.

Incidence in PDAC The Hirshberg Foundation for Pancreatic Cancer Research estimates that 66,440 Americans will be diagnosed with PDAC in 2024. Similarly, data from the European Commission indicates that 100,152 individuals in the EU were diagnosed with PDAC in 2020, which can be used as an estimate for 2024. In China, the number of pancreatic cancer cases was estimated at 114,964 in 2019 according to an article by He Y., et al (Disease Burden of Pancreatic Cancer - China, 1990-2019). According to the WHO, ~30% of PDAC cases are diagnosed as locally advanced and unresectable, while ~50% are identified as metastatic. Based on statistical data on the incidence of the different cancer types, we project the following target population in the core regions.

Table 2: New cases of PDAC diagnosed annually

Types of cancer (PDAC)	Segmentation (% of PDAC)	Newly diagnosed in the US each year (k)	Newly diagnosed in the EU each year (k)	Newly diagnosed in China each year (k)
PDAC	100%	66	100	115
Metastatic	50%	33	50	57
LANR	30%	20	30	34
Earlier-stage	20%	13	20	24

Source: First Berlin Equity Research; WHO; PCE; The Hirshberg Foundation for Pancreatic Cancer Research; He Y., et al. Disease Burden of Pancreatic Cancer - China, 1990-2019, China CDC

Incidence of advanced-stage colon cancer The American Cancer Society expects 106,590 new cases of colon cancer in the US in 2024. The European Commission estimates that there were 341,419 new cases of colon cancer in the European Union in 2020. In China, colon cancer is on the rise. According to an article by Global Burden of Disease, 607,900 new cases were diagnosed in mainland China in 2019.

Incidence of appendiceal cancer (AC) AC is a rare disease. According to the MD Anderson Cancer Center, only 3,000 new cases of AC are diagnosed in the US each year. In addition, Patrick-Brown TD et al., 2021, estimated the incidence of AC at ~3.2 persons per million in Europe. Based on the EU population, ~1,430 new AC cases are diagnosed each year.

Incidence of cholangiocarcinoma (CCA) CCA is also a rare disease. According to Servier, estimates of incidence in Western Europe and North America vary between 0.3 and 3.5 cases per 100,000 every year. Based on these statistics, we estimate the prevalence of CA at ~8,000 cases in the US and ~9,000 in the EU.

Incidence of glioblastoma multiforme (GBM) GBM is another rare disease. According to a study published by Gallego O. in August 2015, the annual incidence of glioblastoma multiforme is 3.19 cases per 100,000 inhabitants, which equates to ~11,000 new cases in the US and ~14,000 in the EU.

Table 3: Overview of new cases of different solid tumours diagnosed annually

# of patients p.a.	Colon	Appendiceal	CCA	GBM
Total (k)	1,056	4	17	25
USA (k)	107	3	8	11
EU (k)	341	1	9	14
China (k)	608	-	-	-

Source: First Berlin Equity Research

Licensing and royalties (PACME) We assume that the company will license certepetide in mPDAC to a pharmaceutical partner after the successful completion of the ongoing phase 2b study and demonstration of efficacy, receiving a royalty rate of 22% upon commercialisation, which also equates to the PACME margin. Lisata is entitled to receive tiered royalties from Qilu in China ranging from 10% to 15%of net sales. We expect that the US/European partner will organise the manufacturing of the product by Lisata's CRMO, take over development and registration, carry out commercialisation and bear the costs of marketing and distribution in the corresponding regions. Based on standard development timelines, we anticipate that the lead mPDAC drug could enter phase 3 trials in 2026 and reach the market in 2030. We note that Lisata has both fast track and orphan drug designations from the FDA, and orphan drug designation from the EMA for mPDAC. This enables faster review processes in both the US and the EU and could shorten the approval period by 6 to 12 months (i.e. 2029). We expect the European/US partner to in-license an option for the additional solid tumour indications which would take effect upon proof of concept in phase 2b. We expect that the three rare disease indications could also be launched by 2030 as these require smaller studies that could even benefit from accelerated approval. Meanwhile we assume that the colorectal indication could be approved and launched by 2032.

Market share and market growth of solid tumour cases We assume that Lisata will achieve a market share of ~2-15% in the target markets USA, Europe and China (where applicable) in the various indications. We consider this conservative given that there are currently no treatment alternatives on the market in most of these indications that can improve patient survival beyond standard treatment. We have also assumed that PDAC and the additional targeted indications for solid tumours will grow at a CAGR of 3% until 2040. We project total peak sales potential of ~USD532m five years after launch for certepetide in the core US market, ~USD497m in Europe and ~USD569m in China. Further assumptions are summarised in our SOTP valuation model (table 1).

COMPANY PROFILE

CERTEPETIDE: DRIVING INNOVATION IN ONCOLOGY AND BEYOND

Company overview Lisata Therapeutics Inc (Lisata), headquartered in Basking Ridge, New Jersey, is a US clinical-stage pharmaceutical company focused on the development of innovative therapies for advanced solid tumours and other serious diseases. The company was originally founded in 1980 with a focus on gene and cell therapies and underwent a transformative change in 2022 when it acquired immuno-oncology specialist Cend Therapeutics. Following the merger, the company was renamed Lisata Therapeutics, possessing Cend's proprietary CendR Platform® technology and lead drug candidate certepetide (also known as LSTA1 or CEND-1) as a new development focus in oncology. Lisata is listed on NASDAQ under the ticker symbol LSTA.

CendR Platform® technology – it leverages a natural biological pathway to optimise drug delivery and efficacy Lisata's proprietary CendR Platform® technology incorporates novel methods to enhance the targeting and penetration of standard anti-cancer drugs into tumours and other diseased tissues. The platform can also selectively modify the tumour microenvironment (TME) by targeting non-cancerous, immunosuppressive cells within the tumour, thereby improving the patient's immune response and the efficacy of immunotherapies. The platform is highly versatile, with applications spanning small molecule drugs, biologics, gene and cell therapies, and immunotherapies. It is particularly effective in delivering chemotherapeutic agents, monoclonal antibodies, peptides, proteins, and nucleic acid-based therapies, including mRNA and siRNA. By improving the delivery of these therapies to tumour sites, the CendR Platform® enhances therapeutic efficacy while reducing off-target toxicity and systemic side effects. In the case of immunotherapies, it increases access to immune cells and tumour antigens, thereby boosting their efficacy even in dense, immunosuppressive TMEs. Importantly, the products developed are complementary, i.e. they are designed to improve the efficacy of approved standard therapies and not compete with them. This lowers potential barriers to adoption.

Certepetide-based R&D pipeline Lisata's pipeline incorporates the CendR Platform® into a range of therapeutic strategies, with its lead candidate, certepetide, being a prominent example. Certepetide is a groundbreaking cyclic peptide that can be best described as a pipeline in a drug as it is currently under clinical investigation for its ability to improve chemotherapy and immunotherapy delivery in a wide range of solid tumours such as metastatic pancreatic cancer (mPDAC - lead indication), cholangiocarcinoma, glioblastoma, colon and appendiceal cancer (see figure 1 below).

Figure 1: Overview of certepetide's development programmes

Sponsor(s)	Indication	Description	Current Phase		
			Phase 1	Phase 2	Phase 3
AGITG/Lisata	First-line mPDAC	▪ ASCEND: Phase 2b, placebo-controlled trial (N=158) ▪ Gemcitabine/nab-paclitaxel + certepetide or placebo ▪ Australia/New Zealand	Enrollment complete		
Lisata	*First- and Second-line Cholangiocarcinoma (CCA)*	▪ BOLSTER: Phase 2a, placebo-controlled trial (N=80) ▪ 1L CCA: Gemcitabine/cisplatin/durvalumab with certepetide or placebo ▪ 2L CCA: FOLFOX with certepetide or placebo ▪ United States	1L CCA Enrollment complete	2L CCA Enrolling	
KUCC/Lisata *Investigator-initiated trial*	*Pancreatic, Colon, and Appendiceal Cancers*	▪ CENDIFOX: Phase 1b/2a, open-label trial (N=51) ▪ *FOLFIRINOX + panitumumab* + certepetide* ▪ United States	Enrolling		
Qilu/Lisata	*First-line mPDAC*	▪ Phase 1b/2a, open-label trial (N=55) ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	Enrollment complete		
WARPNINE/Lisata	*Locally advanced, non-resectable PDAC*	▪ iLSTA: Phase 1b/2a, open-label trial (N=30) ▪ *Gemcitabine/nab-paclitaxel/durvalumab + certepetide* ▪ Australia	Enrolling		
Tartu University/Lisata *Investigator-initiated trial*	*First-line Glioblastoma Multiforme (GBM)*	▪ Phase 2a, placebo-controlled trial (N=30) ▪ *Temozolomide +/- certepetide* ▪ Estonia/Latvia	Enrolling		
Qilu/Lisata	*First-line mPDAC*	▪ Phase 2, placebo-controlled trial (N=120) ▪ *Gemcitabine/nab-paclitaxel + certepetide* ▪ China	Enrolling		
Lisata	*Second-line mPDAC*	▪ FORTIFIDE: Phase 1b/2a placebo-controlled trial (N=30) ▪ Gemcitabine/nab-paclitaxel + continuous infusion of certepetide/placebo ▪ United States	Enrolling soon		

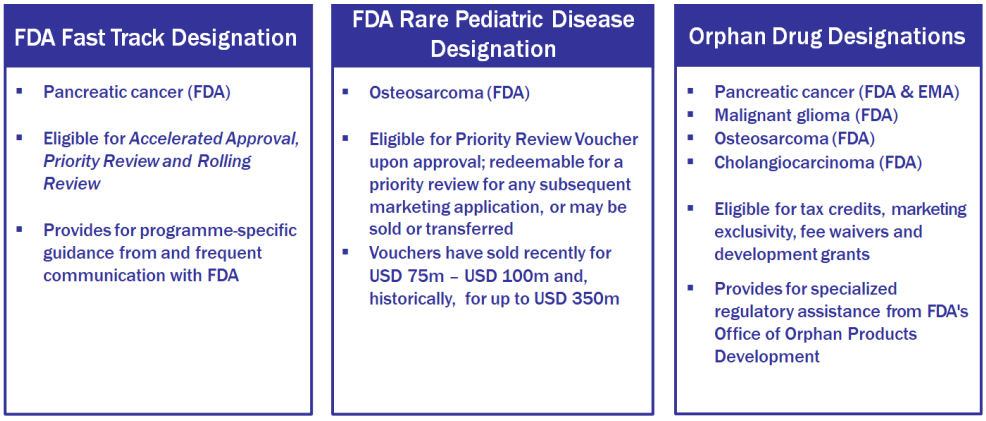
Source: First Berlin Equity Research, Lisata Therapeutics Inc

Mixed funding of pipeline development While the lead phase 2b ASCEND trial in mPDAC is largely funded by the company's own resources, some of the other studies are funded either by the Chinese partner Qilu Pharmaceuticals (phase 1b/2a and phase 2 mPDAC studies in China) or by academic institutions (CENDIFOX phase 1b/2a study sponsored by University of Kansas Cancer Center - KUCC - and phase 2a study in glioblastoma sponsored by the Tartu University). Overall, the clinical studies have shown encouraging results so far with evidence of improved drug penetration and therapeutic outcomes, including extended progression-free and overall survival in patients with very aggressive cancers.

Two-pillar development strategy Certepetide's development is structured around two main pillars: (1) focuses on pursuing rapid global registration for the lead pancreatic ductal adenocarcinoma (mPDAC). The strategy involves combining certepetide with standard-of-care (SoC) treatments, specifically gemcitabine and nab-paclitaxel. The phase 2b study has already achieved 100% enrolment and preparations for phase 3 trials are currently underway. (2) emphasizes demonstrating the effectiveness of certepetide across a broader range of solid tumours. This involves evaluating its performance when combined with various other SoC regimens, such as chemotherapy, immunotherapy, and other treatments.

Certepetide has achieved valuable regulatory designations Lisata has received multiple regulatory designations that highlight its therapeutic potential and provide pathways for expedited development and review. These include the FDA's Breakthrough Therapy Designation, which facilitates more intensive FDA guidance and faster review processes for drugs addressing unmet medical needs, and Orphan Drug Designation, which offers incentives such as market exclusivity and tax credits for rare disease treatments. These designations not only underscore the potential of certepetide to address critical medical needs but could also accelerate its clinical development and regulatory approval, enhancing its prospects for timely availability to patients.

Figure 2: Certepetide special regulatory designations and benefits



Source: First Berlin Equity Research, Lisata Therapeutics Inc

Patent portfolio Lisata holds a portfolio of patents related to its proprietary CendR Platform® technology and certepetide. These patents encompass methods and compositions designed to enhance the delivery and efficacy of anti-cancer therapies by targeting and penetrating solid tumours more effectively. The intellectual property covers various therapeutic modalities, including chemotherapeutics, immunotherapies, and RNA-based treatments. The status of these patents varies, with some granted and others pending in multiple jurisdictions.

