UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: **001-39717**

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-2903526**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
433 Plaza Real, Suite 275 **Boca Raton, Florida** (Address of principal executive offices)	**33432** (Zip Code)

Registrant's telephone number: **(631) 830-7092**

Securities registered pursuant to Section 12(b) of the Act: Common Stock, $0.0001 par value.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	LIXT	The NASDAQ Stock Market LLC

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If the securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2025 was approximately $1,983,710. The Company had 11,617,944 shares of common stock issued and outstanding as of March 31, 2026.

Documents incorporated by reference: None.

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Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "we," "us," "our," "our company," "Lixte," the "Company" and the "Registrant" refer to Lixte Biotechnology Holdings, Inc., a Delaware corporation, and Lixte Biotechnology, Inc., a Delaware corporation, our wholly-owned subsidiary.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Report") contains certain forward-looking statements. For example, statements regarding our financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements. These statements are generally accompanied by words such as "intend," "anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Report.

If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. Any forward-looking statement you read in this Report reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, growth strategy, and liquidity. All subsequent forward-looking statements attributable to us or individuals acting on our behalf are expressly qualified in their entirety by this paragraph. You should specifically consider the factors identified in this Report, which would cause actual results to differ before making an investment decision. We are under no duty to update any of these forward-looking statements after the date of this Report or to conform these statements to actual results.

PART I

ITEM 1. BUSINESS

Company Overview

The Company is a clinical-stage biopharmaceutical and proton cancer therapy company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company's drug product pipeline is primarily focused on inhibitors of protein phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity.

The Company is the majority shareholder of Liora Technologies Europe Ltd., which is pioneering the development of electronically controlled proton therapy systems for treating tumors in various types of cancers. Liora's proprietary technology, known as LiGHT System (Linac for Image Guided Hadron Therapy), has significant advantages over currently available technologies for treating tumors with proton therapy. Liora is an excellent complement to the pharmaceutical side of the Company's business and ongoing clinical trials with LB-100 for Ovarian Clear Cell Carcinoma and Metastatic Colon Cancer,

LB-100

The Company believes that the mechanism by which LB-100 affects cancer cell growth is different from cancer agents currently approved for clinical use. LB-100 is currently being tested in clinical trials in Ovarian Clear Cell Carcinoma, Metastatic Micro Satellite Stable (MSS) Colon Cancer, and Advanced Soft Tissue Sarcoma. LB-100 has shown anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. LB-100 has also been shown to enhance the effectiveness of commonly used anti-cancer drugs in animal models of melanoma, breast cancer and sarcoma. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that, when combined with standard anti-cancer regimens against many tumor types, LB-100 will improve therapeutic benefit.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, relies on stock-based compensation for a substantial portion of employee and consultant compensation, and is dependent on periodic access to equity capital to fund its operating requirements.

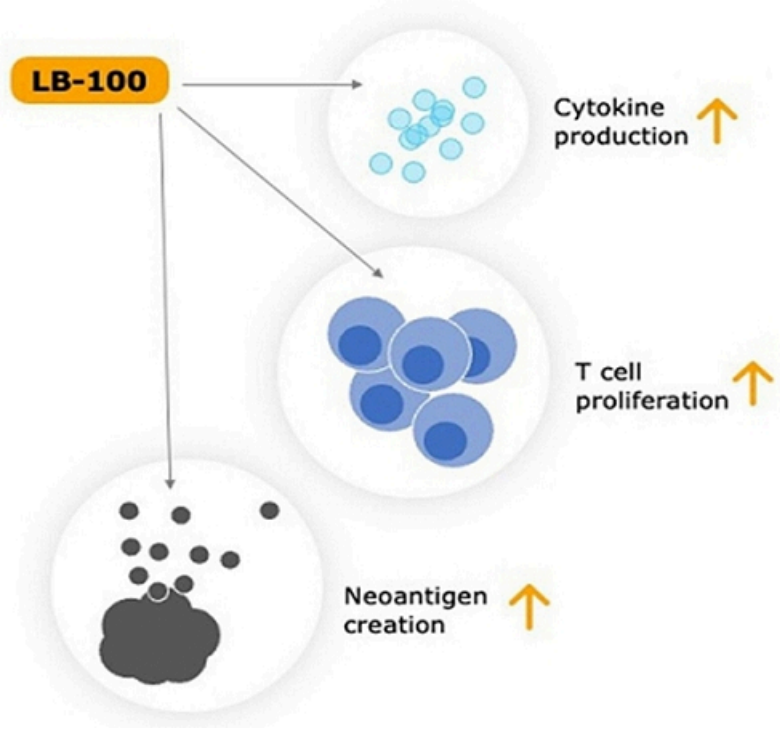
Description of LB-100 Business

Most cancer patients are treated with either chemotherapy or immunotherapy or both. These therapies often have limited benefit and there is a high unmet medical need to enhance their effects. In many preclinical models we have shown that LB-100 enhances the effect of both chemotherapy and Immunotherapy

LB-100, a small molecule potent inhibitor of PP2A, was designed and developed by us. Numerous preclinical studies have documented that LB-100 potentiates most if not all anti-cancer drugs that damage DNA. LB-100 is not associated with any increase in cytotoxicity when given with cytotoxic drugs. This synergy involves transient interruption of several DNA damage repair pathways by LB-100 and an increase in cell division rate. LB-100 has FDA Investigational New Drug status in the US and Investigational Medicinal Product Dossier approval in the European Union.

In its initial Phase 1 clinical trial, LB-100 given alone daily for 3 days was non-toxic, except for a transient increase in serum creatinine believed to be caused by inhibition of PP2A in the renal tubules. In the Phase 1 clinical trial, the Maximum Tolerated Dose ("MTD") was 2.33mg/m2 daily for 3 days every 3 weeks. Of the 25 patients with heavily-treated advanced solid tumors with measurable disease, 3 patients had stable disease for 2 cycles, 3 patients had stable disease for 4 cycles, and 3 patients had stable disease for 6 cycles. One patient with pancreatic cancer had a partial response after 12 cycles lasting 534 days.

Low doses of LB-100 have now been shown to enhance immune checkpoint inhibition ("ICI") by several different mechanisms affecting the tumor compartment and immune T-cell compartment. LB-100 increases CD8+T-cell infiltration and CD8-Treg ratio, CD8+T-cell proliferation, and cytokine production induces microsatellite instability, neoantigen production and immune responsiveness, converting immunologically "cold" to "hot" cancers.



Ovarian clear cell carcinoma patients with inactivating mutations in PPP2R1A, a gene coding for a scaffold component of PP2A, and treated with immune checkpoint inhibitors, were recently found to have markedly longer survival than patients without the mutation in their cancers. Retrospective reviews of patients with a variety of cancers treated with ICI or chemotherapy show much longer survival of ICI-treated patients with a PPP2R1A mutation in their tumors.

Based on the observations in ovarian clear cell carcinoma, we have initiated a clinical trial in this disease combining LB-100 with a monoclonal antibody blocking PD-1, a protein found on T-cells (NCT06065462).

Given these preclinical and clinical observations, it is likely that LB-100 may be a general way to enhance immunotherapy responses.

		Pre-Clinical	Phase 1b	Phase 2	Phase 3	Status
LB-100 + Immunotherapy	Ovarian Clear Cell Cancer	NCT06065462				Actively Recruiting at MD Anderson And Northwestern. GSK sponsored, completed enrollment first 21 patients. Starting second cohort of 21 patients in 2026
LB-100 + Immunotherapy	Metastatic MSI Low Colon Cancer	NCT06012734				Open at Netherlands Cancer Institute Roche sponsored.
LB-100 + Chemotherapy	Advanced Soft Tissue Sarcoma (ASTS)	NCT05809830				Completed enrollment 1b dose escalation phase. Closing the trial. Full report Q1 2026

The research on the LB-100 series was initiated in 2006 under a Cooperative Research and Development Agreement (“CRADA”) with the National Institute of Neurologic Disorders and Stroke or NINDS of the National Institutes of Health or NIH dated March 22, 2006 that was subsequently extended through a series of amendments until it terminated on April 1, 2013.

We have also designed and developed the LB-200 series, which consists of histone deacetylase inhibitors (HDACi). LB-200 has not advanced to the clinical stage and would require additional capital to fund further development. Accordingly, because of our focus on the clinical development of LB-100 and analogs for cancer therapy as described below in more detail, we have decided not to actively pursue the preclinical development of our LB-200 series of compounds at this time.

Clinical Trial Agreements

Spanish Sarcoma Group Collaboration Agreement

Effective July 31, 2019, we entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information with respect to the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little improvement in survival from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. We agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter approximately 150 to 170 patients in this clinical trial over a period of two to four years. The Phase 1 portion of the study began in the quarter ended June 30, 2023 to determine the recommended Phase 2 dose of the combination of doxorubicin and LB-100. As advanced sarcoma is a very aggressive disease, the design of the Phase 2 portion of the study assumes a median progression-free survival ("PFS"), no evidence of disease progression or death from any cause) of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

On October 13, 2022, we announced that the Spanish Agency for Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or "AEMPS") had authorized a Phase 1b/randomized Phase 2 study of LB-100, our lead clinical compound, plus doxorubicin, versus doxorubicin alone, the global standard for initial treatment of advanced soft tissue sarcomas (ASTS). Consequently, this clinical trial commenced during the quarter ended June 30, 2023 and to be completed and a report prepared by December 31, 2026. In April 2023, GEIS completed its first site initiation visit in preparation for the clinical trial at Fundación Jiménez Díaz University Hospital (Madrid). Up to 170 patents will be entered into the clinical trial. The recruitment phase of the Phase 1b portion of the protocol was completed during the quarter ended September 30, 2024. We expect to have data on toxicity and preliminary efficacy from this portion of the clinical trial during the quarter ending March 31, 2026.

Given the focus on the combination of LB-100 with immunotherapy in ovarian clear cell carcinoma and colorectal cancer and the availability of capital resources, the Company entered into Amendment No. 1 to the Collaboration Agreement effective March 11, 2025 that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000. As a result, the Phase 2 portion of this clinical trial will not proceed and the trial will be closed after completion of the first phase in Q1 2026.

Clinical Research Support Agreement Relating to Small Cell Lung Cancer

We had executed a Clinical Research Support Agreement with the City of Hope National Medical Center to carry out a Phase 1b clinical trial of LB-100 combined with an FDA-approved standard regiment for treatment of untreated extensive-stage disease small cell lung cancer. The clinical trial was initiated on March 9, 2021. However, due to the lack of patient accrual, the Company provided notice to the City of Hope National Medical Center of the Company's intent to terminate the Clinical Research Support Agreement effective as of July 8, 2024.