MULTIPLE PARTNERSHIPS VALIDATE CERTEPETIDE

Lean R&D structure comprising own expertise and complemented by cooperation partners' capabilities and know-how – the partnerships provide significant advantages Lisata has implemented a resource efficient R&D structure that combines its CendR Platform® technological resources, immuno-oncology and drug development expertise with complementary external scientific and clinical development expertise in key areas from well-chosen cooperation partners from academia. Lisata is collaborating with the Australasian Gastro-Intestinal Trials Group (AGITG – has a network of up to 40 sites in Australia and New Zealand) on the lead ASCEND trial, a phase 2b clinical study evaluating certepetide in combination with chemotherapy for first-line treatment of mPDAC. The company is also collaborating with WARPNINE Incorporated, Australia's first not-for-profit clinical research organisation (CRO) focusing on pancreatic, gastrointestinal, and rare cancers, to conduct the iLSTA trial. The iLSTA trial is a phase 1b/2a study evaluating certepetide in combination with SOC and the checkpoint inhibitor durvalumab as a first-line treatment for patients with locally advanced, non-resectable PDAC. These are important institutions given that (1) Clinical trials conducted in Australia are cheaper than in the US and Lisata also receives substantial discounts on the costs incurred and (2) clinical studies conducted in Australia and New Zealand are generally accepted for drug approval in the US, as their regulatory frameworks (e.g. the Therapeutic Goods Administration (TGA) in Australia and Medsafe in New Zealand) closely align with those of the FDA. Also, the methods of treatment in Australia and New Zealand are similar to those in the US. Therefore, clinical trials in Australia and New Zealand are often designed to meet international standards and principles of Good Clinical Practice (GCP) as outlined by the International Council for Harmonisation (ICH).

Development and commercial partnership with heavyweight Qilu Pharmaceuticals validate the company's technology and lead candidate Lisata has entered into a collaboration and license agreement for certepetide with Qilu Pharmaceutical, one of the largest pharmaceutical manufacturers in China with a significant presence in the global market and revenue in the multibillion USD range. Under this agreement, Qilu holds exclusive rights to develop and commercialise the drug in Greater China, including Taiwan, Hong Kong, and Macau. Qilu is responsible for all development and commercialisation activities and costs within these territories. Lisata stands to receive up to USD221m in milestone payments across multiple indications, contingent upon specific development and commercial achievements. Additionally, Lisata is entitled to tiered double-digit royalties on product sales in the region.

Further preclinical collaborations to expand indications Lisata is conducting further preclinical activities for certepetide in collaboration with reputable partners for two additional indications, endometriosis and melanoma:

- **Collaboration with the University of Cincinnati in the US** In the study focused on endometriosis, the objective is to evaluate the therapeutic effect of adding certepetide to bevacizumab, a vascular endothelial growth factor (VEGF) inhibitor. The study aims to determine how this combination impacts the size and number of endometriotic lesions in a murine endometriosis model (C57BL/6J mice) The company plans the release of data from this study in Q1 2025.
- **Collaboration with Valo Therapeutics in Finland** In a study targeting melanoma, the partner is assessing the combined therapeutic effects of *PeptiCRAd* (an oncolytic virus), certepetide, and a checkpoint inhibitor (CPI). This research aims to evaluate the impact of the combination therapy on systemic T cell responses, T cell infiltration into tumours, and tumour growth control. The preclinical study uses the murine melanoma model B16-OVA. The company expects release of data from this study in Q2 2025.

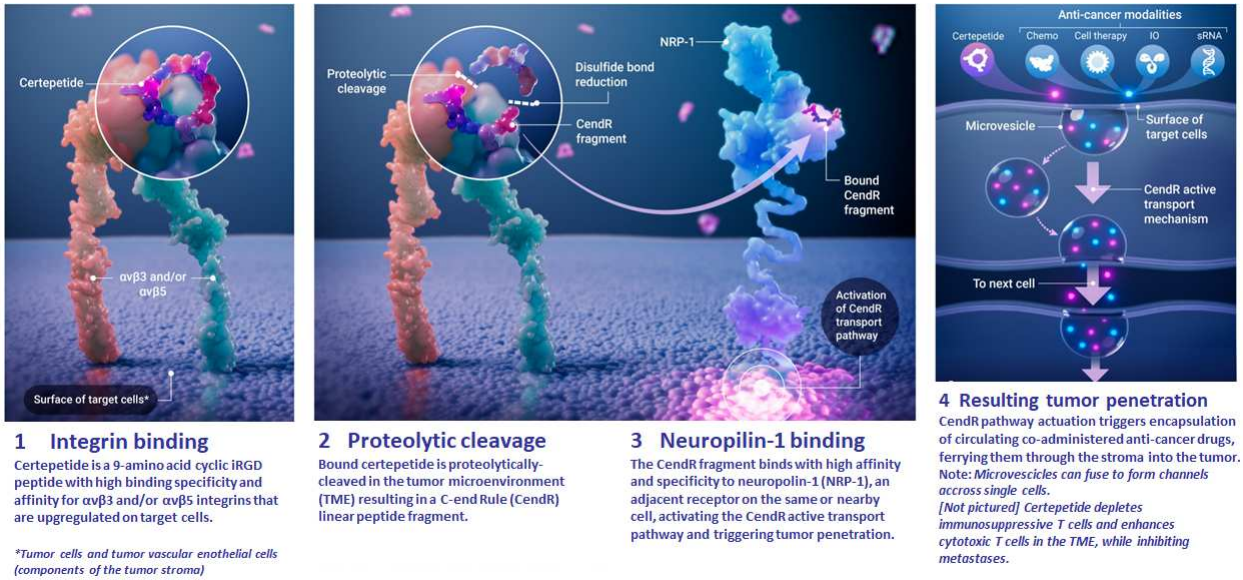
Global collaboration and license agreement with Kuva Labs to develop advanced magnetic resonance (MR) imaging agents for the detection of solid tumour cancers This partnership leverages Lisata's investigational iRGD cyclic peptide, certepetide, as a targeting and enhanced delivery agent integrated with Kuva's NanoMark™ platform technology. The combination aims to enable safe, non-invasive, and precise detection of solid tumours through improved imaging contrast and specificity. Under the agreement, Kuva Labs assumes responsibility for all research, development, and commercialisation costs associated with NanoMark™, while Lisata will supply certepetide. The terms include an upfront license fee, potential milestone payments, and royalties on future product sales to Lisata. This collaboration underscores certepetide's versatility, extending its application beyond therapeutic uses into cancer diagnostics, potentially leading to earlier treatment and improved patient outcomes. Kuva's NanoMark™ technology is designed to provide a targeted, non-radioactive imaging option with unparalleled contrast resolution, significantly advancing the early detection and diagnosis of solid tumours.

LEAD DRUG CANDIDATE CERTEPETIDE

CERTEPETIDE – MODE OF ACTION

Dual mode of action The Company's investigational compound, certepetide (LSTA1), developed as part of the innovative CendR Platform®, is designed to improve the targeting and penetration of solid tumours by anti-cancer drugs. certepetide is a nine amino acid cyclic internalising RGD ("iRGD") peptide which activates a specific uptake pathway that enables co-administered or molecularly linked therapies to penetrate tumours more effectively, enhancing the accumulation of anti-cancer agents while minimising effects on healthy tissues. The CendR Platform® integrates advanced technologies to (1) improve tumour-specific delivery facilitating deeper drug penetration into tumours and (2) selectively targeting non-cancerous, immunosuppressive cells within the tumour. This dual mechanism reduces the tumour's defences against the body's immune system, making it more responsive to immunotherapies and enabling a more effective fight against cancer.

Figure 3: Certepetide selective tumour targeting and penetration mechanism of action



1 Integrin binding
Certepetide is a 9-amino acid cyclic iRGD peptide with high binding specificity and affinity for αvβ3 and/or αvβ5 integrins that are upregulated on target cells.

**Tumor cells and tumor vascular enothelial cells (components of the tumor stroma)*

2 Proteolytic cleavage
Bound certepetide is proteolytically-cleaved in the tumor microenvironment (TME) resulting in a C-end Rule (CendR) linear peptide fragment.

3 Neuropilin-1 binding
The CendR fragment binds with high affinity and specificity to neuropolin-1 (NRP-1), an adjacent receptor on the same or nearby cell, activating the CendR active transport pathway and triggering tumor penetration.

4 Resulting tumor penetration
CendR pathway actuation triggers encapsulation of circulating co-administered anti-cancer drugs, ferrying them through the stroma into the tumor.
Note: *Microvescicles can fuse to form channels accross single cells.*
[Not pictured] Certepetide depletes immunosuppressive T cells and enhances cytotoxic T cells in the TME, while inhibiting metastases.

Source: Ding et. al., Nature Comm, 2019; Lisata Therapeutics Inc

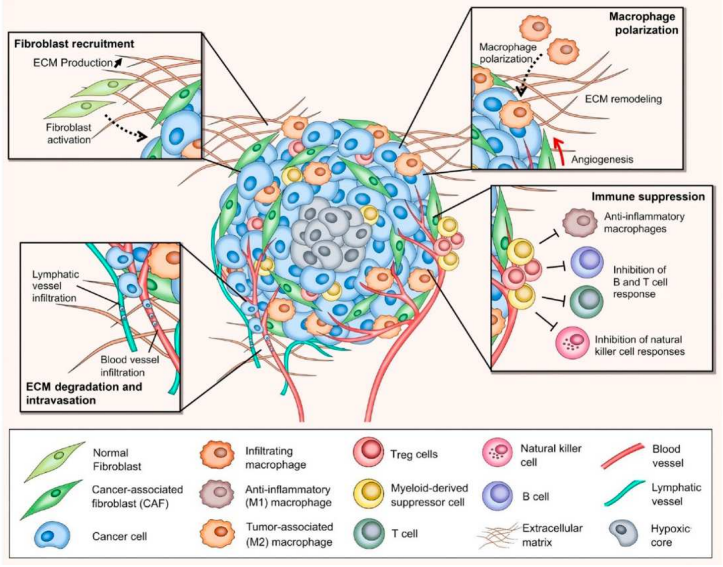
The tumour microenvironment (TME) – a difficult barrier for anticancer-drugs to overcome One of the major challenges in treating solid tumours is the TME, which consists of non-cancerous components such as the extracellular matrix, blood vessels, and immune cells. The extracellular matrix forms a dense, desmoplastic stroma around tumour cells, creating a physical barrier that limits drug delivery. Additionally, the poor and abnormal vascular structure of tumours, along with high interstitial pressure, restricts drug penetration. The tumour microenvironment also prevents immune cells from infiltrating the tumour, while immune-suppressing cells like cancer-associated fibroblasts, regulatory T cells, and tumour-associated macrophages secrete immunosuppressive cytokines that create a protective shield around the tumour.

As an internalising RGD, certepetide improves the tumour penetration and efficacy of chemotherapeutics The clinical efficacy of chemotherapeutic drugs is frequently hampered either by a lack of selectivity between cancerous and healthy cells or by poor pharmacokinetic properties, including cancer homing and penetration. This is especially true for solid tumours, which are frequently characterised by the upregulation of junction proteins and extracellular matrix components (i.e., fibrinogen and collagen), which form a physical barrier to the intracellular transport of exogenous molecules (*Kang et.al., Polymers 2020, 12, No. 1906*). Therefore, anticancer compounds often need to be administered at high doses to exert relevant pharmacological effects, with the rise of serious adverse reactions (*Mould*

et.al., J. Clin. Pharmacol. 2017, 57, S116−128). A solution to the tissue penetration problem is represented by peptides called internalising RGDs (Arginine-Glycine-Aspartic Acid) that can vehicle the desired drug to extravascular cancer tissue, endowed with remarkable tumour-homing properties (ability to preferentially localise to tumour tissues while avoiding healthy tissues). RGDs specifically bind to certain integrins, such as αvβ3, αvβ5, α5β1, and others, which are often overexpressed in tumour cells and angiogenic blood vessels, making RGD peptides valuable in targeting these cells. As an internalising RGD, certepetide (LSTA1) improves the tumour penetration and efficacy of chemotherapeutics. It can be either covalently bioconjugated to organic and peptidic drugs or attached to the surface of other delivering systems such as nanoparticles, liposomes, or oncolytic viruses (*Yin et al., Review, Mol. Med. Rep. 2017, 15, 2925−2930*). On the other hand, the tumour endocytosis of cytotoxic agents such as cisplatin, gemcitabine, doxorubicin, nab-paclitaxel, and trastuzumab is enhanced by simple coadministration. As a result, hundreds of distinct applications involving iRGD have been published during the past decade, demonstrating the potential of this peptide as a game changer in the anticancer field (*D'Amore et.al., J. Chem. Inf. Model. 2023, 63, 6302−6315*).

Certepetide has the potential to convert tumour stroma into a conduit of anti-cancer agents and modify the TME The interactions of cancer cells with their microenvironment consisting of tumour stromal cells including stromal fibroblasts, endothelial cells (form the blood vessels that supply oxygen and nutrients to the tumour) and immune cells (macrophages, T cells, B cells, and neutrophils) are essential to tumour growth, progression, metastasis, and resistance to therapy. The tumour thus creates an environment in which not only its growth is optimised, but also the immune defence against it is paralysed. The modification of the TME makes tumours more susceptible to immunotherapies and inhibits metastasis, the spread of cancer to other parts of the body. Tumour stroma acts as a physical barrier to anti-cancer agents. Since certepetide converts tumour stroma from a barrier to a conduit for anti-cancer drugs, it consequently enables a modification of the immunosuppressive environment of the tumour and thus an enhanced immune response against it (*Sugahara et al. Mol Cancer Ther; 14(1) January 2015; Hamilton et al., J MolMed. April 2015; and Miyamura et al., bioRxiv. May 2023*). Beyond facilitating drug delivery, certepetide also modulates the TME in other ways. It reduces the immunosuppressive nature of the TME, potentially by depleting regulatory T cells (Tregs) and increasing the activity of cytotoxic T cells, which enhances the immune response against cancer cells. Additionally, certepetide inhibits the metastatic cascade, thereby reducing the likelihood of cancer spreading to other parts of the body.