MD Anderson Cancer Center Clinical Trial

On September 20, 2023, we announced an investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). The clinical trial is being sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") and is being conducted at The University of Texas - MD Anderson Cancer Center. We are providing LB-100 and GSK is providing dostarlimab-gxly and financial support for the clinical trial. On January 29, 2024, we announced the entry of the first patient into this clinical trial. We currently expect that this clinical trial will be completed by December 31, 2028.

On February 25, 2025, we announced that we had added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer. Patient recruitment is underway, and the first patient has been dosed.

On December 23, 2025 we announced that we are going to expand the enrollment of the trial from 21 to 42 patients in collaboration with GSK, MD Anderson and Northwestern University. We completed the enrollment of the first 21 patients in Q4, 2025 and expect patient 22 to be enrolled in Q1 2026.

Netherlands Cancer Institute Clinical Trial

Effective June 10, 2024, we entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with microsatellite stable metastatic colon cancer. Under the agreement, we will provide our lead clinical compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. We have no obligation to and will not provide any reimbursement of clinical trial costs. Pursuant to the agreement and the protocol set forth in the agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The agreement provides for the protection of the respective intellectual property rights of each of Lixte, NKI and Roche.

This Phase 1b clinical trial will evaluate safety, optimal dose and preliminary efficacy of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the preliminary efficacy, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial opened in August 2024 with the enrollment of the first patient. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab is currently investigating two Serious Adverse Events ("SAEs") observed in the clinical trial that was launched in August 2024. The Investigational Review Board (IRB) of the Netherlands Cancer Institute requested additional information with respect to these SAEs and the study has been paused for enrollment until the IRB's questions were addressed, as more fully discussed at "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Specific Risks Associated with the Company's Business Activities – Serious Adverse Events". As of Q4 2025 the questions of the IRB have been sufficiently addressed, and the trial opened for enrollment again.

Patent and License Agreements

National Institute of Health

Effective February 23, 2024, we entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, we have licensed exclusively NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, unless sooner terminated.

The License Agreement contemplates that we will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet certain benchmarks. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, we would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

Other Significant Agreements and Contracts

Netherlands Cancer Institute

On October 8, 2021, we entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam ("NKI"), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, for a term of three years. The Development Collaboration Agreement was subsequently modified by Amendment No. 1 thereto.

The Development Collaboration Agreement is a preclinical study intended to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. We agreed to fund the preclinical study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the preclinical study.

On October 3, 2023, we entered into Amendment No. 2 to the Development Collaboration Agreement with NKI, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and added 500,000 Euros to the operating budget being funded by us.

On October 4, 2024, we entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year and starts upon the dosing of the first patient in the clinical trial at a project cost of 100,000 Euros.

On March 31, 2025 we announced we will conduct a new pre-clinical study in collaboration with the NKI to test whether "initiated" cells that carry mutations found in cancer cells can be eliminated by treatment with LIXTE's proprietary compound LB-100.

Effective as of June 15, 2022, Dr. René Bernards was appointed to our Board of Directors as an independent director. Dr. Bernards is a leader in the field of molecular carcinogenesis and is employed by NKI. On August 18, 2025, Dr. Bernards resigned from the board and was appointed Chairman of the Scientific Advisory Board.

Intellectual Property

Our intellectual property includes proprietary know-how, proprietary methodologies and extensive clinical validation data and publications. To provide legal protection of our intellectual property, we rely on a combination of patents, licenses, trade secrets, trademarks, confidentiality and non-disclosure clauses and agreements, and other forms of intellectual property protection to define and protect our rights to our products.

Our products are expected to be covered by our patents. These patents now cover sole rights to the composition and synthesis of our LB-100 series of drugs, which is the Company's lead clinical compound in development. Lixte has filed patent applications covering the treatment of cancer with LB-100. Lixte has also filed joint patent applications with the NIH and the Netherlands Cancer Institute for the treatment of cancer using LB-100 in combination with other drugs like immune checkpoint inhibitors and WEE1 inhibitors.

Patent applications for the LB-100 series have been filed in the United States and internationally under the Patent Cooperation Treaty. Patents for composition of matter and for several uses of the LB-100 series have been issued in the United States, Mexico, Australia, Japan, China, Hong Kong, Canada, and by the European Patent Office

The Company strives to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of its business, including seeking, maintaining, and defending its patent rights, which are owned solely by our wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc., except in several instances jointly with one of many of our collaborators. The Company also relies on trade secrets relating to its proprietary pipeline of product candidates and on know-how and continuing technological innovation to develop and strengthen its pipeline. The Company intends to rely on regulatory protection afforded by regulatory agencies through data exclusivity, market exclusivity, and patent term extensions, where available.

The Company's success will depend in large part on its ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to its business; defend and enforce its patents; preserve the confidentiality of its trade secrets; and operate without infringing valid and enforceable patents or proprietary rights of third parties. The Company's ability to stop third parties from making, using, selling, offering to sell, or importing our technology may depend on the extent to which the Company has rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, enforcement of these rights may depend on cooperation of the joint owners of our jointly owned patents and patent applications.

With respect to both the Company's solely and jointly owned intellectual property, the Company cannot be sure that patents will be granted on any of its pending patent applications or on any patent applications filed solely or jointly by the Company in the future; we cannot be sure that any of the Company's existing patents or any patents that may be granted to us in the future will be commercially useful in protecting the Company's intended commercial products or therapeutic methods; and the Company cannot be sure that an agency or court would determine that the Company's solely or jointly owned patents are valid and enforceable.

The patent portfolios for the Company's most important programs involving the development of the LB-100 series are summarized and presented below, along with related information, as of January 12, 2026, followed by a detailed listing of U.S. and non-U.S. patents that have been issued. The projected patent expiration dates noted below assume that that all required maintenance or annuity fees for the patents are timely paid and that a court or agency does not determine that the patents are invalid or unenforceable.

LB-100. The Company's lead compound LB-100 is covered by U.S. Patent Nos. 8,822,461 and 7,998,957, which are solely owned by Lixte Biotechnology, Inc. These patents are projected to expire in 2030 or 2028, exclusive of any available patent term extension. Counterpart non-U.S. patents are projected to expire in 2028. Pharmaceutical compositions of LB-100 are covered by U.S. Patent Nos. 10,532,050, 10,023,587 and 8,822,461, which are solely owned by Lixte Biotechnology, Inc. These patents and their non-U.S. counterparts are projected to expire in 2034 or 2028, exclusive of any available patent term extension.

LB-100 Combination Therapy with a Checkpoint Inhibitor. LB-100 combination therapy with a checkpoint inhibitor for treating cancer is covered by U.S. Patent No. 12,168,008 and a pending U.S. patent application, as well as by non-U.S. patents and patent applications. These patents and patent applications are jointly owned by Lixte Biotechnology, Inc., and The United States of America, as represented by the Secretary, Department of Health and Human Services. These patents and patents issuing from these patent applications are projected to expire in 2037, exclusive of any patent term extension.

LB-100 Combination Therapy with Doxorubicin. LB-100 combination therapy with doxorubicin for treating soft tissue sarcoma is covered by U.S. Patent No. 12,343,342, which is solely owned by Lixte Biotechnology, Inc. This patent is projected to expire in 2034, exclusive of any patent term extension.

LB-100 Combination Therapy with Another Investigational Compound. LB-100 combination therapy with one of several other investigational compounds for treating cancer, or preventing, inhibiting or reducing risk of metastasis of cancer, is covered by pending U.S. and non-U.S. patent applications that are jointly owned by Lixte Biotechnology, Inc., and Stichting Het Nederlands Kanker Instituut – Antoni Van Leeuwenhoek Ziekenhuis. Patents issuing from these patent applications are projected to expire in 2043, exclusive of any patent term extension.

LB-100 for Treating Cancer. LB-100 for treating breast cancer, colon cancer, large cell lung cancer, adenocarcinoma of the lung, small cell lung cancer, stomach cancer, liver cancer, ovary adenocarcinoma, pancreas carcinoma, prostate carcinoma, promyelocytic leukemia, chronic myelocytic leukemia or acute lymphocytic leukemia, is covered by U.S. Patent No. 9,079,917, which is solely owned by Lixte Biotechnology, Inc. LB-100 for treating glioblastoma multiforme, medulloblastoma, ovarian cancer, kidney cancer and colorectal cancer is covered by U.S. Patent No. 10,399,993. These patents and their non-U.S. counterparts are projected to expire in 2028, exclusive of any patent term extension.

LB-100 Prodrugs and Analogs. LB-100 prodrugs and analogs are covered by U.S. Patent Nos. 11,866,444, 10,618,908, 10,364,252, 9,988,394, 8,822,461, 8,541,458, 8,426,444, 8,227,473 and 7,998,957, which are solely owned by Lixte Biotechnology, Inc. These patents and their non-U.S. counterparts are projected to expire in 2036, 2030 or 2028, exclusive of any patent term extension. Pharmaceutical compositions of LB-100 prodrugs or analogs are covered by U.S. Patent Nos. 11,931,354, 11,236,102, 10,532,050, 10,023,587, 8,822,461, 8,227,473 and 7,998,957, which are solely owned by Lixte Biotechnology, Inc. These patents and their non-U.S. counterparts are projected to expire in 2034, 2030 or 2028, exclusive of any patent term extension.

Our portfolio of solely or jointly owned U.S. and non-U.S. issued patents is summarized below. We have additional U.S. and non-U.S. patent applications pending.

Oxabicycloheptanes and Oxabicycloheptenes, Their Preparation and Use

Patent	Issue/Grant Date	Expiration Date
AU 2008214299	1/19/2014	2/6/2028
CA 2,676,422	10/16/2018	2/6/2028
CN 101662939	11/25/2015	2/6/2028
CN 103788108	4/12/2017	2/6/2028
EP 21245501	4/19/2017	2/6/2028
JP 5693850	4/1/2015	2/6/2028
JP 5666443	12/19/2014	12/19/2029
US 7,998,957	8/16/2011	2/20/2030
US 8,227,473	7/24/2012	3/11/2030
US 8,426,444	4/23/2013	2/6/2028
US 8,541,458	9/24/2013	7/17/2029
US 8,822,461	9/2/2014	2/6/2028
US 9,079,917	7/14/2015	2/6/2028
US 10,023,587	7/17/2018	2/6/2028
US 10,399,993	9/3/2019	2/6/2028

[1] EP 2124550 validated and pending in Germany, Spain, France, United Kingdom and Italy

Formulations of Oxabicycloheptanes and Oxabicycloheptenes

Patent	Issue/Grant Date	Expiration Date
AU 2014251087	5/2/2019	4/8/2034
CA 2909160	5/25/2021	4/8/2034
CN 105209036	10/26/2018	4/8/2034
EP 29836611	5/29/2024	4/8/2034
HK 1221416	12/06/2024	4/8/2034
IL 241945	4/30/2019	4/8/2034
US 10,532,050	1/14/2020	7/5/2034
US 11,931,354	3/19/2024	4/8/2034
US 12,343,342	7/1/2025	4/8/2034

[1] EP 2983661 validated and pending as Unitary Patent, and in Spain, United Kingdom and Switzerland

Process of Synthesizing 3-(4-Methylpiperazine-1-Carbonyl)-7-Oxabicyclo [2.2.1] Heptane-2-Carboxylic Acid

Patent	Issue/Grant Date	Expiration Date
US 9,994,584	6/12/2018	10/14/2035

Oxabicycloheptane Prodrugs

Patent	Issue/Grant Date	Expiration Date
AU 2016263079	8/15/2019	5/12/2036
CA 2,986,104	12/16/2025	5/12/2026
EP 32942871	4/8/2020	5/12/2036
EP 37362752	7/3/2024	5/12/2036
HK 1247576	3/5/2021	5/12/2036
IL 255516	2/27/2020	5/12/2036
IL 272027	22/1/2022	5/12/2036
IN 394963	4/19/2022	5/12/2036
JP 7187023	12/2/2022	5/12/2036
MX 386975	10/12/2021	5/12/2036
MX 393461	6/28/2022	5/12/2036
TW I693226	5/11/2020	5/12/2036
TW I757720	3/11/2022	5/12/2036
US 9,988,394	6/5/2018	5/13/2036
US 10,364,252	7/30/2019	5/13/2036
US 10,618,908	4/14/2020	5/13/2036
US 11,236,102	2/1/2022	5/13/2036
US 11,866,444	1/9/2024	5/13/2036

[1] EP 3294287 validated and pending in Austria, Switzerland, Czechia, Germany, Denmark, Spain, France, United Kingdom, Hungary, Ireland, Italy, Netherlands, and Sweden

[2] EP 3736275 validated and pending as Unitary Patent, and in Spain, United Kingdom and Switzerland

Oxabicycloheptanes for Modulation of Immune Response

Patent	Issue/Grant Date	Expiration Date
AU 2017370731	9/15/2022	12/8/2037
CN 110234647	5/23/2023	12/8/2037
EP 35516291	11/15/2023	12/8/2037
HK 40015901	4/12/2024	12/8/2037
IL 267134	7/2/2022	12/8/2037
IL 290857	2/2/2023	12/8/2037
JP 7246309	3/16/2023	12/8/2037
MX 396386	10/12/2022	12/8/2037
US 12,168,008	12/17/2024	12/8/2037

[1] EP 3551629 validated and pending in Belgium, Germany, Denmark, Spain, France, United Kingdom, Ireland, Iceland, Italy, Netherlands, Norway, Sweden and Switzerland

The Market

Anti-Cancer Drugs

We believe that the mechanism by which compounds of the LB-100 series affects cancer cell growth is different from cancer agents currently approved for clinical use. Lead compounds of the LB-100 series have activity against a broad spectrum of common and rarer human cancers in cell culture systems. In addition, lead compounds of the LB-100 series have anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. Lead compounds of the LB-100 series also have activity against melanoma, breast cancer and sarcoma in animal models and enhance the effectiveness of commonly used anti-cancer drugs in animal models. The enhancement of anti-cancer activity of these commonly-used anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that when combined with standard anti-cancer regimens against many tumor types, LB-100 will improve therapeutic benefit without unacceptable toxicity in humans.

LB-100 is part of a pioneering effort in an entirely new field of cancer biology – activation lethality – that is advancing a new treatment paradigm. The Company is the only company that has a drug in clinical trials with demonstrated capacity to over-activate oncogenic signaling. The pre-clinical data obtained with LB-100 were recently posted online in a paper titled “Paradoxical Activation of Oncogenic Signaling as a Cancer Treatment Strategy” in the scientific journal *Cancer Discovery*, and were published in the July 2024 issue of *Cancer Discovery*. This study showed that LB-100 triggers hyper-activation of the signals that are responsible for the deregulated proliferation of cancer cells, thus leading to cell death. This approach is the opposite of most of the current generation of cancer therapies and opens potentially new treatment strategies.

Marketing Plan

Our primary goal to date has been to take our primary compound, LB-100, through Phase 2 clinical trials evaluating whether LB-100 will enhance anti-cancer therapies. Because of the novelty and spectrum of activity of LB-100, we believe it is reasonably likely we may find a partner in the pharmaceutical industry with interest in this compound at some stage of its clinical development. However, we would prefer to delay the partnering/licensing decision until the potential value of our products are augmented by demonstrating there is no impediment to clinical evaluation and a therapeutic dose level is determined in clinical trials. Demonstration of clinical usefulness would be expected to substantially increase the value of our product.

Product Development

We are subject to FDA regulations as it conducts clinical trials. Additionally, any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturer or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Competition

The life sciences industry is highly competitive and subject to rapid and profound technological change. Our present and potential competitors include major pharmaceutical companies, as well as specialized biotechnology and life sciences firms in the United States and in other countries. Most of these companies have considerably greater financial, technical and marketing resources than we do. Additionally, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Our existing or prospective competitors may develop processes or products that are more effective than ours or be more effective at implementing their technologies to develop commercial products faster. Our competitors may succeed in obtaining patent protection and/or receiving regulatory approval for commercializing products before we do. Developments by our competitors may render our product candidates obsolete or non-competitive.

We also experience competition from universities and other research institutions, and we are likely to compete with others in acquiring technology from those sources. There can be no assurance that other organizations will not develop technologies with significant advantages over those that we are seeking to develop. Any such development could harm our business.

We compete with universities and other research institutions engaged in research in these areas. Many of our competitors have greater technical and financial resources than we do.

Our ability to compete successfully is based on numerous factors, including:

- the cost-effectiveness of any product that we ultimately commercialize relative to competing products;
- the ease of use and ready availability of any product that we bring to market; and
- the relative speed with which we are able to bring any product resulting from its research to market in our target markets.

If we are unable to distinguish our products from competing products, or if competing products reach the market first, we may be unable to compete successfully with current or future competitors.

Facilities

As of March 31, 2026, the Company does not operate or lease any facilities for LB-100. We contract out research and development activities, drug production, and drug storage to various commercial laboratories, drug manufacturers and storage facilities.

Government Regulation

Our business is subject to the regulations of the FDA as it conducts clinical trials. Clinical trials are research studies to answer specific questions about new therapies or new ways of using known treatments. Clinical trials determine whether new drugs or treatments are both safe and effective and the FDA has determined that carefully conducted clinical trials are the fastest and safest way to find treatments that work in people.

The FDA also requires that an independent review body consider the benefits and risks of a clinical trial and grant approval for the proposed study including selecting of initial doses, plans for escalation of dose, plans for modification of dose if toxicity is encountered, plans for monitoring the wellbeing of individuals participating in the study, and for defining and measuring, to the extent possible, any untoward effects related to drug administration. Serious adverse effects, such as life-threatening toxicities and death, are immediately reportable to the review body and to the FDA. To minimize risk when studying a new drug, the initial dose is well below that expected to cause any toxicity. No more than three patients are entered at a given dose. In general, a dose is not escalated within an individual patient. Once safety is established by the absence of toxicity or low toxicity in a group of three patients, a planned higher dose is then evaluated in a subsequent group of three individuals and so on until dose-limiting toxicity is encountered. The dose level producing acceptable toxicity is then selected as the dose level to be evaluated in Phase 2 trials. Thus, the goal of Phase 1 studies is to determine the appropriate dose level for evaluation of drug efficacy in patients with cancer.

In addition to regulations imposed by the FDA, depending on our future activities, we may become subject to regulation under various federal and state statutes and regulations, such as the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Research Conservation and Recovery Act, national restrictions on technology transfer, and import, export and customs regulations. From time to time, other federal agencies and congressional committees have indicated an interest in implementing further regulation of biotechnology applications. We are not able to predict whether any such regulations will be adopted or whether, if adopted, such regulations will apply to our business, or whether we or our collaborators would be able to comply with any applicable regulations.

In addition, as we intend to market our products in international markets, we will be required to obtain separate regulatory approvals from the European Union and many other foreign jurisdictions. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

LIORA TECHNOLOGIES EUROPE LTD.

The primary aim of radiation therapy is to irradiate the cancer cells and minimize radiation to healthy cells. X-rays radiate all cells along their trajectory, the healthy cells in front of, and behind the tumor. Protons are subatomic particles with a positive electric charge. Due to an effect called the Bragg peak, a proton radiates a small volume at a depth (d) given by the incident energy of the proton. The radiation at depths greater than d is zero.

The required range of depths, dictated by the location of the tumor is controlled by variation of the proton beam energy. Since the proton is charged, the radiation deposition can be controlled in the horizontal and vertical dimensions by electromagnets.

Cyclotrons are fixed-energy accelerators. For proton therapy, the required beam energy is achieved in cyclotrons by placing an object ("absorber") in the beam path. The mechanical absorber not only reduces the beam energy but also greatly reduces the beam intensity and produces a large amount of unwanted radiation. The unwanted radiation must be shielded by large concrete blocks.

Description of Business

The Liora's LiGHT machine is a proton linear accelerator that electronically controls the beam energy and does not need absorbers. The LiGHT machine is superior to existing cyclotrons both from treatment efficiency and overall cost considerations.

The linear accelerator concept originated from research conducted at CERN and the TERA Foundation, and was further developed by ADAM SA, which was a spin-off from CERN. The accelerator chain consists of:

- a Radio Frequency Quadrupole (RFQ),
- Side-Coupled Drift Tube Linac (SCDTL) modules, and
- Coupled Cavity Linac (CCL) modules, together designed to accelerate protons to therapeutic energies of up to approximately 230 MeV.

The combination of proton therapy and immune checkpoint inhibition acts at several stages of the antitumor response, suggesting a mechanism of synergy between the two modalities. The possibility of reducing the side-effects of oncology therapy and reversing the spread of metastatic disease has created tremendous global demand for this type of treatment. However, widespread use of the combination therapies is limited by the availability of proton therapy centers. As of early 2026, there are only 47 centers in the U.S.