Figure 4: The TME – its components and interactions

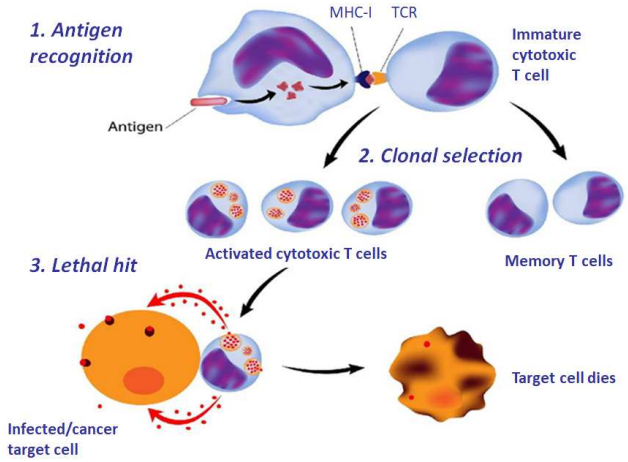


Source: Imlimthan et al. Pharmaceuticals, October 2021

PRECLINICAL DATA

Dual mode of action has been demonstrated In terms of preclinical data, the property of certepetide to selectively and efficiently facilitate intratumoral penetration has been validly proven in vitro as well as in an animal model for solid tumours, especially in a pancreatic ductal adenocarcinoma (PDAC) model with human immunity (Miyamura et al., bioRxiv. May 2023). These data show that certepetide selectively depletes immunosuppressive T cells while enhancing the concentration of cytotoxic T cells - suggesting that the immunosuppressive effect of the tumour microenvironment has been weakened (see figure 5 below).

Figure 5: Certepetide triggers T cell activation and cancer cell killing



Source: https://ar.inspiredpencil.com/pictures-2023/cytotoxic-t-cells-cancer

Through extensive collaborations with research partners, the company has gathered substantial preclinical data demonstrating that certepetide enhances the delivery of a wide range of cancer therapies, including chemotherapy, immunotherapy, and RNA-based treatments A very large quantity of significant non-clinical data demonstrates enhanced delivery of a wide range of existing and emerging anti-cancer therapies, including chemotherapeutics, immunotherapies – cellular and monoclonal antibody therapies - and RNA-based therapeutics resulting in reduction of tumour load and/or improved survival demonstrating the broad applicability of certepetide. This was shown, e.g., for lung cancer and PDAC in combination with gemcitabine (Zhang et.al., Plos One, 2015 and Hurtado de Mendoza et.al., Nat Comms, 2021), breast cancer in combination with Herceptin (monoclonal antibody, or with nanoparticle Abraxane (Sugahara et.al., 2010), or in combination with cytotoxic t-cells in GI cancer (Ding et.al., Nature, 2019). By overcoming the barriers imposed by TME, certepetide has shown promising results in improving the efficacy of these therapies across multiple solid tumour models.

TARGETED CANCER SEGMENTS

Certepetide is being studied in a range of advanced solid tumours Currently, certepetide is the subject of a range of phase 1b/2a, 2 and 2b clinical studies being conducted globally in a variety of solid tumour types, including metastatic Pancreatic Ductal Adenocarcinoma (mPDAC), cholangiocarcinoma, appendiceal cancer, colon cancer and glioblastoma multiforme in combination with a variety of anti-cancer regimens. We give a brief introduction to standard of care treatments in key advanced solid tumours.

High unmet medical need in advanced solid tumours Cancer is a leading cause of death and generates among the highest costs to healthcare systems around the globe. Due to low specificity, traditional chemotherapy usually applied to treat cancer also kills healthy cells, is poorly tolerated and has therapeutic and safety limitations. Tumour resistance is a

further obstacle to effective treatment. Current research is therefore focusing on treatment approaches such as growth factor inhibitors, anti-angiogenesis factors and immune therapy that limit damage to healthy cells and more specifically target cancerous cells. However, the unmet medical need in solid tumours remains very high. If cancer is not detected before it spreads outside of the location in which it arises, the risk for patients that treatment will not be successful is this greatly increased. Five-year survival statistics for advanced solid cancers can be as low as 1-10% for many solid tumours (e.g. lung, brain, colorectal or pancreatic cancer), highlighting a clear need for better treatments for these patient groups.

Little progress achieved in the treatment of pancreatic cancer so far Pancreatic cancer is one of the few cancers for which survival has not improved substantially over nearly 40 years. It is an aggressive and deadly disease with few symptoms until the cancer is advanced. The vast majority of pancreatic cancer cases are diagnosed in late stage; more than half of patients are diagnosed once the disease has metastasised. As a result, this type of cancer is one of the most difficult to treat and this is reflected in the low survival rate. The survival outlook for PDAC patients remains grim, with only 3% surviving for five years and an average survival time of just 4.6 months following diagnosis. By 2030, PDAC is expected to become the second leading cause of cancer-related mortality.

First-line standard of care therapy for mPDAC The standard of care for advanced or metastatic PDAC primarily involves systemic chemotherapy, as the disease is typically too advanced for surgical intervention or radiation therapy. Treatment aims to improve survival, alleviate symptoms, and maintain quality of life. Chemotherapy is often administered in combination regimens to maximise efficacy because combining drugs with different mechanisms of action, toxicity profiles, and resistance patterns can improve cancer cell kill, minimise resistance development, and broaden the therapeutic impact. The choice of therapy depends on the patient's performance status, comorbidities, and tumour characteristics. For patients with good performance status, chemotherapy in FOLFIRINOX regimen, a combination of oxaliplatin, irinotecan, leucovorin, and 5-fluorouracil, is often the preferred regimen. This treatment has demonstrated significant improvements in overall survival and progression-free survival compared to gemcitabine alone, though its higher toxicity limits its use to fitter patients. An alternative first-line treatment for patients who may not tolerate FOLFIRINOX is the combination of chemotherapeutic agents gemcitabine and nab-paclitaxel (gem/nab-pac), which also offers a survival advantage over gemcitabine monotherapy. For patients with poor performance status or significant comorbidities, gemcitabine monotherapy remains a standard option, providing modest survival benefits with minimal side effects.

Second-line-therapy in mPDAC If the disease progresses after first-line therapy, the second-line treatment depends on what the first-line treatment was. For patients who received FOLFIRINOX, second line therapy may be the chemotherapeutic combination gem/nab-pac. If the first line therapy was gem/nab-pac, the second line treatment options include FOLFIRINOX, or oxaliplatin + fluorouracil (5-FU) + leucovorin (known as FOLFOX regimen) or gemcitabine monotherapy. However, the benefit is generally limited. In addition, targeted therapies play a role in a subset of patients with specific genetic mutations.

Significant medical need in mPDAC Despite these therapeutic options, mPDAC remains a highly aggressive cancer with a poor prognosis. Median survival typically ranges from six to twelve months, depending on the therapy. Current research is focused on improving outcomes through novel approaches such as immunotherapy, targeted treatments, and strategies to modulate the TME, which may offer hope for future advancements.

Treatment of cholangiocarcinoma (CCA) CCA is a rare and aggressive cancer arising from the bile ducts, which are part of the biliary system responsible for transporting bile from the liver to the gallbladder and small intestine. The standard first-line treatment is the combination of the chemotherapeutic agents gemcitabine and cisplatin. Immunotherapy

Durvalumab (PD-L1 inhibitor) is integrated into the first-line treatment regimen for biliary tract cancers. After progression on first-line therapy, second-line options like FOLFOX or clinical trial participation are explored.

Treatment of glioblastoma multiforme (GBM) GBM is the most common and aggressive malignant brain tumour in adults. It is a grade IV glioma characterised by rapid progression and a poor prognosis. Treatment begins with maximal safe surgical resection to remove as much of the tumour as possible without impairing neurological function. Surgery is followed by concurrent chemoradiation, which involves radiation therapy combined with the oral chemotherapy drug temozolomide. After this phase, temozolomide is continued for six months to one year as adjuvant therapy, which has been shown to improve survival. When GBM recurs, options are limited. Enrolment in clinical trials is often encouraged, as novel therapies, including immunotherapies and experimental drugs, offer potential avenues for improved outcomes.

Solid tumour market to grow at a CAGR of 7.45% until 2034 The solid tumours market was valued at USD170.3bn in 2023 and the market is expected to hit USD375.4bn by 2034, rising at a CAGR of 7.45% during the forecasting period. The market is driven by advancements in targeted therapies, immunotherapies such as checkpoint inhibitors, CAR-T therapies, combinations with other cancer therapies as well as personalised medicine (source: Biospace). In 2022, there were 20m new cancer cases globally, resulting in 10m deaths, with over 90% of these cancers classified as solid tumours. Looking ahead to 2050, the number of new cancer cases is projected to rise by 77% to 35m, while cancer-related deaths are expected to reach 18.5m (sources: Lisata and International Agency for Research on Cancer – IARC- and Globocan, 2020).

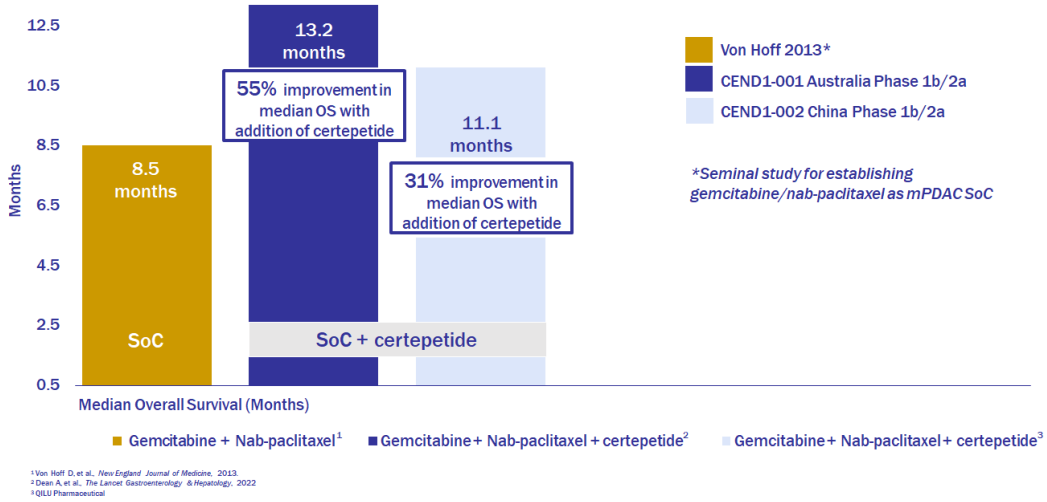
COMPLETED TRIALS IN LEAD INDICATION OF FIRST-LINE MPDAC

Preclinical studies in mPDAC Preclinical findings showed that certepetide, when combined with standard chemotherapy, led to significant tumour growth inhibition and enhanced anti-tumour activity compared to chemotherapy alone. Tumour models in mice revealed a marked reduction in tumour size and improved survival outcomes. certepetide appeared to complement the cytotoxic effects of chemotherapy by targeting pathways involved in tumour progression and immune evasion, resulting in greater overall tumour suppression. The safety profile in in-vivo preclinical models across multiple species including mice, rats, dogs, and monkeys, was favourable. certepetide exhibited low systemic toxicity, with no significant adverse effects observed at therapeutic doses. Haematological and biochemical analyses indicated no major organ toxicity or severe adverse reactions, suggesting that the drug is well tolerated in combination with chemotherapy, supporting its progression to clinical trials (source: Järveläinen et al., 2023).

Two separate open-label phase 1b/2a trials of certepetide + chemotherapy in mPDAC run in Australia and China showed significant efficacy improvement against chemotherapy alone Lisata conducted two independent open-label 1b/2a trials of certepetide in combination with standard of care (SOC) consisting of chemotherapeutic agents gemcitabine and nab-paclitaxel to assess the safety, tolerability, and preliminary efficacy of this combination therapy in first-line mPDAC patients. The first trial was conducted at three sites in Australia. In the dose-escalating phase 1b stage, 31 patients received intravenous chemotherapy in combination with escalating doses of certepetide which ranged from 0.2 mg/kg to 3.2 mg/kg. Following the establishment of the recommended dose at 3.2 mg/kg where no dose-limiting toxicities (DLTs) were observed, phase 2a evaluated the combination therapy's efficacy and safety profile further and the results were published in the Lancet Gastroenterology & Hepatology in 2022 (Dean et al; 2022., and https://clinicaltrials.gov/study/NCT03517176). Positive preliminary results of the second trial in China (n=55), which had a similar design to the Australian trial, were published in April 2024. Both studies reported substantial efficacy improvement in key median overall survival (OS - usually the primary endpoint of pivotal studies) compared with

historical efficacy in mPDAC trials of SOC administration, as described in the scientific literature (source: von Hoff et al., 2013, New England Journal of Medicine). The addition of certepetide to standard therapy improved median OS rates by 55% (8.5 to 13.2 months) in Australia and 31% in China (8.5 to 11.1 months); see an overview of OS results on both studies in figure 6.