Cancer irradiation with hadron beams, a method to which CERN contributed by advancing carbon ion therapy of radioresistant tumors into the medical world some thirty years ago, has treated more than 300,000 patients to date. Unfortunately, present proton and ion therapy centers are large and very demanding on the design of accelerators and guiding systems.

The highly adaptable Linac Image-Guided Hadron Technology (LiGHT) accelerator developed by Liora provides a proton beam allowing the delivery of ultra-high dose rates to deep-seated tumors. LiGHT, the first linear accelerator used for proton cancer treatment worldwide, operates with components and designs developed by CERN, the linac design reduces beam losses, stray radiation and, consequently, the volume of shielding material required. This will allow not only large tertiary care centers to provide proton therapy.

The unique biologic effects of ultra-high-dose-rate radiotherapy delivered at more than 40 Gy/sec, now known as FLASH therapy, were first reported more than 50 years ago. Interest in this modality began re-emerging recently.

Multiple animal experiments have demonstrated that FLASH can increase the therapeutic ratio of radiotherapy by decreasing normal tissue injury while maintaining the tumoricidal effects of conventional-dose-rate radiotherapy (conventional radiotherapy) or by allowing for dose escalation and improved tumor control probability without increasing normal tissue injury.

As such, FLASH is the holy grail in the industry. As its name sounds, this consists of delivering radiation in a "flash". By doing so, the opportunity is to treat a cancer patient in a single visit as opposed to 25/35 visits. Typically, radiation (measured in Grays (Gy)) is delivered at a rate of 2Gy per minute. With FLASH, radiation must be delivered at … 40-60Gy per … second. The higher the number of Gy is, the higher the number of protons in a pulse. This means that the delivery of a FLASH treatment requires two things:

Fast delivery: a fast delivery of radiation and a high level of radiation (i.e. number of protons per pulse). LiGHT – because of its design and the electronic (i.e. without a slow mechanical) control of the proton beam – can deliver pulses of proton at a frequency of 200 times per second as opposed to conventional systems which deliver radiation at a frequency of only 2-3 times per second. This means the property of protons (i.e. its high precision) is leveraged for the benefits of patients in the case of FLASH when using our LiGHT system: Within a second, LiGHT can hit various points (voxels) of the tumour.

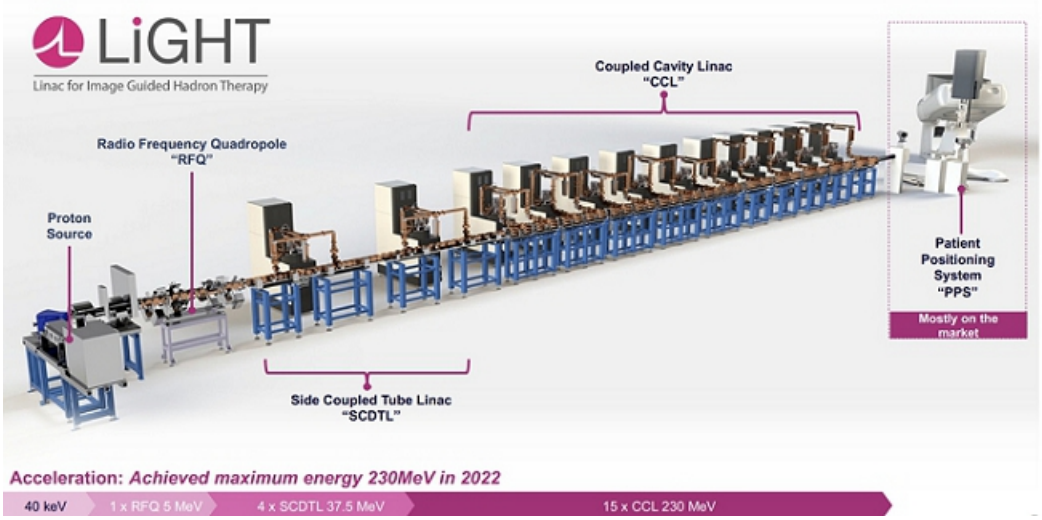
High throughput: The LiGHT system is highly efficient. In other words, up to 98/99% of the protons which are accelerated and energised reach their targets, i.e. the tumour. With circular accelerators, that % is as low as 1/2% when treating superficial tumours, the rest of the accelerated and energised protons being "lost" and creating neutrons, which must be shielded to protect operators and patients. This advantage of LiGHT is therefore compounded in the case of FLASH whereby the dose rate (40-60Gys per second) is high, and a high number of protons must be accelerated.

Current Development

The LiGHT machine is a physically complete linear accelerator, with all components manufactured and assembled, that has demonstrated the ability to generate a 230 MeV proton beam, which is widely recognized as the clinical gold standard for proton therapy. Unlike conventional proton therapy systems, which typically rely on large cyclotrons or synchrotrons, the LIGHT Machine is based on a modular, high-frequency linear accelerator architecture. The design enables a more compact footprint for precise control of the treatment dose delivery, rapid energy modulation, and ultimately lower installation and operating costs for single-room proton therapy facilities. Proton energy can be modulated up to 200Hz in a range from 70 to 230 MeV by varying the gradient of the accelerating structures. Achieving a stable 230 MeV beam is the point at which proton accelerators can be clinically used.

The LiGHT system's main aspects are complete, and no substantive research and development is needed. It is currently a non-clinical prototype system. However, the system was powered down for an extended period prior to the acquisition by the Company. The system will be subject to a safety assessment to be done before switching on the equipment. This will require updating all computers, screens, and software in the control rooms, beamline integration, safety checks, and regulatory clearance. The timeline to make the LiGHT machine operational is estimated to take twenty-four months and cost approximately two million dollars.

There is no resolving scientific uncertainty, inventing new technology, or proving that the LIGHT system can do what physics already has shown it can do. Liora is not planning incremental research and development beyond commissioning.



The Market

The LiGHT System is the first Linac system in the market, as all other proton therapy systems are based on cyclotron technology. This makes the LiGHT system a disruptive technology offering applications that are not possible with the current cyclotron technology and offers a much increased capacity of patient throughput.

Whether the LiGHT system beam is directed at a brain tumor, a prostate tumor, or another tissue does not change the fundamental nature of the Accelerator. The LiGHT machine produces a proton beam with defined energy, stability, and modulation. How the beam is clinically applied is a decision that does not fundamentally alter the machine. The LiGHT system is not tied to a single experiment, a single protocol, or a single disease. It is inherently capable of supporting multiple clinical uses over a long period of time.

Marketing Plan

Liora does not plan to make the LiGHT system saleable as a clinical system. To become operational for clinical use would require tens of millions of dollars in additional funding for key elements, including but not limited to integrated patient positioning and imaging, clinical commissioning and dosimetry validation, certified safety interlock systems, extensive reliability, endurance testing, and site-specific installation, shielding, and licensing.

The Company's marketing plan for the LiGHT system is to position it as a functional prototype asset (rather than a turnkey clinical system), valued primarily for its intellectual property, accelerator hardware configuration, and accumulated engineering work, without immediate clinical operability. It will be saleable as a functional unlicensed prototype to be copied and licensed at locations closer to large patient populations.

The LiGHT machine offers cost advantages over competitors in the proton therapy market. These advantages include:

- Low unwanted radiation levels:
    - Huge reduction in radiation shielding,
    - Lower replacement rate of electronics and components,
    - Reduced downtime: lower radiation levels allow rapid human access for repair of technical faults inside the accelerator.
- Fast depth modulation with higher intensity spots also allows 'hypofractionation', which substantially reduces the patient treatment time and increases throughput. Also FLASH compatible.
- Construction in reasonable-sized modules allows reduced infrastructure and installation costs
- Small beam cross-section allows smaller and cheaper magnets for beam transfer to the treatment area.

Competition

The market for proton therapy products is still developing and is characterized by rapidly evolving technology and pricing pressure. Our primary competitors in the proton therapy market are IBA Worldwide, Varian Medical Systems (Siemens Healthineers), Hitachi, Mevion Medical Systems, ProNova Solutions, P-Cure, and Sumitomo Heavy Industries. These companies dominate the market by providing advanced, high-energy particle accelerators for pencil beam scanning and intensity-modulated proton therapy. These manufacturers primarily focus on improving tumor-targeting precision while minimizing damage to healthy tissues, particularly using Pencil Beam Scanning (PBS) technology.

The Company's ability to compete successfully depends, in part, on their ability to lower product costs, and develop and provide a technically superior, proven product that delivers precise, cost-effective, high-quality capabilities. Because of the large footprint and high price of many proton therapy systems, there is increasing demand for the development of smaller, more compact proton therapy systems.

Facilities

Liora's equipment and operations are located in part of the Tower at Daresbury Laboratory, Daresbury Cheshire, United Kingdom, pursuant to a lease agreement with the United Kingdom Research and Innovation. The annual rent is £590,384.79, which is approximately $787,278, per annum. The annual Rent and any VAT are payable in quarterly instalments on April 1, June 1, September 1, and December 1.

Government Regulation

The Company intends to pursue regulatory clearance based on substantial equivalence to existing proton therapy systems. This regulatory pathway does not require the development of new scientific principles, novel mechanisms of action, or experimental validation beyond standard safety and performance testing. The Company's regulatory activities are not indicative of substantive research and development. The Company is looking at substantial equivalence versus existing technology. That means that if the LIGHT machine does the same (shooting 230 MeV protons out of a beam) as existing proton therapy machines, Liora will achieve regulatory clearance for the effectiveness proven by the so-called "predicate device". Liora utilizes a different way to get to the same result. The LIGHT system accelerates linear, while other companies in proton beam radiotherapy accelerate circular.

Employees and Human Capital Resources

As of March 31, 2026, we had three officer/employees, our Chief Executive Officer, our Chief Financial Officer, our Chief Scientific Officer, and our Director of Administration. The Company relies to a significant extent on outside consultants and advisors with various technical skills and expertise that the Company can draw on as necessary to conduct its research and development and clinical trial programs. We consider our relationship with our employees to be good. Our future performance depends significantly upon the continued service of our key personnel and our ability to attract highly skilled employees. We provide our officer/employees and consultants with opportunities for equity ownership.

Legal Proceedings

On November 19, 2025, the Company received a written demand from FX Group Inc. and certain related parties ("FX"), asserting that FX was entitled to consulting fees in connection with capital offerings completed by the Company during June and July 2025. The Company denied the allegations, and negotiations continued after year-end. On January 22, 2026, the Company entered into a settlement agreement, under which the Company agreed to pay a one-time settlement amount of $100,000 to FX in exchange for mutual releases of all claims. As of December 31, 2025, management recorded an accrual of $100,000 for the settlement expense.

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of December 31, 2025 and 2024, the Company was not subject to any other threatened or pending lawsuits, legal claims or legal proceedings.

ITEM 1A. RISK FACTORS

The following risk factors, together with the other information presented in this document, including the financial statements and the notes thereto, should be considered by investors.

Risks Related to Our Financial Resources and Capital Needs

We are engaged in early-stage research and as such might not be successful in our efforts to develop a portfolio of commercially viable products.

A key element of our strategy is to develop LB-100 in combination with other anti-cancer therapies to treat cancer. We are seeking to do so through our internal research programs or strategic partnerships. A significant portion of the research and development that we are conducting involves new and unproven technologies. Research programs to identify new disease targets and product candidates or to develop them require substantial technical, financial and human resources whether or not any candidates or technologies are ultimately identified or proven successful. Our research programs might initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for the following reasons:

- the research methodology used might not be successful in identifying potential product candidates; or
- product candidates for drugs might on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

If we are unable to discover suitable potential product candidates, develop additional delivery technologies through internal research programs or strategic partnerships, or in-license suitable products or delivery technologies on acceptable business terms, our business prospects will suffer. Even if we discover additional product candidates, new clinical trials of one or more additional drug candidates may show that these product candidates are unsafe or ineffective.

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company that uses biomarker technology to identify enzyme targets associated with serious common diseases and then design novel compounds to attack those threats. We do not have any products approved by a regulatory authority and have not generated any revenue from collaboration or licensing agreements or product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses since our inception. For the years ended December 31, 2025 and 2024, we reported a net loss of $6,009,520 and $3,585,965, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $58,077,213 and $52,067,693, respectively.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for one or more of our product candidates and any additional product candidates we might acquire, and potentially begin to commercialize product candidates that might achieve regulatory approval. We might also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that could adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our expenses will further increase as we:

- conduct clinical trials of our lead product candidate, LB-100;
- in-license or acquire rights to, and pursue development of, other products, product candidates or technologies;

- hire additional clinical, administrative, manufacturing, quality control, quality assurance and scientific personnel;
- seek marketing approval for any product candidates that successfully complete clinical trials;
- develop our outsourced manufacturing and commercial activities and establish sales, marketing and distribution capabilities, if we receive, or expect to receive, marketing approval for any product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel.

There is substantial doubt about our ability to continue as a going concern.

The Company has no recurring source of revenue and has used cash in operating activities since inception. As a result, management has concluded, and our independent registered public accounting firm has agreed with our conclusion, that there is a substantial doubt regarding the Company's ability to continue as a going concern for a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. As a result, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2025, includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern.

We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our lead product candidate, LB-100. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect that our existing cash resources as of December 31, 2025 will provide sufficient working capital resources to fund our operations, including our clinical trial programs with respect to the development of our lead anti-cancer clinical compound LB-100, through approximately September 30, 2026. Our existing cash resources will not be sufficient to complete development of and obtain regulatory approval for our lead product candidate, and we will need to raise significant additional capital to be able to continue our efforts in this regard. The Company estimates that it will need to raise additional capital to fund its operations by mid-2026, including its various clinical trial commitments, to be able to proactively manage its current business plan during the remainder of 2026 and during 2027. In addition, our operating plan might change as a result of many factors currently unknown to us, including possible additional clinical trials, and we might need additional funds sooner than planned. The Company is considering various strategies and alternatives to obtain the required additional capital.

We expect to expend substantial resources for the foreseeable future to continue the clinical development and production of our lead product candidate. These expenditures will include costs associated with research and development, potentially acquiring new product candidates or technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products.

Budgets and future capital requirements depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned development programs for our lead product candidate, as well as any additional clinical trials we undertake to obtain data sufficient to seek marketing approval for our lead product candidate;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead drug candidate if our clinical trials are successful;
- the cost of commercialization activities for our lead product candidate, if it is approved for sale, including marketing, sales and distribution costs;

- the cost of manufacturing our lead product candidate for clinical trials in preparation for regulatory approval, including the cost and timing of process development, manufacturing scale-up and validation activities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs to in-license future product candidates or technologies;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the costs in defending and resolving future derivative and securities class action litigation;
- our operating expenses; and
- the emergence of competing technologies or other adverse market developments.

Additional funds might not be available when we need them on terms that are acceptable to us, or at all. We have no committed source of additional capital. If adequate funds are not available to us on a timely basis, we might not be able to continue as a going concern or we might be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or target indications, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our lead product candidate.

We currently have no source of revenues. We might never generate revenues or achieve profitability.

Currently, we do not generate any revenues from product sales or otherwise. Even if we are able to successfully achieve regulatory approval for our lead product candidate, we do not know when we will generate revenues or become profitable, if at all. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully commercialize products, including our lead product candidate, LB-100, and any other product candidates that we might develop, in-license or acquire in the future. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete development activities, including the necessary clinical trials;
- complete and submit a New Drug Application ("NDA") to the FDA and obtain U.S. regulatory approval for an indication for which there is a commercial market;
- complete and submit applications to foreign regulatory authorities;
- obtain regulatory approval in territories with viable market sizes;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our intended product, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties and/or build our own manufacturing facility and ensure adequate, legally and globally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- develop distribution processes for our lead product candidate;
- develop commercial quantities of our lead product candidate, once approved, at acceptable cost levels;
- obtain additional funding, if required to develop and commercialize our lead product candidate;

- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves, in the markets in which we choose to commercialize on our own;

- achieve market acceptance of one or more of our intended products;

- attract, hire and retain qualified personnel; and

- protect our rights in our intellectual property portfolio.

Our revenues for any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable-disease patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we might not generate significant revenues from sales of such products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we might not become profitable and might need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we might be unable to continue our operations at planned levels and might be forced to reduce our operations.

Our efforts to integrate acquired businesses may not be successful, and this may adversely affect our financial results.

The success of business acquisitions may depend on our ability to successfully integrate the operations of the acquired business. Integrating the operations of acquired businesses requires significant efforts, including the coordination of operations, manufacturing, personnel, information technologies, research and development, sales and marketing and finance. These efforts can be compounded when the acquisitions are in new geographies or business lines. If these integration efforts are not successful, the anticipated benefits and synergies of the acquisition may not be realized fully, may take longer to realize than expected, or may not be realized at all. Our efforts to successfully integrate acquisitions may also result in additional expenses and divert significant amounts of management's time from other projects.

Acquiring or implementing new business lines or offering new products and services may subject us to additional risks.

From time to time, we may acquire or implement new business lines or offer new products and services within existing lines of business. For example, with our November 2025 acquisition of Liora Technologies Europe Ltd., we entered the radiotherapy segment of cancer care treatment space. There are substantial risks and uncertainties associated with these efforts. We may invest significant time and resources in developing, marketing, or acquiring new lines of business and/or offering new products and services. Initial timetables for the introduction and development or acquisition of new lines of business and/or the offering of new products or services may not be achieved, and price and profitability targets may prove to be unachievable. Our lack of experience or knowledge, as well as external factors, such as compliance with regulations, competitive alternatives and shifting market preferences, may also impact the success of an acquisition or the implementation or of a new line of business or a new product or service. Entry into a new line of business and/or offering a new product or service may also subject us to new laws and regulations with which we are not familiar and may lead to increased litigation or regulatory risk. Furthermore, any new business line and/or new product or service could have an adverse impact on the effectiveness of our system of internal controls. New business lines or new products and services within existing lines of business could affect the sales and profitability of existing lines of business or products and services, including as a result of sales channel conflicts. Other risks include: (i) potential diversion of management's attention, available cash, and other resources from our existing businesses; (ii) unanticipated liabilities or contingencies; (iii) the need for additional capital and other resources to expand into or acquire the new line of business; (iv) potential damage to existing customer relationships, lack of customer acceptance or inability to attract new customers; and (v) the inability to compete effectively. These risks would be magnified to the extent that any new business line would result in a significant increase in operations in developing markets. Failure to successfully manage these risks in the implementation or acquisition of new lines of business or the offering of new products or services could have a material adverse effect on our reputation, business, results of operations, and financial condition.

We compete in highly competitive markets, and we may lose market share to companies with greater resources or more effective technologies or be forced to reduce our prices.

The market for proton therapy products is still developing and is characterized by rapidly evolving technology and pricing pressure. Our primary competitors in the proton therapy market are Varian Medical Systems, Ion Beam Applications S.A. (IBA) and Hitachi Ltd. Our ability to compete successfully depends, in part, on our ability to lower our product costs, and develop and provide technically superior, proven products that deliver precise, cost-effective, high-quality capabilities.

Our ability to use net operating losses to offset future taxable income might be subject to limitations.

For the period ended 12/31/2025, the Company had federal and states net operating loss carryforwards of approximately $34.8M and $36.8M respectively. Of the federal amount, $14.0 have a limited carryforward period and will begin to expire in 2029 the remaining $20.8M will have an indefinite carryforward period. Of the state post-apportioned amount, $14.1M have a limited carryforward period and will begin to expire in 2038; the remaining $22.7 will have an indefinite carryforward period.

The Company has $732,880 of Federal, R&D ax credit carryforwards as of December 31, 2025.

In accordance with Section 382 and Section 383, utilization of the NOL and tax credit carryforwards may be subject to limitations based on prior or future ownership changes.

Additionally, after weighing up all available positive and negative evidence for the period ending 12/31/2025, the Company has recorded a full valuation allowance.

On July 4th, 2025, the President signed into law significant federal tax legislation, H.R.1 (the “Tax Reform Act of 2025”). The legislation includes numerous changes to U.S. corporate income tax law, including but not limited to permanent 100% bonus depreciation for qualified property, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest expense, increased Section 179 expensing limits, changes to the international tax regime, and expanded limitations on the deductibility of executive compensation under IRC Section 162(m). Most provisions are effective for tax years beginning after December 31, 2024, with certain transition rules and exceptions.

The Company has not recognized any signifcnt impact from the change in the tax law.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

Clinical-stage biopharmaceutical companies with product candidates in clinical development face a wide range of challenging activities which might entail substantial risk.