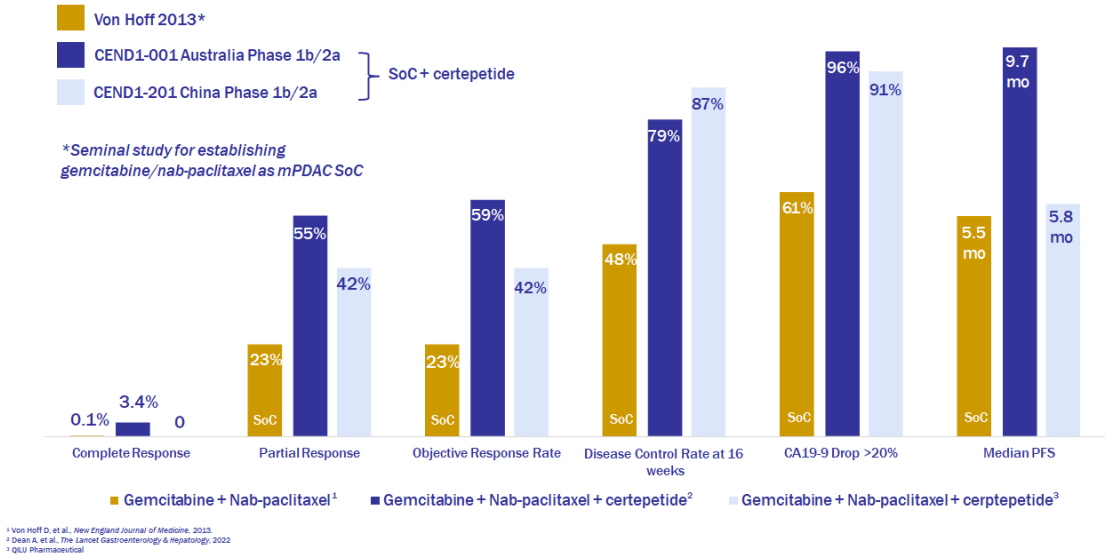
Figure 6: Improved survival in *mPDAC* in two independent phase 1b/2a studies



Source: First Berlin Equity Research, Lisata Therapeutics Inc

All other investigated efficacy endpoints also showed a consistent improvement in both trials The studies assessed further key efficacy endpoints, including partial response (PR), progression-free survival (PFS), disease control rate (DCR), and objective response rate (ORR). The combination was associated with prolonged overall survival, delayed disease progression, high rates of disease control, and a manageable safety profile. From a safety perspective, certepetide was well tolerated when used at the recommended dose of 3.2mg/kg in combination with chemotherapy. These findings provided a strong foundation for the continued development of certepetide in later-phase clinical trials. The results were particularly promising given the aggressive nature of mPDAC and the limited success of current therapies.

Figure 7: Consistency of response in the two phase 1b/2a studies



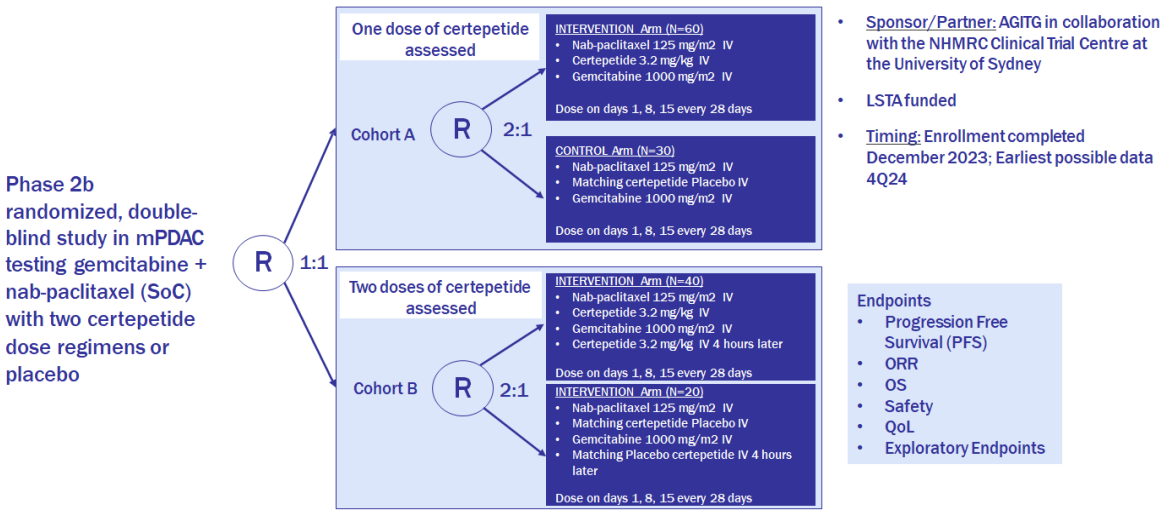
Source: First Berlin Equity Research, Lisata Therapeutics Inc

ONGOING TRIALS IN LEAD INDICATION FIRST-LINE MPDAC

Two-cohort, placebo-controlled ASCEND phase 2b trial of certepetide in combination with chemotherapy as a first-line treatment of mPDAC in Australia (n=155) When Lisata acquired Cend Therapeutics in 2022, it inherited an ongoing single-cohort phase 2b study in mPDAC in Australia in collaboration with the AGITG to evaluate the efficacy, safety, and tolerability of certepetide at a fixed dose of 3.2 mg/kg (on days 1, 8, and 15 of a 28-day cycle) in combination with standard-of-care chemotherapy consisting of gemcitabine (1000 mg/m²) and nab-paclitaxel (125 mg/m²). However, Lisata management's analysis of existing pharmacokinetic and pharmacodynamic data suggests that the therapeutic activity of certepetide could potentially be optimised with an additional administration of certepetide, potentially allowing greater exposure of the co-administered chemotherapeutics to the tumour due to a prolonged activation of the C-end rule transport mechanism. Preclinical and phase 1/2a studies indicated a dose-dependent relationship, with higher doses of certepetide demonstrating enhanced anti-tumour activity without a corresponding increase in toxicity, suggesting room for dose escalation within a safe range. As a result, management decided to add a second cohort with a modified dosing regimen in which a second intravenous push dose of 3.2 mg/kg certepetide is administered four hours after the initial dose.

Overall, this change would allow investigators to compare the two dosing regimens directly to determine the optimal balance between efficacy, safety, and quality of life for patients, as well as provide critical insights into the most effective dosing strategy for pivotal phase 3 clinical trials. The study will evaluate whether the combination therapy improves clinical outcomes such as overall survival (OS), progression-free survival (PFS), overall response rate (ORR), and disease control rate (DCR), while maintaining a manageable safety and tolerability profile (for more details on the ASCEND study see Lee et al., 2023). Lisata completed enrolment in December 2023. The company will report top-line data from an interim analysis for 95 patients assigned to Cohort A of the study at the American Society of Clinical Oncology Gastrointestinal (ASCO-GI) Cancers Symposium in San Francisco, CA on 23-25 January 2025 (https://conferences.asco.org/gi/program). The complete data set of all 155 patients including both cohorts from the study will be published by mid-2025. We give an overview of the phase 2b study design in figure 8 below.

Figure 8: Study design of ASCEND - Phase 2b, blinded, randomised trial in mPDAC

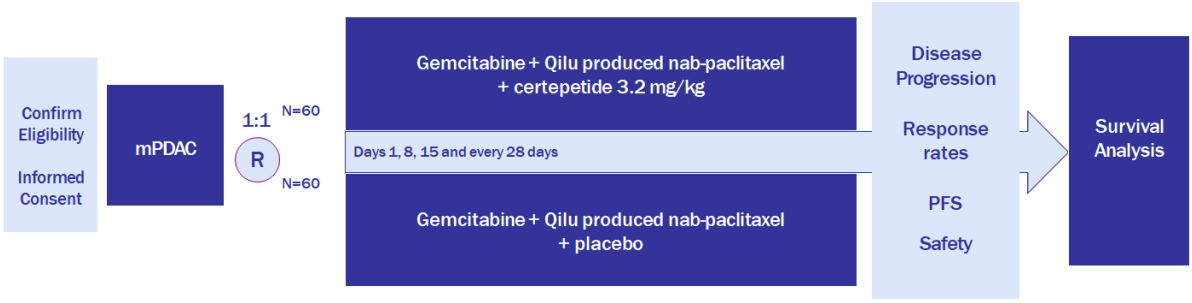


Source: First Berlin Equity Research, Lisata Therapeutics Inc

Qilu Pharmaceutical is also conducting a first-line mPDAC phase 2 trial in China (n=120) The purpose of this double-blind, placebo-controlled, randomised, multi-centre trial is to evaluate the efficacy and safety of certepetide administered at a 3.2 mg/kg dose as a

single IV push in combination with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel and placebo as first-line treatment in 120 patients with mPDAC. The first patient was enrolled in April 2024 and it is planned that enrolment will take around 18 months and patient follow-up, data analysis and reporting will take a further 13 months (see https://clinicaltrials.gov/study/NCT06261359). The publication of the preliminary ORR data is expected in Q3 2025.

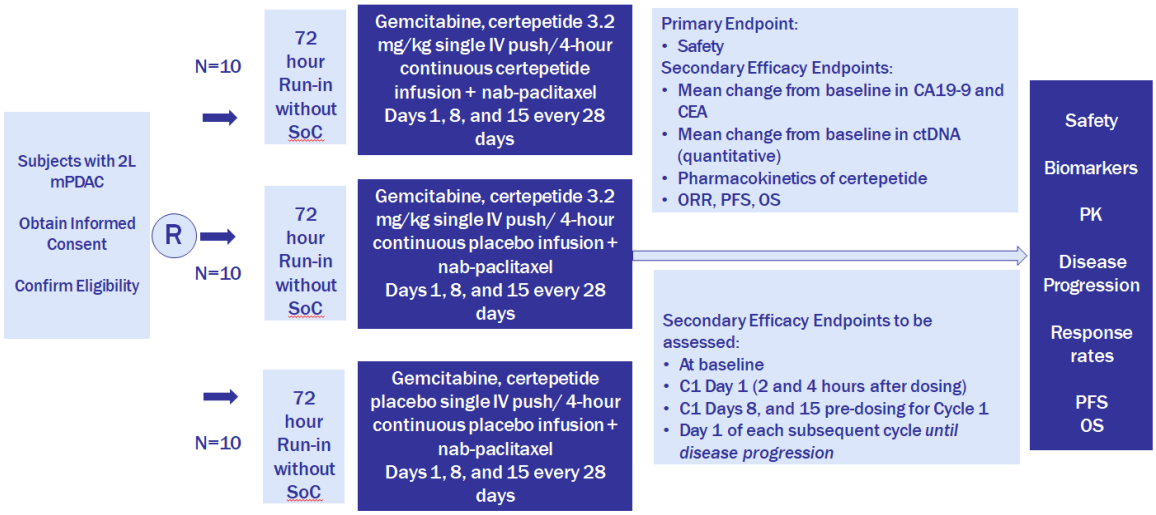
Figure 9: Study design of the phase 2 blinded, placebo-controlled trial in mPDAC in China



Source: First Berlin Equity Research, Lisata Therapeutics Inc

Randomised, placebo-controlled, three-arm FORTIFIDE phase 1b/2a trial in second line mPDAC patients in the US run by Lisata to explore potential dosing improvement which could potentially be translated to the lead first-line mPDAC indication (n=30) Lisata is conducting a phase 1b/2a, double-blind, placebo-controlled, three-arm, randomised study evaluating continuous infusion of certepetide over 4 hours + SOC versus a single intravenous push of certepetide + SOC versus SOC alone in patients with mPDAC who have progressed on FOLFIRINOX. We note that a continued infusion of certepetide allows for a more sustained and controlled release of certepetide into the bloodstream. This can help maintain therapeutic drug concentrations over a longer period which may better align with certepetide's pharmacokinetic properties, potentially improving certepetide's efficacy by ensuring prolonged interaction with target cells. Also, the standard single IV push delivers the drug rapidly, often leading to a sharp peak in plasma concentration, which can cause higher toxicity and adverse effects. A slower, continuous infusion can avoid these peaks, providing a more gradual drug exposure that can lower toxicity and side effects. We give an overview of the study design and the primary and secondary endpoints in figure 10 below.

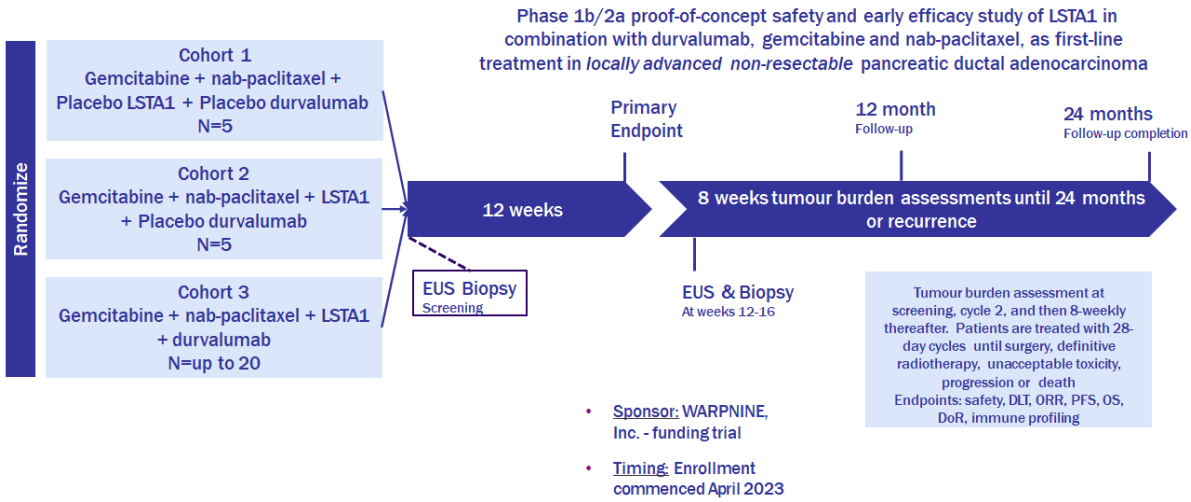
Figure 10: FORTIFIDE - Phase 1b/2a continuous infusion study of certepetide



Source: First Berlin Equity Research, Lisata Therapeutics Inc

Phase 1b/2a trial in locally advanced, non-resectable PDAC in Australia in collaboration with WARPNINE to demonstrate certepetide's performance in combination with SOC consisting of immunotherapy + chemotherapy (n=30) This study aims to determine the safety and tolerability as well as early efficacy of certepetide in combination with the immuno-therapeutic drug durvalumab and chemotherapy consisting of gemcitabine, and nab-paclitaxel in subjects with locally advanced PDAC. The trial also seeks to identify the optimal dosing regimen of certepetide to maximise its performance while minimising side effects, laying the groundwork for further clinical studies.