We are a clinical-stage biopharmaceutical company with a lead product candidate in clinical development. The success of our lead product candidate will depend on several factors, including the following:

- designing, conducting and successfully completing preclinical development activities, including preclinical efficacy and IND-enabling studies, for our lead product candidate or product candidates that we might, in the future, in-license or acquire;
- designing, conducting and completing clinical trials with positive results for our lead product candidate;
- receipt of regulatory approvals from applicable authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our lead product candidate;

- making arrangements with third party manufacturers, receiving regulatory approval of our manufacturing processes and our third-party manufacturers' facilities from applicable regulatory authorities and ensuring adequate supply of drug product;
- manufacturing our lead product candidate at an acceptable cost;
- effectively launching commercial sales of our lead product candidate, if approved, whether alone or in collaboration with others;
- achieving acceptance of our lead product candidate, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- if our lead product candidate is approved, obtaining and maintaining coverage and adequate reimbursement by third party payors, including government payors, for our lead product candidate;
- complying with all applicable regulatory requirements, including FDA current Good Clinical Practices ("GCP"), Current Good Manufacturing Practices ("CGMP"), and standards, rules and regulations governing promotional and other marketing activities;
- maintaining a continued acceptable safety profile of the lead product candidate during development and following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our lead product candidate, which could materially harm our business.

We might find it difficult to enroll patients in our clinical trials which could delay or prevent the start of clinical trials for our product candidate.

Identifying and qualifying patients to participate in clinical trials of our lead product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our lead product candidate, and we might experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our lead product candidate will most likely be delayed.

Many factors might affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the lead product candidate under study and the participation in a clinical trial generally in relation to other available therapies, including any new drugs that might be approved for the indications we are investigating;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- willingness of physicians to participate in our planned clinical trials;

- severity of the disease under investigation;
- proximity of patients to clinical sites;
- patients who are noncompliant or do not otherwise complete the trials; and
- issues with a contract research organization (a "CRO") and/or with other vendors that are involved with our clinical trials.

We might not be able to initiate or continue to support clinical trials of LB-100, our lead product candidate, for one or more indications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or one or more other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our lead product candidate might increase and the completion of our trials might be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our lead product candidate, the commercial prospects of our lead product candidate could be harmed, and our ability to generate product revenue from any of our product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences might harm our business, financial condition, and prospects significantly.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our lead product candidate in clinical trials, and any other product candidates that might advance into clinical trials, might not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than we have, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials.

Despite the results reported in earlier preclinical studies or clinical trials for our lead product candidate, we do not know whether the clinical trials that we might conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our lead product candidate for a particular indication, in any particular jurisdiction. Efficacy data from prospectively designed trials might differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our lead product candidate might be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market our lead product candidate or any future product candidates, the FDA or other regulatory authorities might not agree and might require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, with the outcome inherently uncertain. Failure can occur at any time during the clinical trial process. Before obtaining approval from regulatory authorities for the sale of our lead product candidate, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our lead product candidate in humans. Prior to initiating clinical trials, a sponsor must complete extensive preclinical testing of a product candidate, including, in most cases, preclinical efficacy experiments as well as IND-enabling toxicology studies. These experiments and studies might be time-consuming and expensive to complete. The necessary preclinical testing might not be completed successfully for a preclinical product candidate and a potentially promising product candidate might therefore never be tested in humans. Once it commences, clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials might not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. We might experience numerous unforeseen events during drug development that could delay or prevent our ability to receive marketing approval or commercialize our lead product candidate. In particular, clinical trials of our lead product candidate might produce inconclusive or negative results. We have limited data regarding the safety, tolerability and efficacy of our lead product candidate. Clinical trials also require the review and oversight of an institutional review board ("IRB"). An inability or delay in obtaining IRB approval could prevent or delay the initiation and completion of clinical trials, and the FDA might decide not to consider any data or information derived from a clinical investigation not subject to initial and continuing IRB review and approval.

We might experience delays in our ongoing or future clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA or another regulatory agency will not put clinical trials of our lead product candidate on hold in the future. Clinical trials might be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a foreign regulatory authority on a clinical trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- failure of our third party clinical trial managers, CROs, clinical trial sites, contracted laboratories or other third party vendors to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- alteration of trial design necessitated by re-evaluation of design assumptions based upon observed data;
- feedback from the FDA, the IRB or a foreign regulatory authority, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;
- a decision by the FDA, the IRB, a foreign regulatory authority, or us to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;

- failure to demonstrate a benefit from using a product candidate;
- difficulties in manufacturing, obtaining, from one or more third parties, or qualifying sufficient quantities of a product candidate to start or to use in clinical trials;
- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions or lack of adequate funding to continue a clinical trial.

If we experience delays in the completion or termination of any clinical trial of our lead product candidate, the approval and commercial prospects of our lead product candidate will be harmed, delaying our ability to generate product revenues from such product candidate and our costs will most likely increase. The required regulatory approvals may also be delayed, thereby jeopardizing our ability to commence product sales and generate revenues and the period of commercial exclusivity for our intended product may be shortened. Regulatory approval of our lead product candidate may be denied for the same reasons that caused the delay.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We are currently conducting clinical trials in Spain and the Netherlands. Consequently, we will also be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for drug approvals and regulation of approved drugs in foreign countries;
- more stringent privacy requirements for data to be supplied to our operations in the United States, but generated outside of the United States, e.g., General Data Protection Regulation in the European Union;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign countries, economies or markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding or payroll taxes;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions or events, including civil or political unrest (such as the ongoing conflict between Ukraine and Russia), sanctions, war and terrorism.

Our current and future product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our current or future product candidates, their delivery methods or dosage levels could cause us, our collaborators or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval or termination of clinical trials by the FDA or other foreign regulatory authorities; or an IRB, that approves and, monitors biomedical research to protect the rights and welfare of human subjects. As a result of safety or toxicity issues that we might experience in our clinical trials, or negative or inconclusive results from the clinical trials of others for drug candidates that might be similar to our own, we might not receive approval to market our current lead product candidate or any product candidates we may pursue, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity or incidence of side effects. In such an event, our trials or those or our collaborators could be suspended or terminated, and the FDA or foreign regulatory authorities could order us or our collaborators to cease further development of or deny approval of our current or any future product candidates for any or all targeted indications. Any drug-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete clinical trials or result in potential product liability claims. Any of these occurrences could have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if our lead product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of such product;
- regulatory authorities might withdraw their approvals of such product;
- regulatory authorities might require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such product;
- we may be required to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our lead product candidate, if approved.

Our product development program might not uncover all possible adverse events that patients who take our lead product candidate may experience. The number of subjects exposed to our lead product candidate and the average exposure time in the clinical development program might be inadequate to detect rare adverse events or chance findings that might only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured that rare and severe side effects of our lead product candidate will be uncovered. Such rare and severe side effects might only be uncovered with a significantly larger number of patients exposed to our lead product candidate. If such safety problems occur or are identified after our lead product candidate reaches the market, the FDA might require that we amend the labeling of the product or recall the product, or might even withdraw approval for the product.

There is a risk that one or more of our clinical trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to our drug candidate or to another company's drug used in combination in one of our clinical trials.

It is possible that the SAEs could be attributable to our drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. The Institutional Review Board of the Netherlands Cancer Institute has put the colorectal cancer study on hold, as more fully discussed at "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Specific Risks Associated with the Company's Business Activities – Serious Adverse Events".

Our future success is dependent on the regulatory approval of our lead product candidate.

Our business is dependent on our ability to obtain regulatory approval for our lead product candidate in a timely manner. We cannot commercialize our lead product candidate in the United States without first obtaining regulatory approval for the product from the FDA. Similarly, we cannot commercialize our lead product candidate outside of the United States without obtaining regulatory approval from one or more foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our lead product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

Even if a product candidate were to successfully obtain approval from the FDA and one or more foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Also, any regulatory approval of our lead product candidate or any future product candidates we may pursue, once obtained, may be withdrawn.

Our lead product candidate and future product candidates could fail to receive regulatory approval from the FDA.

We have not obtained regulatory approval for our lead product candidate, and it is possible that our lead product candidate or any future product candidates will not obtain regulatory approval, for many reasons, including:

- disagreement with the regulatory authorities regarding the scope, design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for our proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our lead product candidate to support the submission and filing of an NDA or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a foreign regulatory authority might require more information, including additional preclinical or clinical data, to support approval or additional studies, which might delay or prevent approval or our commercialization plans, or we might decide to abandon the development program. The FDA or a foreign regulatory authority might also require the manufacture of a new lead product candidate in accordance with new or revised standards. If we were to obtain approval, regulatory authorities might approve our lead product candidate and any future product candidates we might pursue for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), might grant approval contingent on the performance of costly post-marketing clinical trials, or might approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we are unable to obtain regulatory approval for our lead product candidate in one or more jurisdictions, or if any approval contains significant limitations, we might not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate.

Failure to obtain regulatory approval in international jurisdictions would prevent our lead product candidate from being marketed abroad.

In addition to regulations in the United States, to market and sell our lead product candidate in the European Union, in the United Kingdom, in many Asian countries and in other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval procedure varies among countries and can require additional data or involve additional testing. The time required to obtain foreign approval may differ substantially from that required to obtain FDA approval. We might not be able to obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Clinical trials accepted in one country might not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country might not receive reimbursement approval in that country.

We might not be able to file for regulatory approvals and might not receive necessary approvals to commercialize our intended product in any market. If we are unable to obtain approval of any of our current product candidate or any future product candidates we might pursue by regulatory authorities in the European Union, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate might be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

Even if our current primary product candidate received regulatory approval, it might still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our lead product candidate, LB-100, that approval would be subject to ongoing requirements by the FDA and foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements can include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our CMOs and CROs for any post-approval clinical trials that we or our collaborators might conduct. The safety profile of any product will continue to be closely monitored by the FDA and foreign regulatory authorities after approval. If the FDA or foreign regulatory authorities become aware of new safety information after approval of our lead product candidate, they might require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with CGMP, GCP, and other regulations. If we, a collaborator or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency might impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our lead product candidate or the manufacturing facilities for our lead product candidate fail to comply with applicable regulatory requirements, a regulatory agency might:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us or a collaborator;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above might inhibit our ability to successfully commercialize our intended product and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the United States is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States is heavily scrutinized by foreign regulatory authorities. Violations, including actual or alleged promotion of our intended product for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements can have a negative impact on our business.

Risks Related to Our Dependence on Third Parties

We depend on certain key scientific personnel for our success who do not work full time for us. The loss of any such personnel could adversely affect our business, financial condition and results of operations.