Figure 11: Phase 1b/2a trial in locally advanced non-resectable PDAC + chemo & IO

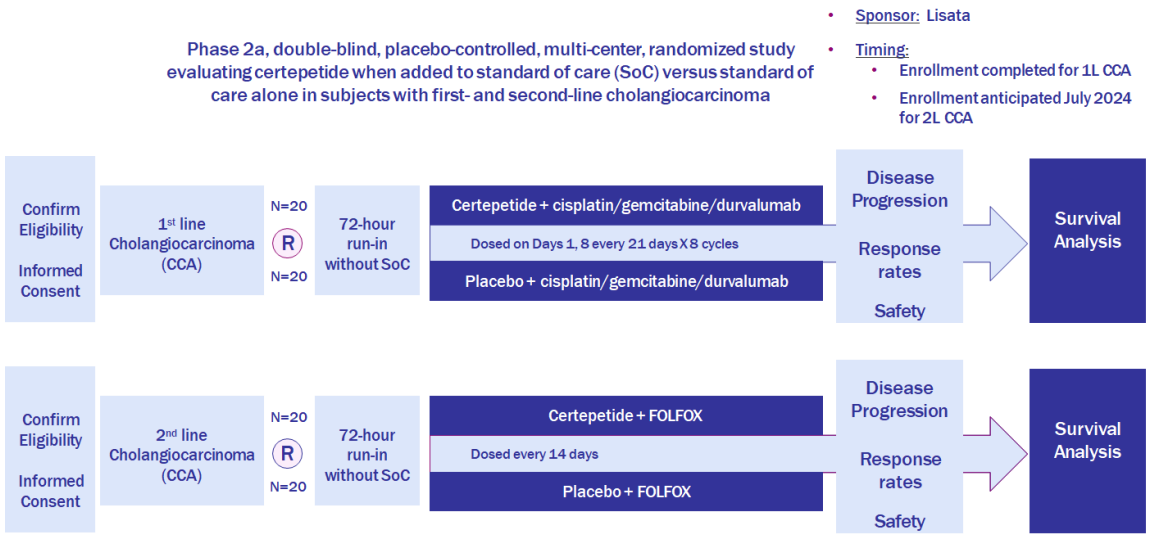


Source: First Berlin Equity Research, Lisata Therapeutics Inc

CLINICAL DEVELOPMENT IN OTHER CANCER INDICATIONS

First-and second-line BOLSTER phase 2a trial in cholangiocarcinoma (CCA) patients in the US run by Lisata (n=80) This is a double-blind, placebo-controlled, multi-centre, randomised phase 2a trial of certepetide in combination with SOC compared to SOC alone in first- and second-line patients with advanced CCA, a form of bile duct cancer. The chemotherapeutic agents gemcitabine and cisplatin + the immune checkpoint inhibitor durvalumab are administered as SOC in first-line patients and the FOLFOX regimen in second-line patients. We give an overview of the BOLSTER study design on figure 12 below.

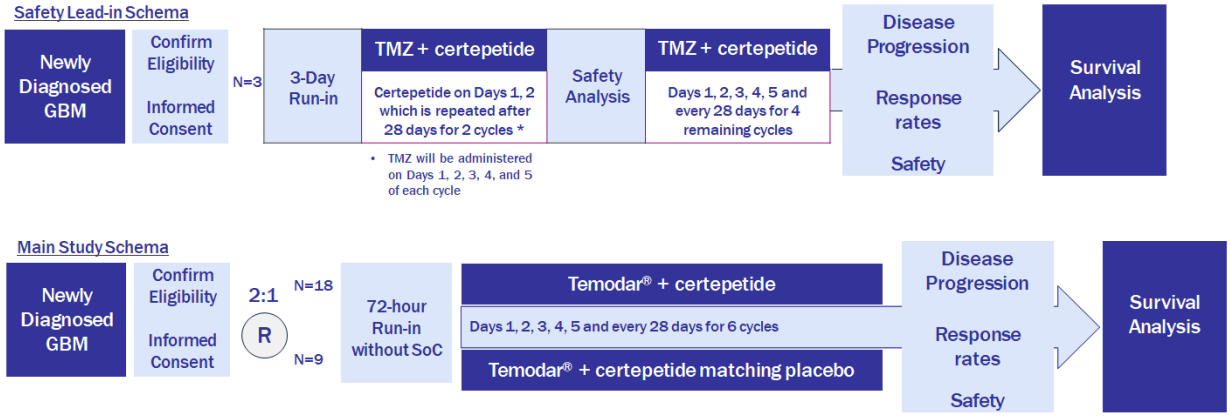
Figure 12: BOLSTER – Phase 2 blinded, randomised PoC trial in various cancers



Source: First Berlin Equity Research, Lisata Therapeutics Inc

First-line glioblastoma multiforme (GBM) phase 2a trial in Estonia/Latvia with Tartu University (n=30) The objective of this phase 2a trial is to evaluate safety, tolerability, and therapeutic efficacy of certepetide in combination with the chemotherapeutic drug temozolomide (SOC) in patients with previously untreated GBM, the most common malignant brain tumour in adults. Endpoints are objective response rate, progression free survival, overall survival, and disease control rate.

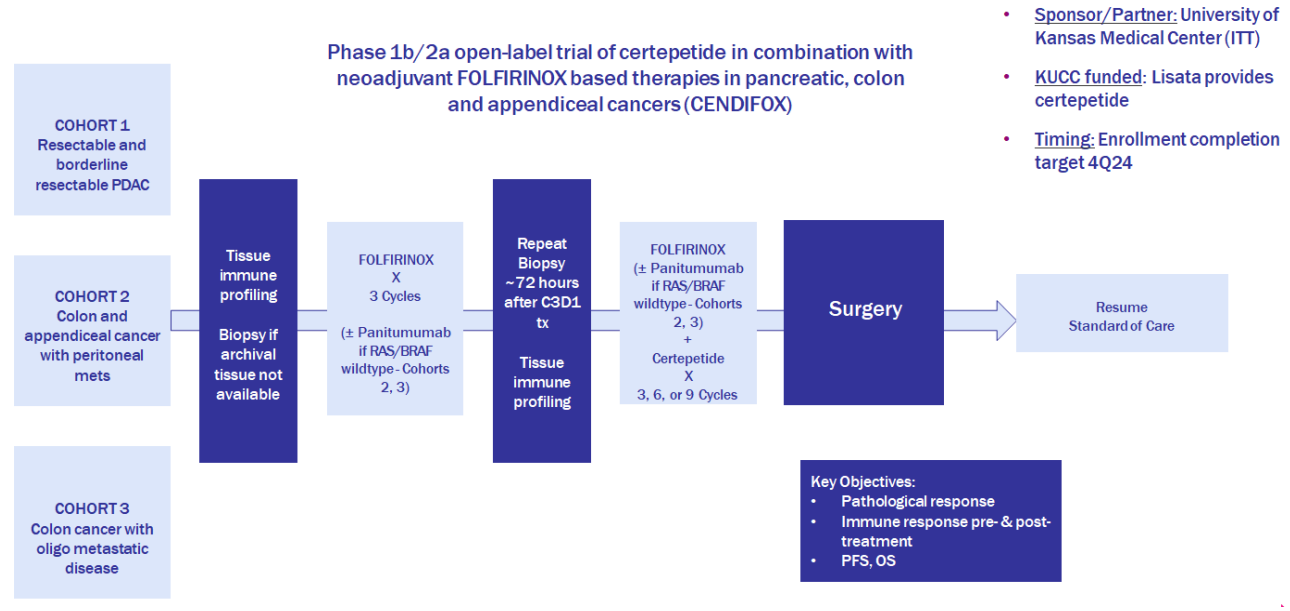
Figure 13: Phase 2a trial of certepetide with SoC in first-line in GBM



Source: First Berlin Equity Research, Lisata Therapeutics Inc

Investigator-initiated phase 1b/2a open-label trial in the US of certepetide in combination with SOC consisting of FOLFIRINOX-based chemotherapy, with or without EGFR-inhibiting targeted therapy panitumumab, in pancreatic, colon and appendiceal cancers (n=66) Lisata is conducting the CENDIFOX trial, a phase 1b/2a open-label trial in collaboration with The University of Kansas Cancer Center (KUCC). In December 2024, the study completed enrolment in 66 patients across three cohorts: (1) 35 patients with resectable pancreatic cancer; (2) 18 patients with colon and appendiceal cancer with peritoneal metastasis; and (3) 13 patients with colon cancer with oligo-metastatic disease. The trial aims to assess the combination's safety and therapeutic effects, providing valuable pre- and post-treatment tumour tissue data for immune profiling and long-term patient outcomes. Conducted solely at KUCC, the trial is funded by the centre, with Lisata supplying certepetide. Results from this study are anticipated in 2025.

Figure 14: CENDIFOX - Phase 1b/2a open-label trial in PDAC and other cancers



Source: First Berlin Equity Research, Lisata Therapeutics Inc

The case report of a patient who achieved a complete response in another advanced cancer, metastatic gastroesophageal adenocarcinoma, illustrates the potential of Certepetide in other solid tumour types In December 2023, a case report published in the *Oncology & Cancer Case Reports Journal* detailed the treatment of a patient with metastatic gastroesophageal adenocarcinoma who, after months of standard-of-care (SoC) therapy—including chemotherapy and immunotherapy—achieved only a partial response. Upon the addition of certepetide to the existing regimen, the patient experienced a complete response, confirmed through both radiographic imaging and surgical assessment. This case underscores the potential of certepetide to enhance the efficacy of standard treatments in solid tumours, particularly in challenging cases like metastatic gastroesophageal adenocarcinoma. Given its mechanism of action, certepetide is considered potentially beneficial across various advanced solid tumours.

COMPETITIVE ENVIRONMENT

EMERGING TECHNOLOGIES ADRESSING PDAC & SOLID TUMOURS

The industry's late-stage PDAC pipelines are mainly filled with chemotherapy combinations and chemotherapy+immunotherapy and/or small molecule combinations, suggesting that chemotherapy will remain the backbone of PDAC therapy in the coming years (source: Sally et al, 2022). The competitive landscape for therapies targeting advanced PDAC and other solid tumours is evolving rapidly, driven by emerging technologies that aim to overcome limitations in chemotherapy, immunotherapy, and targeted therapies. A key focus is addressing challenges such as poor drug penetration, the immunosuppressive tumour microenvironment (TME), and treatment resistance. We believe that new technologies addressing solid tumours such as Lisata's CendR Platform® technology and certepetide show potential to treat PDAC and other difficult-to-treat tumours. We summarise some relevant approaches below.

Liposomal and nanoparticle-based drug delivery systems are a prominent technology which involves, exemplified by Ipsen's Onivyde® (this drug was licensed from Merrimack Pharmaceutials), a liposomal formulation of the chemotherapeutic agent irinotecan that significantly improves survival compared to standard chemotherapy. Liposomal formulations encapsulate chemotherapeutic agents, prolonging drug circulation and enhancing accumulation in tumours via the enhanced permeability and retention (EPR) effect. While effective, this passive targeting strategy is limited by the variability of the EPR effect across tumour types.

Antibody-drug conjugates (ADCs) are gaining momentum. ADCs combine the specificity of monoclonal antibodies with the potency of cytotoxic agents, enabling targeted delivery of chemotherapy to tumour cells while sparing healthy tissue. Recent advancements in linker technologies have improved the stability and efficacy of ADCs, and there is growing interest in ADCs that target components of the TME, such as fibroblast activation protein (FAP), which is expressed by stromal cells in many solid tumours.

Bispecific antibodies and immune-checkpoint modulators are also emerging as critical tools in the treatment of solid tumours. Bispecific T-cell engagers (BiTEs) directly link T cells to tumour cells, enhancing immune-mediated killing. Meanwhile, therapies that target immune-suppressive components of the TME, such as tumour-associated macrophages (TAMs) and myeloid-derived suppressor cells (MDSCs), are being explored to enhance the effectiveness of immune checkpoint inhibitors. These approaches aim to overcome the immunosuppressive nature of the TME, particularly in tumours like mPDAC that have historically been resistant to immunotherapy.

Oncolytic viruses and immune-stimulating gene therapies are another promising approach. Oncolytic viruses selectively infect and destroy tumour cells while simultaneously stimulating the immune system by releasing tumour antigens. Advances in genetic engineering have allowed oncolytic viruses to deliver immune-stimulating cytokines, such as GM-CSF, or disrupt ECM components to improve therapeutic penetration. These therapies offer a dual mechanism of direct tumour lysis and immune activation.

Targeted radiopharmaceuticals, which deliver localised radiation to tumours, are also being developed as a method to overcome barriers to treatment delivery. By coupling radioactive isotopes with tumour-specific targeting agents, such as antibodies or peptides, these therapies can achieve precise and effective tumour ablation while minimizing collateral damage to healthy tissue.

IMPORTANT MPDAC PLAYERS

Some relevant players active in the mPDAC field are: Eli Lilly (dominates the first-line treatment of mPDAC with gemcitabine-based chemotherapy regimens), Ipsen and Merrimack Pharmaceuticals (leading companies in the mPDAC market through Onivyde®, a liposomal irinotecan formulation), Halozyme Therapeutics (key player that markets the chemotherapeutic agent PEGPH20, a recombinant hyaluronidase enzyme targeting hyaluronic acid in the TME, which is however restricted to hyaluronic-acid-rich tumours), Medac (focus on chemotherapeutic agents and supportive treatments for solid tumours). Lisata's differentiation against these peers lies in its active modulation of the TME, which could address limitations seen with passive targeting strategy using liposomal delivery (Onivyde) or ECM-specific modulators (PEGPH20). This positions Lisata at the intersection of TME modulation, enhanced drug delivery, and immune activation, making it uniquely competitive in a challenging oncology landscape.

FINANCIAL HISTORY AND OUTLOOK

Lisata Therapeutics' financial statements are prepared in accordance with US Generally Accepted Accounting Principles (US GAAP). The company's financial year aligns with the calendar year and runs from 1 January to 31 December. Lisata emerged from the 2022 Merger between Caladrius Biosciences and Cend Therapeutics. The 2023 annual report is the first full year report since the merger.

FINANCIAL HISTORY

2023 income statements – Reduction in operating expenses against 2022 Lisata's financial statements are typical of a development-stage biotech company. The company is not generating any revenue and is incurring losses. In 2023, the company was able to reduce both general & administrative costs by 8% y/y to USD13.0m, and research & development costs by 3% y/y to USD12.7m (see table 4). As a result, OPEX decreased by 6% y/y to USD25.7m. In 2022, Lisata recognised a non-cash expense for "in-process research and development" (IPR&D) of USD30.4m in connection with the merger of Caladrius and Cend. This brought the company's EBIT in 2022 to USD-57.6m.

The rise in interest rates led to Lisata's 2023 net financial result more than doubling y/y to USD2.7m. Due to losses, the company recorded tax income benefits of USD2.3 in 2023 (2022: USD2.5m). Adjusted for IPR&D expenses, the company incurred a USD20.8m loss in 2023, a slight improvement on the loss of USD23.8m in 2022.

Table 4: profit & loss statements 2023 vs 2022 (KPIs)

in USD'000	2023	2022	Delta
Revenue	**0**	**0**	**-**
General & Administrative	12,974	14,141	*-8%*
Research & Development	12,734	13,067	*-3%*
OPEX	25,708	27,208	*-6%*
In-process research & development	0	30,393	*-100%*
EBIT	**-25,708**	**-57,601**	***n.a.***
Net financial result	2,724	1,052	*159%*
Non-operating income/expenses	-186	-155	*n.a.*
EBT	**-23,170**	**-56,704**	*n.a.*
Tax result	2,330	2,479	*-6%*
Net income (loss)	**-20,840**	**-54,225**	***n.a.***
Adjusted net income (loss)*	**-20,840**	**-23,832**	***n.a.***

**Net income is adjusted for the non-cash "in-process R&D" expense, for better comparability*

Source: First Berlin Equity Research, Lisata Therapeutics Inc.

9M 2024 P&L – Further reduction in OpEx R&D expenses of USD 8.4m and general & administrative expenses of USD 9.1m resulted in OpEx of USD 17.5m in 9M 2024 (9M/23: USD 19.7m). Due to lower investment income and income tax benefits in 9M/24 compared to 9M/23, Lisata reported a 9M/24 net loss of USD-15.4m – a similar level to the previous year (9M/23: USD -15.5m).

Balance sheet 2023 and 9M/2024 – solid total liquidity of USD 35.9m at 9M/24 Lisata's total liquidity declined by 27% y/y to USD 50.5m at YE/23 (YE/22: USD 69.2m) due to funding of ongoing operations. This figure comprises USD 22.6m in cash and USD 27.9m in marketable securities. Total liquidity declined further to USD 35.9m at 9M/24. Similarly, Lisata's equity position dropped from USD 66.6m at YE 2022 to USD 48.1m at YE 2023 and USD33.4m at 9M/24, corresponding to a roughly stable equity ratio (ER) of 88% at 9M/24 (2023ER: 88%; 2022 ER: 91%). We give an overview of the main Balance sheet items in table 5 overleaf.

Table 5: balance sheets 2023 vs 2022 (KPIs)

in USD'000	2023	2022	Delta
Cash and cash equivalents	22,593	32,154	*-30%*
Marketable securities	27,942	37,072	*-25%*
Other assets	4,159	3,808	*9%*
Assets, Total	**54,694**	**73,034**	***-25%***
Accrued liabilities	4,169	3,728	*12%*
Other liabilities	2,631	2,982	*-12%*
Total Liabilities	**6,800**	**6,710**	*1%*
Minority interests	**-254**	**-254**	**-**
Equity	**48,148**	**66,578**	***-28%***
Equity ratio	88%	91%	*-3 pp*
Liabilities and Equity, Total	**54,694**	**73,034**	***-25%***

Source: First Berlin Equity Research, Lisata Therapeutics Inc.

2023 cash flow statement In 2023, the company reported cash outflow from operating activities of USD20.0m (2022: USD 21.2m). With cash inflows from investing activities of USD 10.1m and financing cash flow of USD 0.4m, net cash flows amounted to USD -9.6m in 2023. As a result, total liquidity amounted to USD 50.5m in 2023, down from USD 69.2m in 2022.

Table 6: Cash flow statements 2023 vs 2022 (KPIs)

in USD'000	2023	2022	Delta
Operating cash flow	-20,032	-21,170	*n.a.*
Cash flow from investing	10,102	28,911	*-65%*
Cash flow from financing	385	-224	-
Impact of exchange rates on cash	-16	-10	
Net cash flow	-9,561	7,507	-

Source: First Berlin Equity Research, Lisata Therapeutics Inc.

9M 2024 Cash Flow Statement For the nine months ended 30 September, Lisata reported operating cash flow of USD -14.8m. This represents a 7% decrease in the company's cash burn compared to 9M/23 (9M/23: USD -16.0m). Investing cash flow of USD 11.8m and financing cash flow of USD -0.1m led net cash flows to USD -3.1m. Overall, Lisata had cash and cash equivalents of USD 19.5m and total liquidity of USD 35.9m.

Conclusion With total liquidity of USD35.9m, Lisata should be able to finance operations for about 6 quarters at a burn rate of about USD6m per quarter (currently USD 4.9m). While Lisata has a cash runway into Q1/26, we believe that the company will raise an additional USD 10m in 2025 and USD 10m 2026 to finance operations into 2027.

FINANCIAL OUTLOOK

Income Statement We expect Lisata's OpEx to decrease by 6% y/y to USD 24.1m in 2024E (see table 7 overleaf). We forecast this reduction in OpEx to be driven by a 4% decline in R&D costs to USD 12.2m, and an even larger 8% drop in G&A expenses to USD 11.9m. These costs should rise again in 2025E, with R&D cost growth outpacing G&A as certepetide and related programmes move closer towards phase 3 trials. For 2024E and 2025E we forecast a net loss of USD -21.3m and USD -22.7m respectively. As the company's cash reserves decline, and central banks reduce their interest rates, Lisata's investment income is set to fall. This will reduce the difference between OpEx and bottom line.

We expect that Lisata will enter into a licensing partnership with a pharmaceutical company to fund certepetide's development, which could enter phase 3 clinical trials in the lead first-line mPDAC in 2026. We project only a minor increase in OpEx, as we assume that the partner will make payment for the development costs directly to the external CRO. Assuming successful development, we anticipate first revenues from the potential market launch of certepetide in 2029 (for orphan drug indication) and/or 2030 (for mPDAC).

Table 7: Income statement 2021-2026E (KPIs)

in USD'000	2021	2022	2023	2024E	2025E	2026E
Revenue	1	0	0	0	0	0
General & Administrative	-11,474	-14,141	-12,974	-11,900	-12,800	-13,000
Research & Development	-17,576	-13,067	-12,734	-12,200	-12,600	-13,000
In-process R&D		-30,393				
OPEX	-29,050	-27,208	-25,708	-24,100	-25,400	-26,000
EBIT	**-29,050**	**-57,601**	**-25,708**	**-24,100**	**-25,400**	**-26,000**
Net financial result	76	897	2,538	1,600	1,200	1,000
EBT	**-28,974**	**-56,704**	**-23,170**	**-22,500**	**-24,200**	**-25,000**
Net income	**-27,466**	**-54,225**	**-20,840**	**-21,300**	**-22,700**	**-23,800**

Source: First Berlin Equity Research estimates, Lisata Therapeutics Inc.

Balance sheet development Cash, cash equivalents and marketable securities, which make up the bulk of Lisata's assets, are modelled to fall to USD 31.0m by end of 2024E. We expect the company to raise a further USD 20m through two separate share issues of USD 10m each in 2025 and 2026 to extend its liquidity headroom into 2027. For the future, we assume a mixed model of non-dilutive (50% through milestone payments from licensing) and dilutive (50% through capital increases) financing of business operations.

Table 8: Balance sheet 2021-2026E (KPIs)

in USD'000	2021	2022	2023	2024E	2025E	2026E
Cash and cash equivalents	24,647	32,154	22,593	13,968	13,377	6,749
Marketable securities	70,323	37,072	27,942	17,000	7,000	2,000
Other current assets	1,212	2,650	3,389	3,728	3,616	3,508
Current Assets, Total	**96,182**	**71,876**	**53,924**	**34,696**	**23,993**	**12,257**
Property plant and equipment	62	296	175	93	46	59
Intangible assets	0	334	263	195	177	245
Financial and other LT assets	764	528	332	311	289	269
Non-Current Assets, Total	**826**	**1,158**	**770**	**599**	**512**	**573**
Accounts payable	1,934	2,655	2,421	2,300	2,116	2,137
Other current liabilities	2,589	3,728	4,169	4,336	4,509	4,690
Other LT liabilites	485	327	210	185	163	146
Total Liabilities	**5,008**	**6,710**	**6,800**	**6,821**	**6,788**	**6,973**
Minority interests	**-254**	**-254**	**-254**	**-254**	**-254**	**-254**
Equity	**92,254**	**66,578**	**48,148**	**28,728**	**17,971**	**6,110**
Equity ratio	95%	91%	88%	81%	73%	48%

Source: First Berlin Equity Research, Lisata Therapeutics Inc.

Cash flow Statement We model operating cash outflow of USD 19.5m and USD 20.4m for 2024E and 2025E respectively. This corresponds to a quarterly cash burn of roughly USD 5.0m, which is slightly below the rate needed to maintain operations into Q2/26. As the clinical trials are progressing towards phase 3, we assume a slightly growing trend of cash burn in the period 2024E-2026E.

Table 9: Cash flow statement 2021-2026E (KPIs)

in USD'000	2021	2022	2023	2024E	2025E	2026E
Operating cash flow	-22,245	-21,170	-20,032	-19,491	-20,434	-21,403
Cash flow from investing	-54,896	28,911	10,102	10,945	9,922	4,852
Cash flow from financing	85,276	-224	385	-79	9,921	9,923
Impact of exchange rates on cash	0	-10	-16	0	0	0
Net cash flow	8,135	7,507	-9,561	-8,625	-591	-6,628

Source: First Berlin Equity Research, Lisata Therapeutics Inc.

NEWSFLOW

In our view, Lisata Therapeutics' stock price will be driven by news about its pipeline as well as by the achievement of financial milestones. We expect the company to make a number of announcements during the coming 12-18 months which will act as catalysts for the stock. These include:

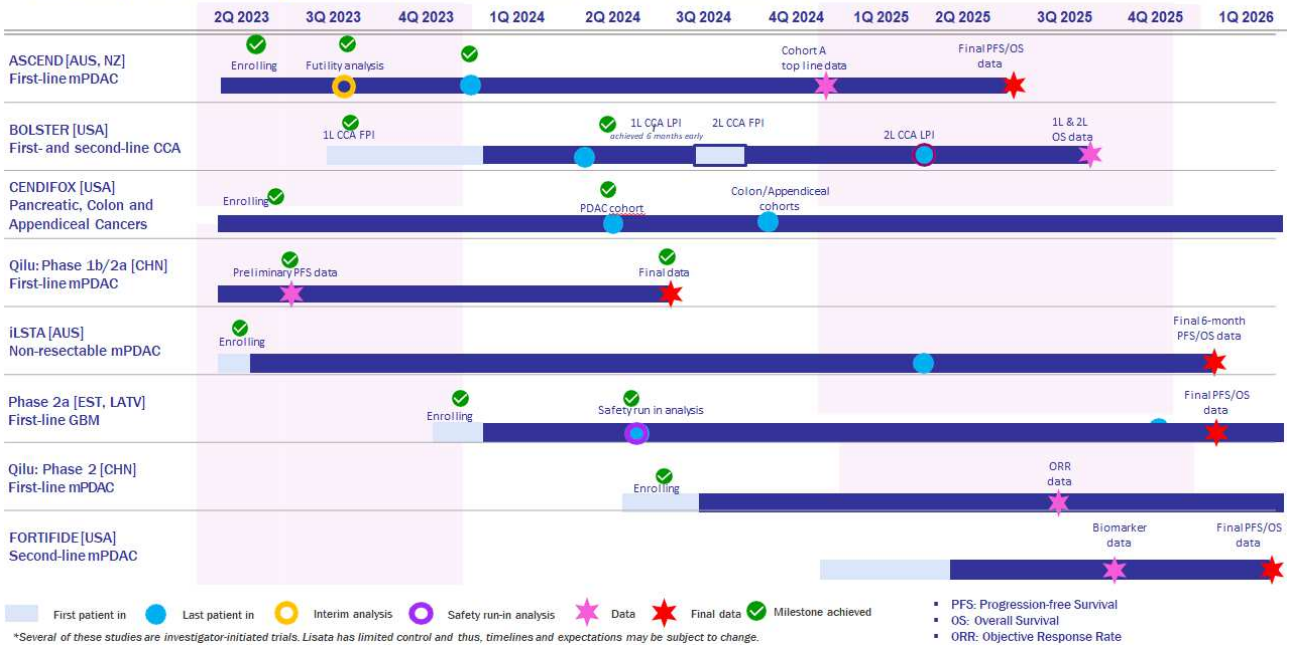
Anticipated financial results reporting dates

- FY 2024 results including business update is due on 27 February 2025;
- Q1 2025 results including business update is due on 8 May 2025;
- Q2 2025 results including business update is due on 7 August 2025;
- Q3 2025 results including business update is due on 6 November 2025;

Certepetide

- The ASCEND trial will provide first-line data from the first cohort in January 2025 and final data from the second cohort in the third quarter of 2025. We expect the company to initiate phase 3 trials in 2026;
- Multiple additional clinical milestones are due throughout 2025 and in Q1/26, including data on (1) the phase 2a Bolster trial (CCA), (2) the WAPNINE/ILSTA trial in non-resectable mPDAC, (3) the phase 2a trial in first-line treatment of GBM, (4) Qilu's phase 2 study in mPDAC, and (5) FORTIFIDE trial in 2nd line treatment of mPDAC. We give an overview of the main upcoming milestones in figure 15 below.