Effective September 26, 2023, Bastiaan van der Baan, who had served as a director of the Company since June 17, 2022, replaced our founder, John S. Kovach, as President and Chief Executive Officer. Dr. Kovach passed away on October 5, 2023. Effective October 6, 2023, Mr. van der Baan was appointed Chairman of the Board of Directors.

Effective June 16, 2025, Mr. van der Baan resigned as Chairman of the Board and Chief Executive Officer. Mr. van der Baan remained President and a member of the Board of Directors and also assumed the role of Chief Scientific Officer. At that time, Geordan Pursglove was appointed Chairman of the Board of Directors and Chief Executive Officer.

Effective September 1, 2025, Mr. van der Baan resigned from the Board of Directors and resigned as President of the Company.

Although our success depended, in part, on the continued availability and contributions of Dr. Kovach, we were able to replace Dr. Kovach on a timely basis with a qualified replacement in Mr. van der Baan and subsequently Mr. Pursglove. Furthermore, recruiting and retaining qualified scientific personnel to perform future research and development work is critical to our success. Our inability to attract or retain qualified personnel or advisors in the future could significantly weaken our management, harm our ability to compete effectively, and harm our business. The competition for qualified personnel in the pharmaceutical field is intense and, as a result, we might be unable to attract and retain qualified personnel necessary for the development of our business.

Additionally, we replaced our previous Chief Medical Officer, Dr. James S. Miser, with Dr. Jan Schellens during 2024, and we reallocated the responsibilities of Eric J. Forman, our Vice President and Chief Operating Officer, who resigned on December 31, 2024. Effective as of July 31, 2025, the Company agreed to accept the resignation of Dr. Schellens and to terminate his consulting agreement to allow Dr. Schellens to pursue employment opportunities. We believe that Mr. Van der Baan is capable of managing the Company’s research and clinical activities.

Our business may suffer if we are not able to hire and retain qualified personnel.

Our future success depends, to a great degree, on our ability to retain, attract, expand, integrate and train our management team and other key personnel, such as qualified engineering, service, sales, marketing and other staff. We compete for key personnel with other clinical-stage pharmaceutical and med-tech companies, as well as universities and research institutions. As we continue to grow our software revenues, we face intense competition for personnel from software and technology companies. Because this competition is intense, compensation-related costs could increase significantly if the supply of qualified personnel decreases or demand increases. If we are unable to hire and train qualified personnel, we may not be able to maintain or expand our business. In addition, some of our executive officers have had long careers at our company. If these executives retire or leave, and we are unable to locate qualified or suitable replacements in a timely manner, our business could be adversely affected.

We expect to rely heavily on third parties for the conduct of clinical trials of our product candidates. If these clinical trials are not successful, or if we or our collaborators are not able to obtain the necessary regulatory approvals, we will not be able to commercialize our product candidates.

In order to obtain regulatory approval for the commercial sale of our product candidates, we or our collaborators will be required to complete extensive preclinical studies as well as clinical trials in humans to demonstrate to the FDA and foreign regulatory authorities that our product candidates are safe and effective.

We expect to rely on collaborative partners and CROs for their performance and management of clinical trials of our product candidates.

Our intended products under development might not be effective in treating any of our targeted disorders or might prove to have undesirable or unintended side effects, toxicities or other characteristics that might prevent or limit their commercial use. Institutional review boards or regulators, including the FDA, might hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks. Additionally, failure of third parties conducting or overseeing the operation of the clinical trials to perform their contractual or regulatory obligations in a timely fashion could delay the clinical trials. Failure of clinical trials can occur at any stage. Any of these events would adversely affect our ability to market a product candidate.

The development process necessary to obtain regulatory approval is lengthy, complex and costly. If we or our collaborative partners do not obtain necessary regulatory approvals, then our business would not be successful, and the market price of our common stock could decline substantially.

To the extent that we, or our collaborative partners, are able to successfully advance a product candidate through the clinic, we, or such partner, will be required to obtain regulatory approval prior to marketing and selling such product. The process of obtaining FDA and other required regulatory approvals is costly and lengthy. The time required for FDA and other approvals is uncertain and can typically take several or many years, depending on the complexity and novelty of the product.

Any regulatory approval to market a product might be subject to limitations on the indicated uses for which we, or our collaborative partners, may market the product. These limitations might restrict the size of the market for the product and affect reimbursement by third party payors. In addition, regulatory agencies might not grant approvals on a timely basis or might revoke or significantly modify previously granted approvals.

We, or our collaborative partners, also are subject to numerous foreign regulatory requirements governing the manufacturing and marketing of our potential future products outside of the United States. The approval procedure varies among countries, additional testing might be required in some jurisdictions, and the time required to obtain foreign approvals often differs from that required to obtain FDA approvals. Moreover, approval by the FDA does not ensure approval by regulatory authorities in other countries, and vice versa.

As a result of these factors, we, or our collaborative partners, might not successfully complete clinical trials in the time periods estimated, if at all. Moreover, if we, or our collaborative partners, incur unanticipated costs and/or delays in development programs or if we fail to successfully develop and commercialize products based upon our technologies, we might not be able to generate significant operating revenues or sustainable profitability, as a result of which our stock price could decline substantially.

Business interruptions could adversely affect future operations, revenues, and financial conditions, and might increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Operating as a virtual company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations might be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it might cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we will rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events as those described previously relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or misappropriation or disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our lead product candidate could be delayed or altogether terminated.

Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition or results of operations.

Our strategy for the development and commercialization of our proprietary product candidates might include the formation of collaborative arrangements with third parties. We have entered into a number of agreements with third parties as described elsewhere in this document. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and might not perform their obligations as expected. Potential third party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions, government agencies and other entities. Third party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we might be required to undertake product development and commercialization at our own expense. Such an undertaking might limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties might subject us to a number of risks. If we fail to comply with our obligations under these agreements, of if one or more third parties allege that we fail to comply, then one or more third parties might terminate the agreements. In this event, we might not be able to develop, manufacture or market our product candidates. This would materially adversely affect our business prospects.

These agreements might not be on terms that prove favorable to us and might require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a particular territory, research area, or therapeutic field of use, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators might lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

In addition, our agreements might not be assignable by us without the consent of the respective other party or parties, which might limit or delay our ability to consummate transactions, adversely impact the value of those transactions, or limit our ability to pursue research, development or other activities.

We might be subject to claims by third parties asserting that our employees, consultants, collaborators contractors or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Our employees, consultants, collaborators or contractors have been previously employed at universities or third-party pharmaceutical companies, including our actual or possible competitors, and received confidential and proprietary information from them. Although we try to ensure that our employees, consultants, collaborators or contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees, consultants, collaborators or contractors, or we, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any former employer. We might also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. We might not be successful in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and reputational loss and be a distraction to our business.

In addition, while it is our policy to require our employees, consultants, collaborators and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we might be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Such assignment agreements might not be self-executing or may be breached, and we might be forced to bring claims against third parties or defend claims that third parties might bring against us, to determine the ownership of what we regard as our intellectual property.

The financial results of our Liora LiGHT system business may be unpredictable and if our proton therapy customers are unsuccessful, our financial results will be adversely affected.

The success of our Liora LiGHT system business will depend upon widespread awareness, acceptance and adoption by the oncology market of proton therapy systems for the treatment of cancer. This technology is expensive and has not been widely adopted. Future developments may not be adopted as quickly as technological developments in more traditional areas of radiation therapy.

Our estimates as to future operating results include certain assumptions about the future results of Liora LiGHT system' business. If we are incorrect in our assumptions, our financial results could be materially and adversely affected. It is possible that Liora LiGHT system could perform significantly below our expectations due to a number of factors that cannot be predicted with certainty, including future market conditions, market acceptance of proton therapy and reimbursement rates. These factors could adversely impact Liora LiGHT system's ability to meet its projected results.

Our Liora LiGHT system business may subject us to increased liability.

Our Liora LiGHT system's business may subject us to increased liability. For example, because proton therapy projects are large in scale and require detailed project planning, failure to deliver or delays in delivering on our commitments could result in greater than expected liabilities, as we could be required to indemnify business partners and customers for losses suffered or incurred if we are unable to deliver our products in accordance with the terms of customer contracts. Additionally, customers have in the past requested and may in the future request that the systems vendor, as the primary technology provider, provide guarantees for and suffer penalties in relation to the overall construction project. Since the cost of a proton therapy center project is typically between $25 million and $200 million, the amount of potential liability and potential for financial loss would likely be higher than the levels historically assumed by us for our traditional radiation therapy business and may also exceed the project's value. Insurance covering these contingencies may be unobtainable or expensive. If we cannot reasonably mitigate or eliminate these contingencies or risks, our ability to competitively bid upon proton center projects will be negatively impacted or we may be required to assume material amounts of potential liability, all of which may have adverse consequences to us.

Risks Related to Our Intellectual Property

We cannot be certain we will be able to obtain patent protection to protect our product candidates and technology.

Our patents and patent applications are owned solely by our wholly owned subsidiary, Lixte Biotechnology, Inc., except in several instances where they are jointly owned with one of our collaborators.

The patent prosecution process is expensive and time-consuming, and we might not be able to file or prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research or development before it is too late to obtain patent protection. Therefore, these patents and applications might not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries might not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our solely owned or jointly owned patents or pending patent applications, or that we were the first inventors to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications might not result in patents being issued that protect our technology or products, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Changes in the patent laws or their interpretation by courts or patent offices might diminish the value of our patents or patent applications or narrow their scope.

The issuance of a patent is not conclusive as to its inventorship, scope, term, validity or enforceability, and our solely or jointly owned patents might be challenged in a U.S. or non-U.S. court or patent office. Such challenges might result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for research, development, testing or regulatory review of product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved or commercialized. As a result, our solely or jointly owned patents might not provide us with sufficient rights to exclude others from commercializing intended products similar or identical to ours.