Figure 15: Overview of certepetide's upcoming milestones until Q1 2026



Source: First Berlin Equity Research, Lisata Therapeutics Inc

MANAGEMENT

President and CEO

David J Mazzo has been President and CEO of Lisata Therapeutics since March 2017. Dr Mazzo has over 40 years of experience in the pharmaceutical industry. Prior to Lisata, he served as CEO at Regado Biosciences, AEterna Zentaris, and Chugai Pharma USA, focusing on biopharmaceuticals and drug development for cardiovascular and oncology treatments. His earlier career included senior leadership roles at Schering-Plough and Hoechst Marion Roussel, later acquired by Merck and Sanofi, respectively. Dr Mazzo has been on the boards of Visioneering Technologies, EyePoint Pharmaceuticals, and Avanir Pharmaceuticals, and is currently Chairman of Feldan Therapeutics. He holds degrees from Villanova University and a Ph.D. in Analytical Chemistry from the University of Massachusetts, Amherst, with postdoctoral research at the Ecole Polytechnique Federale de Lausanne. He was recently recognized in the PharmaVoice 100 for his exceptional leadership and innovation in the life sciences.

Executive Vice President of R&D and Chief Medical Officer

Dr Kristen K Buck joined Lisata Therapeutics in September 2021 as Executive Vice President of R&D and Chief Medical Officer, bringing over 20 years of drug development and clinical operations experience. Previously, she was CMO at ICON plc and held senior roles at Optum Insights and Quintiles/IQVIA, where she led clinical development strategies across various therapeutic areas. Earlier, Dr Buck practiced as a primary care physician and worked at the FDA’s Office of New Drugs, evaluating drug efficacy and safety. At AstraZeneca, she served as a Global Safety and Study Physician, focusing on cardiovascular, oncology, and immunology. She holds a medical degree from Pennsylvania State University School of Medicine and completed her internal medicine residency at Abington Memorial Hospital.

Chief Information Officer and Data Protection Officer

Greg S. Berkin, who joined Lisata in January 2015, has been pivotal in transforming the company's IT support into an efficient in-house team. He oversees all IT departments, including Networking, PC, Cybersecurity, Applications, AI, Business Solutions, and Telecom. Prior to Lisata, he held leadership positions at biotech firms such as Regado Biosciences, Aeterna Zentaris, and Chugai Pharma USA. With 30 years in the tech field and 25 years in management, Greg specializes in production systems, network engineering, project management, hybrid cloud-computing, cybersecurity, and M&A activities. He holds both a BA and an MSc from Fairleigh Dickinson University.

Vice President, Human Resources

Gail Holler joined Lisata as VP of Human Resources in January 2019, bringing over 30 years of HR expertise in areas such as organisational strategy, career development, and compensation management. She oversees HR activities and acts as the liaison to the Board's Compensation Committee. Her extensive experience includes leading global teams and driving organizational change, notably as VP of HR at Innophos Inc., where she managed M&A integration. She also held senior HR roles at Tata Consultancy Services, LifeCell Corporation, and Sanofi Aventis, contributing to talent development and organizational growth. Ms. Holler holds a BA from the University of Delaware.

Vice President, Investor Relations and Corporate Communications

John Menditto, who joined Lisata in 2017, has over 30 years of experience in corporate communications and investor relations. He works closely with teams across Finance, Clinical, Regulatory, Legal, HR, and the Executive department, reporting directly to the CEO. Mr Menditto's expertise spans financial modelling, Regulation FD, corporate governance, investor targeting, and capital raising. He has held senior roles at Novartis Corporation,

Medco Health Solutions, and Argos Therapeutics, along with serving as a senior communications consultant. Recognised for his excellence by IR Magazine and PRSA/Big Apple, John earned degrees in public relations and finance from Susquehanna University in Pennsylvania.

Senior Vice President, Finance and Treasury and Chief Accounting Officer
James Nisco has been with Lisata Therapeutics since 2012 and currently serves as Senior Vice President, Finance and Treasury, and Chief Accounting Officer. He oversees SEC reporting, financial reporting and accounting, treasury operations, and financial planning and analysis, managing all finance activities for the company. With over 25 years of experience in corporate finance, James has previously held senior finance roles at OSI Pharmaceuticals (acquired by Astellas) and Ciba Corporation (acquired by The BASF Group). He began his career at Ciba-Geigy, now Novartis Pharmaceuticals. Mr. Nisco holds an MBA in Financial Management from Pace University and a Bachelor of Science in Business Economics from the State University of New York, College at Oneonta.

Vice President, Global Regulatory Affairs
Dr William K. Sietsema, Vice President of Global Regulatory Affairs at Lisata since 2014, brings 42 years of experience in the pharmaceutical industry. He was previously a Global Regulatory Lead at Amgen and held senior roles at Kendle International/INC Research, where he led multiple projects and accelerated Pharmacia's Celebrex from Phase 2 to approval in under three years. He has also taught drug development at the University of Cincinnati's College of Pharmacy. Dr. Sietsema earned his BA in chemistry from the University of Colorado and a PhD in biochemistry from the University of Wisconsin. He is credited with numerous publications, holds six patents, and was recognized by R&D Directions as a top 20 clinical research scientist in 2007.

Vice President, Chemistry, Manufacturing and Controls
Ryan Quick has over 22 years of experience in the life sciences industry, spanning large pharmaceutical companies and biotech startups, with expertise in cGMP production and bench research. Prior to Lisata, he founded a CMC consulting business, helping global clients develop peptide, oligonucleotide, and ADC therapies. He also co-founded Drive Therapeutics, focusing on next-generation aptamer therapies for eye diseases such as wet AMD and Diabetic Macular Edema. At Vitrisa Therapeutics, he led research chemistry, managing compound synthesis and working closely with the CMC team. Earlier, he headed analytical development at Novan Therapeutics and played a key role in moving a candidate from Phase 2 to Phase 3 at Regado Biosciences. Mr. Quick holds a B.Sc. in Chemical Engineering from NC State University.

Vice President, Business Development and Operations and Corporate Counsel
Tariq Imam joined Lisata Therapeutics in May 2016. Before Lisata, he led business and corporate development roles at Mist Pharmaceuticals, Akrimax Pharmaceuticals, and Rouses Point Pharmaceuticals. Earlier, he worked in corporate integration and M&A at Humana and corporate finance at Orion Health. Mr. Imam started his legal career at Wachtell Lipton, Rosen & Katz, focusing on mergers and acquisitions, before moving to Clifford Chance in corporate restructuring. He holds an A.B. in Politics from Princeton University, a J.D. from NYU School of Law, and an MBA in Finance from NYU Stern School of Business.

SUPERVISORY BOARD

Chairman: Gregory B. Brown
Directors: Steven M.Klosk, David J Mazzo, Cynthia L Flowers, Mohammad Azab, Heidi Henson

SHAREHOLDERS & STOCK INFORMATION

Stock Information	
ISIN	US1280583022
WKN	A3DWGC
Bloomberg ticker	LSTA US
No. of issued shares (million)	8.320
Transparency Standard	FCOI Regulations
Country	USA
Sector	Pharmaceutical
Subsector	Biotechnology

Source: Börse Frankfurt, First Berlin Equity Research

Shareholder Structure	
Erkki Ruoslahti	14.2%
BML Capital Management LLC	3.4%
David Mazzo	2.5%
Vanguard Global Advisers LLC	2.2%

Source: Lisata Therapeutics, Inc.

INCOME STATEMENT

All figures in USD '000	2021	2022	2023	2024E	2025E	2026E
Revenue	**0**	**0**	**0**	**0**	**0**	**0**
Cost of goods sold	0	0	0	0	0	0
Gross profit	0	0	0	0	0	0
General & Administrative	-11,474	-14,141	-12,974	-11,900	-12,800	-13,000
Research & Development	-17,576	-13,067	-12,734	-12,200	-12,600	-13,000
In-process Research & Development		-30,393				
Total operating expenses (OPEX)	**-29,050**	**-57,601**	**-25,708**	**-24,100**	**-25,400**	**-26,000**
Operating income (EBIT)	**-29,050**	**-57,601**	**-25,708**	**-24,100**	**-25,400**	**-26,000**
Net financial result	76	897	2,538	1,600	1,200	1,000
Non-operating income/expenses	0	0	0	0	0	0
Pre-tax income (EBT)	**-28,974**	**-56,704**	**-23,170**	**-22,500**	**-24,200**	**-25,000**
Income taxes	1,508	2,479	2,330	1,200	1,500	1,200
Net income / loss	**-27,466**	**-54,225**	**-20,840**	**-21,300**	**-22,700**	**-23,800**
Diluted EPS (USD)	**-7.45**	**-10.47**	**-2.58**	**-2.53**	**-2.17**	**-0.96**
Ratios						
EBIT Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of OPEX						
General & Administrative	39.5%	24.5%	50.5%	49.4%	50.4%	50.0%
Research & Development	60.5%	22.7%	49.5%	50.6%	49.6%	50.0%
Y-Y Growth						
Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in USD '000	2021	2022	2023	2024E	2025E	2026E
Assets						
Current Assets, Total	**96,182**	**71,876**	**53,924**	**34,696**	**23,993**	**12,257**
Cash and cash equivalents	24,647	32,154	22,593	13,968	13,377	6,749
Marketable securities	70,323	37,072	27,942	17,000	7,000	2,000
Other current assets	1,212	2,650	3,389	3,728	3,616	3,508
Non-Current Assets, Total	**826**	**1,158**	**770**	**599**	**512**	**573**
Property plant and equipment	62	296	175	93	46	59
Intangible assets	0	334	263	195	177	245
Financial and other assets	764	528	332	311	289	269
Total Assets	**97,008**	**73,034**	**54,694**	**35,294**	**24,505**	**12,829**
Shareholders' Equity & Debt						
Current Liabilities, Total	**4,523**	**6,383**	**6,590**	**6,636**	**6,625**	**6,827**
Accounts payable	1,934	2,655	2,421	2,300	2,116	2,137
Other current liabilities	2,589	3,728	4,169	4,336	4,509	4,690
Longterm Liabilities, Total	**485**	**327**	**210**	**185**	**163**	**146**
Other liabilities	485	327	210	185	163	146
Minority interests	**-254**	**-254**	**-254**	**-254**	**-254**	**-254**
Shareholders Equity	**92,254**	**66,578**	**48,148**	**28,728**	**17,971**	**6,110**
Total Consolidated Equity and Debt	**97,008**	**73,034**	**54,694**	**35,294**	**24,505**	**12,829**
Ratios						
Current ratio (x)	21.27	11.26	8.18	5.23	3.62	1.80
Quick ratio (x)	21.27	11.26	8.18	5.23	3.62	1.80
Net gearing	-26.7%	-48.3%	-46.9%	-48.6%	-74.4%	-110.5%
Book value per share (€)	25.01	12.85	5.96	3.42	1.72	0.44
Net debt	-24,647	-32,154	-22,593	-13,968	-13,377	-6,749
Equity ratio	95.1%	91.2%	88.0%	81.4%	73.3%	47.6%

CASH FLOW STATEMENT

All figures in USD '000	2021	2022	2023	2024E	2025E	2026E
Net income	**-27,466**	**-54,225**	**-20,840**	**-21,300**	**-22,700**	**-23,800**
Interest, net	-76	-897	-2,538	-1,600	-1,200	-1,000
Tax provision	-1,508	-2,479	-2,330	-1,200	-1,500	-1,200
Non-operating items	0	0	0	0	0	0
EBIT	**-29,050**	**-57,601**	**-25,708**	**-24,100**	**-25,400**	**-26,000**
Depreciation and amortisation	55	69	189	102	165	87
EBITDA	**-28,995**	**-57,532**	**-25,519**	**-23,998**	**-25,235**	**-25,913**
Share & warrant based payments	2,005	2,636	2,038	1,000	1,000	1,000
Changes in working capital	797	-1,068	-736	-293	101	310
Cash interest net	76	897	2,538	1,600	1,200	1,000
Other adjustments	3,872	33,897	1,647	2,200	2,500	2,200
Operating cash flow	**-22,245**	**-21,170**	**-20,032**	**-19,491**	**-20,434**	**-21,403**
CapEx	-60	-3,605	0	-20	-100	-168
Free cash flow	**-22,305**	**-24,775**	**-20,032**	**-19,511**	**-20,534**	**-21,571**
Other investments	-54,836	32,516	10,102	10,965	10,022	5,020
Cash flow from investing	**-54,896**	**28,911**	**10,102**	**10,945**	**9,922**	**4,852**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	85,252	-224	230	0	10,000	10,000
Other financing activities	24	0	155	-79	-79	-77
Cash flow from financing	**85,276**	**-224**	**385**	**-79**	**9,921**	**9,923**
Impact of exchange rates on cash	0	-10	-16	0	0	0
Net cash flows	**8,135**	**7,507**	**-9,561**	**-8,625**	**-591**	**-6,628**
Cash, start of the year	16,512	24,647	32,154	22,593	13,968	13,377
Cash, end of the year	**24,647**	**32,154**	**22,593**	**13,968**	**13,377**	**6,749**

Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Imprint / Disclaimer

First Berlin Equity Research

First Berlin Equity Research GmbH ist ein von der BaFin betreffend die Einhaltung der Pflichten des §85 Abs. 1 S. 1 WpHG, des Art. 20 Abs. 1 Marktmissbrauchsverordnung (MAR) und der Markets Financial Instruments Directive (MiFID) II, Markets in Financial Instruments Directive (MiFID) II Durchführungsverordnung und der Markets in Financial Instruments Regulations (MiFIR) beaufsichtigtes Unternehmen.

First Berlin Equity Research GmbH is one of the companies monitored by BaFin with regard to its compliance with the requirements of Section 85 (1) sentence 1 of the German Securities Trading Act [WpHG], art. 20 (1) Market Abuse Regulation (MAR) and Markets in Financial Instruments Directive (MiFID) II, Markets in Financial Instruments Directive (MiFID) II Commission Delegated Regulation and Markets in Financial Instruments Regulations (MiFIR).

Anschrift:
First Berlin Equity Research GmbH
Friedrichstr. 69
10117 Berlin
Germany

Vertreten durch den Geschäftsführer: Martin Bailey

Telefon: +49 (0) 30-80 93 9 680
Fax: +49 (0) 30-80 93 9 687
E-Mail: info@firstberlin.com

Amtsgericht Berlin Charlottenburg HR B 103329 B
UST-Id.: 251601797
Ggf. Inhaltlich Verantwortlicher gem. § 6 MDStV
First Berlin Equity Research GmbH

Authored by: Christian Orquera, Analyst
All publications of the last 12 months were authored by Christian Orquera.

Company responsible for preparation: First Berlin Equity Research GmbH, Friedrichstraße 69, 10117 Berlin

The production of this recommendation was completed on 21 January 2025 at 13:34

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

INFORMATION PURSUANT TO SECTION 85 (1) SENTENCE 1 OF THE GERMAN SECURITIES TRADING ACT [WPHG], TO ART. 20 (1) OF REGULATION (EU) NO 596/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF APRIL 16, 2014, ON MARKET ABUSE (MARKET ABUSE REGULATION) AND TO ART. 37 OF COMMISSION DELEGATED REGULATION (EU) NO 2017/565 (MIFID) II.

First Berlin Equity Research GmbH (hereinafter referred to as: "First Berlin") prepares financial analyses while taking the relevant regulatory provisions, in particular section 85 (1) sentence 1 of the German Securities Trading Act [WpHG], art. 20 (1) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) and art. 37 of Commission Delegated Regulation (EU) no. 2017/565 (MiFID II) into consideration. In the following First Berlin provides investors with information about the statutory provisions that are to be observed in the preparation of financial analyses.

CONFLICTS OF INTEREST

In accordance with art. 37 (1) of Commission Delegated Regulation (EU) no. 2017/565 (MiFID) II and art. 20 (1) of Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014, on market abuse (market abuse regulation) investment firms which produce, or arrange for the production of, investment research that is intended or likely to be subsequently disseminated to clients of the firm or to the public, under their own responsibility or that of a member of their group, shall ensure the implementation of all the measures set forth in accordance with Article 34 (2) lit. (b) of Regulation (EU) 2017/565 in relation to the financial analysts involved in the production of the investment research and other relevant persons whose responsibilities or business interests may conflict with the interests of the persons to whom the investment research is disseminated. In accordance with art. 34 (3) of Regulation (EU) 2017/565 the procedures and measures referred to in paragraph 2 lit. (b) of such article shall be designed to ensure that relevant persons engaged in different business activities involving a conflict of interests carry on those activities at a level of independence appropriate to the size and activities of the investment firm and of the group to which it belongs, and to the risk of damage to the interests of clients.

In addition, First Berlin shall pursuant to Article 5 of the Commission Delegated Regulation (EU) 2016/958 disclose in their recommendations all relationships and circumstances that may reasonably be expected to impair the objectivity of the financial analyses, including interests or conflicts of interest, on their part or on the part of any natural or legal person working for them under a contract, including a contract of employment, or otherwise, who was involved in producing financial analyses, concerning any financial instrument or the issuer to which the recommendation directly or indirectly relates.

With regard to the financial analyses of Lisata Therapeutics, Inc. the following relationships and circumstances exist which may reasonably be expected to impair the objectivity of the financial analyses: The author, First Berlin, or a company associated with First Berlin reached an agreement with the Lisata Therapeutics, Inc. for preparation of a financial analysis for which remuneration is owed.

Furthermore, First Berlin offers a range of services that go beyond the preparation of financial analyses. Although First Berlin strives to avoid conflicts of interest wherever possible, First Berlin may maintain the following relations with the analysed company, which in particular may constitute a potential conflict of interest:

- The author, First Berlin, or a company associated with First Berlin owns a net long or short position exceeding the threshold of 0.5 % of the total issued share capital of the analysed company;
- The author, First Berlin, or a company associated with First Berlin holds an interest of more than five percent in the share capital of the analysed company;

- The author, First Berlin, or a company associated with First Berlin provided investment banking or consulting services for the analysed company within the past twelve months for which remuneration was or was to be paid;
- The author, First Berlin, or a company associated with First Berlin reached an agreement with the analysed company for preparation of a financial analysis for which remuneration is owed;
- The author, First Berlin, or a company associated with First Berlin has other significant financial interests in the analysed company;

With regard to the financial analyses of Lisata Therapeutics, Inc. the following of the aforementioned potential conflicts of interests or the potential conflicts of interest mentioned in Article 6 paragraph 1 of the Commission Delegated Regulation (EU) 2016/958 exist: The author, First Berlin, or a company associated with First Berlin reached an agreement with the Lisata Therapeutics, Inc. for preparation of a financial analysis for which remuneration is owed.

In order to avoid and, if necessary, manage possible conflicts of interest both the author of the financial analysis and First Berlin shall be obliged to neither hold nor in any way trade the securities of the company analyzed. The remuneration of the author of the financial analysis stands in no direct or indirect connection with the recommendations or opinions represented in the financial analysis. Furthermore, the remuneration of the author of the financial analysis is neither coupled directly to financial transactions nor to stock exchange trading volume or asset management fees.

INFORMATION PURSUANT TO SECTION 64 OF THE GERMAN SECURITIES TRADING ACT [WPHG], DIRECTIVE 2014/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 15 MAY 2014 ON MARKETS IN FINANCIAL INSTRUMENTS AND AMENDING DIRECTIVE 2002/92/EC AND DIRECTIVE 2011/61/EU, ACCOMPANIED BY THE MARKETS IN FINANCIAL INSTRUMENTS REGULATION (MIFIR, REG. EU NO. 600/2014).

First Berlin notes that is has concluded a contract with the issuer to prepare financial analyses and is paid for that by the issuer. First Berlin makes the financial analysis simultaneously available for all interested security financial services companies. First Berlin thus believes that it fulfils the requirements of section 64 WpHG for minor non-monetary benefits.

PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

The present financial analysis is based on the author's own knowledge and research. The author prepared this study without any direct or indirect influence exerted on the part of the analysed company. Parts of the financial analysis were possibly provided to the analysed company prior to publication in order to avoid inaccuracies in the representation of facts. However, no substantial changes were made at the request of the analysed company following any such provision.

ASSET VALUATION SYSTEM

First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

RISK ASSESSMENT

The First Berlin categories for risk assessment are low, average, high and speculative. They are determined by ten factors: Corporate governance, quality of earnings, management strength, balance sheet and financial risk, competitive position, standard of financial disclosure, regulatory and political uncertainty, strength of brandname, market capitalisation and free float. These risk factors are incorporated into the First Berlin valuation models and are thus included in the target prices. First Berlin customers may request the models.

RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	Today	$3.71	Buy	$15.00

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

UPDATES

At the time of publication of this financial analysis it is not certain whether, when and on what occasion an update will be provided. In general First Berlin strives to review the financial analysis for its topicality and, if required, to update it in a very timely manner in connection with the reporting obligations of the analysed company or on the occasion of ad hoc notifications.

SUBJECT TO CHANGE

The opinions contained in the financial analysis reflect the assessment of the author on the day of publication of the financial analysis. The author of the financial analysis reserves the right to change such opinion without prior notification.

Legally required information regarding

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

can be accessed through the following internet link: https://firstberlin.com/disclaimer-english-link/

SUPERVISORY AUTHORITY: Bundesanstalt für Finanzdienstleistungsaufsicht (German Federal Financial Supervisory Authority) [BaFin], Graurheindorferstraße 108, 53117 Bonn and Marie-Curie-Straße 24-28, 60439 Frankfurt am Main

EXCLUSION OF LIABILITY (DISCLAIMER)

RELIABILITY OF INFORMATION AND SOURCES OF INFORMATION

The information contained in this study is based on sources considered by the author to be reliable. Comprehensive verification of the accuracy and completeness of information and the reliability of sources of information has neither been carried out by the author nor by First Berlin. As a result no warranty of any kind whatsoever shall be assumed for the accuracy and completeness of information and the reliability of sources of information, and neither the author nor First Berlin, nor the person responsible for passing on or distributing the financial analysis shall be liable for any direct or indirect damage incurred through reliance on the accuracy and completeness of information and the reliability of sources of information.

RELIABILITY OF ESTIMATES AND FORECASTS

The author of the financial analysis made estimates and forecasts to the best of the author's knowledge. These estimates and forecasts reflect the author's personal opinion and judgement. The premises for estimates and forecasts as well as the author's perspective on such premises are subject to constant change. Expectations with regard to the future performance of a financial instrument are the result of a measurement at a single point in time and may change at any time. The result of a financial analysis always describes only one possible future development – the one that is most probable from the perspective of the author – of a number of possible future developments.

Any and all market values or target prices indicated for the company analysed in this financial analysis may not be achieved due to various risk factors, including but not limited to market volatility, sector volatility, the actions of the analysed company, economic climate, failure to achieve earnings and/or sales forecasts, unavailability of complete and precise information and/or a subsequently occurring event which affects the underlying assumptions of the author and/or other sources on which the author relies in this document. Past performance is not an indicator of future results; past values cannot be carried over into the future.

Consequently, no warranty of any kind whatsoever shall be assumed for the accuracy of estimates and forecasts, and neither the author nor First Berlin, nor the person responsible for passing on or distributing the financial analysis shall be liable for any direct or indirect damage incurred through reliance on the correctness of estimates and forecasts.

INFORMATION PURPOSES, NO RECOMMENDATION, SOLICITATION, NO OFFER FOR THE PURCHASE OF SECURITIES

The present financial analysis serves information purposes. It is intended to support institutional investors in making their own investment decisions; however in no way provide the investor with investment advice. Neither the author, nor First Berlin, nor the person responsible for passing on or distributing the financial analysis shall be considered to be acting as an investment advisor or portfolio manager vis-à-vis an investor. Each investor must form his own independent opinion with regard to the suitability of an investment in view of his own investment objectives, experience, tax situation, financial position and other circumstances.

The financial analysis does not represent a recommendation or solicitation and is not an offer for the purchase of the security specified in this financial analysis. Consequently, neither the author nor First Berlin, nor the person responsible for passing on or distributing the financial analysis shall as a result be liable for losses incurred through direct or indirect employment or use of any kind whatsoever of information or statements arising out of this financial analysis.

A decision concerning an investment in securities should take place on the basis of independent investment analyses and procedures as well as other studies including, but not limited to, information memoranda, sales or issuing prospectuses and not on the basis of this document.

NO ESTABLISHMENT OF CONTRACTUAL OBLIGATIONS

By taking note of this financial analysis the recipient neither becomes a customer of First Berlin, nor does First Berlin incur any contractual, quasi-contractual or pre-contractual obligations and/or responsibilities toward the recipient. In particular no information contract shall be established between First Berlin and the recipient of this information.

NO OBLIGATION TO UPDATE

First Berlin, the author and/or the person responsible for passing on or distributing the financial analysis shall not be obliged to update the financial analysis. Investors must keep themselves informed about the current course of business and any changes in the current course of business of the analysed company.

DUPLICATION

Dispatch or duplication of this document is not permitted without the prior written consent of First Berlin.

SEVERABILITY

Should any provision of this disclaimer prove to be illegal, invalid or unenforceable under the respectively applicable law, then such provision shall be treated as if it were not an integral component of this disclaimer; in no way shall it affect the legality, validity or enforceability of the remaining provisions.

APPLICABLE LAW, PLACE OF JURISDICTION

The preparation of this financial analysis shall be subject to the law obtaining in the Federal Republic of Germany. The place of jurisdiction for any disputes shall be Berlin (Germany).

NOTICE OF DISCLAIMER

By taking note of this financial analysis the recipient confirms the binding nature of the above explanations.

By using this document or relying on it in any manner whatsoever the recipient accepts the above restrictions as binding for the recipient.

QUALIFIED INSTITUTIONAL INVESTORS

First Berlin financial analyses are intended exclusively for qualified institutional investors.

This report is not intended for distribution in the USA and/or Canada.