We cannot be certain that all patents applied for will be issued. If a third party has also filed a patent application relating to an invention claimed by us, solely or jointly with one of our collaborators, we might be required to participate in an interference or derivation proceeding declared or instituted by the United States Patent and Trademark Office, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future protection for our proprietary rights is uncertain. For example:

- we, solely or jointly with our collaborators, might not have been the first to make the inventions covered by our pending or future patent applications;
- we, solely or jointly with our collaborators, might not have been the first to file patent applications for these inventions;
- others might independently develop identical, similar or alternative technologies;
- it is possible that our patent applications will not result in an issued patent or patents, or that the scope of protection granted by any patents arising from our patent applications will be significantly narrower than expected;
- we might be unaware of prior art that renders one or more of our patent applications unpatentable or one or more of our patents invalid;
- a court might determine that we failed to disclose to a patent office prior art that we were aware of and that is material to patentability and, therefore, conclude that one or more of our patents are unenforceable;
- any patents under which we hold rights might not cover commercially viable products, might not provide us with any competitive advantages or might be challenged by one or more third parties as being not infringed, being invalid, or being unenforceable under United States or foreign laws;
- a court or patent office might determine that two or more of our patents claim patentably indistinct subject matter, which could adversely affect one or more of the patents' term, validity or enforceability;
- a court or patent office might determine that one or more patents issued to us in the future or under which we hold rights are invalid or unenforceable; or
- we might develop additional proprietary technologies that are not patentable and which might not be adequately protected through trade secrets or know-how.

In addition, we solely or jointly own patents or patent applications in jurisdictions having, or that might in the future have, geopolitical disputes, including over sovereignty. We cannot guarantee that patents granted in these jurisdictions will be enforceable. An inability to enforce patents in these jurisdictions could have a material adverse effect on our business.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act or in foreign countries under similar legislation, our business might be materially harmed.

In the United States, the term of a patent that covers an FDA-approved drug, its method for use or method for manufacture, can be eligible for patent term extension. U.S. law provides a patent term extension of up to five years beyond the expiration of the patent for time during which the drug is under regulatory review. Patent term extension cannot extend the term of a patent beyond a total of 14 years from the date of regulatory approval; only one patent can be extended for the same regulatory review period; and the scope of a patent's enforceability during a patent term extension is limited to the scope of FDA approval. There is no guarantee that the relevant agencies, including the United States Patent and Trademark Office ("USPTO"), will agree with our assessment of whether such extensions should be granted, and even if granted, the term of these extensions. We might not be granted patent term extension in the United States or in any foreign country because of, for example, expiration of our patents before obtaining regulatory approval, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of a patent term extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or if the term of any such extension is less than we request, our competitors might obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of our product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought.

If we fail to comply with our obligations in agreements under which we have licensed or, might license, intellectual property rights from third parties, or if we otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We have entered into, and might in the future enter into, one or more intellectual property license agreements that are important to our business. These license agreements might impose various diligence, milestone payment, royalty and other obligations on us. For example, we might be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products and might need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we might be subject to termination of the license agreement in whole or in part, increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes might arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether our technology, product candidates or processes infringe intellectual property rights that are owned by the licensor, but that are not subject to the licensing agreement;
- our diligence obligations under the license agreement and the activities that satisfy those obligations;
- whether we are required to sublicense to a third-party rights that the license grants to us, but that we do not commercially pursue; and
- the ownership of inventions, data and know-how resulting from joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed, or might in the future license, prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop or commercialize the affected product candidates.

We might need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a commercially reasonable cost or on commercially reasonable terms, if at all. Other companies might have a competitive advantage over us due to their larger size or cash resources or greater clinical development and commercialization capabilities. We might be unable to further develop or commercialize one or more of our product candidates, which could harm our business significantly.

We might infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increasing the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our intended products or our product candidates, or manufacture or use of our intended products or our product candidates, will not infringe third party patents. Furthermore, a third party might claim that we are using without permission one or more inventions covered by the third party's patent rights and might go to court to stop us from engaging in our normal operations and activities, including making, offering to sell or selling our product candidates. Still further a third party might go to court seeking judgment that our patents are invalid or unenforceable. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties might be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we might not have a viable way around the patent and might need to halt commercialization of the relevant product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. There is also a risk that a court would decide that one or more of our patents are invalid or unenforceable. In addition, we might be obligated to indemnify our licensors and collaborators against intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

We cannot guarantee that we have identified all third-party patents or pending patent applications that are or might be necessary for the commercialization of our intended products and technologies in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our technologies and intended products could have been filed by others without our knowledge.

Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies or intended products. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our intended products. We might incorrectly determine that our technologies or intended products are not covered by a third-party patent or might incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant might be incorrect, and we might incorrectly conclude that a third-party patent does not cover our technology or intended products, is invalid or is unenforceable. Our inability to identify or correctly interpret relevant patents might negatively impact our ability to develop or market our technologies or intended products. If we fail to identify or correctly interpret relevant patents, we might be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being liable for damages, we might be temporarily or permanently enjoined or otherwise prohibited from commercializing any of technologies or intended products that are held to be infringing. We might, if possible, also be forced to redesign intended products or product formulations so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

As the pharmaceutical or biotechnology industry expands and more patents are issued, the risk increases that our product candidates or intended products give rise to claims of infringement of the patent rights of others. There may be third party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, negotiate and obtain a license under reasonable terms to us or discontinue performing the allegedly infringing activities. We might not be able to do any of these. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we might incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we might be required to seek a license, which might not be available, and then we will have to defend an infringement action, challenge the validity of the patents in the USPTO or in court, or discontinue performing the allegedly infringing activities. Patent litigation is costly and time consuming. We might not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or fail to have infringed patents declared invalid or unenforceable, we might incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, that we were the first to invent the technology or that we were the first to file patent applications covering our technology, because:

- some patent applications in the United States are maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after their earliest claimed priority date; and
- publications in scientific literature often lag behind actual discoveries.

Our competitors might have filed, and might in the future file, patent applications covering technology similar or identical to ours. Any such patent applications might dominate our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed US patent applications that cover inventions similar or identical to ours and claim priority to any applications filed prior to the priority dates of our applications, we might have to participate in an interference proceeding declared or a derivation proceed instituted by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar inventions before us, possibly resulting in a loss of our U.S. patent position with respect to such inventions. Other countries might have similar laws that permit secrecy of patent applications. Either way, the third party's patents or patent applications might be entitled to priority over our applications in such jurisdictions.

Some of our competitors might be able to sustain the costs of a patent challenge more effectively than we can because they have substantially greater resources. In addition, uncertainties regarding the outcome of the challenge could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

We might be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of one or more third parties.

As is common in the biotechnology and pharmaceutical industries, we employ, and might employ in the future, individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we might be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation might be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property might not be sufficient to protect our intended products from competition, which might negatively affect our business as well as limit our partnership or acquisition appeal.

We might be subject to competition despite the existence of intellectual property we license or own. We can give no assurance that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, any actual or perceived limitations, in our intellectual property might lessen the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our intended products or future products.

Our approach includes filing patent applications covering combination therapy with known, studied and/or marketed drugs. Although the protection afforded by our patent applications might be significant, when looking at our patents' ability to block competition, the protection offered by our patents might be, to some extent, more limited than protection provided by patents claiming a composition of matter that is entirely new and previously unknown. If a competitor were able to successfully design around any combination therapy patents we have or might have in the future, our business and competitive advantage could be significantly affected.

We might elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license. We might alternatively elect to sue a third party, or otherwise make a claim, alleging that we don't infringe a third party's patents or that the third party's patents are invalid or unenforceable. Any claims that we assert against a third party could provoke the third party to assert one or more counterclaims against us, for example, alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court might decide that a patent of ours is invalid or unenforceable, in whole or in part; construe the patent's claims narrowly; or refuse to stop the other party from using the technology at issue. Any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Even if we prevail in a lawsuit, a court might not award remedies that sufficiently compensate us for our losses.

If we do not prevail in either type of litigation, we might be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that might have a significant adverse effect on our intended-product pricing, market share, business operations, financial condition, and the commercial viability of our intended products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trials, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party might also challenge the validity, enforceability or scope of the intellectual property rights that we license or own, and the result of these challenges might narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, among other factors.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in non-U.S. jurisdictions. The legal systems of some countries are less supportive of enforcement of patents, trade secrets and other intellectual property protection, than the United States. This could make it difficult for us to enforce our patents or market competing products outside the United States, in violation of our proprietary rights generally. Proceedings to enforce our patent rights in non-U.S. jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We might not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, might not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights in all jurisdictions where we have the rights might be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we seek to protect our intellectual property rights in significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we might wish to market our intended products or our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries might be inadequate, which might have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights might be diminished, and we might face additional competition from others in those jurisdictions.

Changes to patent law, for example the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation in the U.S., might substantially change the regulations and procedures surrounding patent applications, issuance of patents, prosecution of patents, challenges to patent validity, and patent enforcement. We can give no assurance that our patents or those of our licensor(s) can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document-submission, fee-payment and other requirements imposed by the U.S. Patent and Trademark Office and courts, and foreign government patent agencies and courts, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some jurisdictions outside the United States can be less extensive than those in the United States. And filing, prosecuting and defending patents even in only those jurisdictions in which we develop or commercialize our product candidates might be prohibitively expensive or impractical. Competitors might use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or technologies and, further, may export otherwise infringing products or technologies to territories where we and have patent protection, but where enforcement is not as strong as that in the United States. These third-party products or technologies might compete with our product candidates, and our intellectual property rights may not be effective or sufficient to prevent third parties from competing.

In addition, we might decide to abandon national or regional patent applications while they are still pending or to abandon granted patents. This might invite or encourage third parties to develop their products or technologies in jurisdictions where we abandon patent applications or patents.

If we are not able to protect and control our unpatented trade secrets, know-how and other technological innovations, we might suffer competitive harm.

We also rely on proprietary trade secrets and unpatented know-how to protect our research and development activities, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We will attempt to protect our trade secrets and unpatented know-how by requiring our employees, consultants, collaborators, and advisors to execute a confidentiality and non-use agreement. We cannot guarantee that these agreements will provide meaningful protection; that these agreements will not be breached, by, e.g., a misappropriating or disclosing our confidential information; that we will have an adequate remedy for any such breach; or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, and those of our present or future collaborators that we utilize by agreement, might become known or might be independently discovered by others, which could adversely affect the competitive position of our product candidates.

We might incur substantial costs prosecuting our patent applications, maintaining our patents and patent applications, enforcing our patents, defending against third party patent infringement suits, seeking invalidation of third-party patents or in-licensing third party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We might be unaware of or unfamiliar with prior art and/or interpretations of prior art that could potentially impact the validity or scope of our patents or pending patent applications, or patent applications that we will file. We might have elected, or elect now or in the future, not to maintain or pursue intellectual property rights that, at some point in time, might be considered relevant to or enforceable against a competitor.

We take efforts and enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership of and chain of title in intellectual property rights. However, an inventorship or ownership dispute could arise that might permit one or more third parties to practice our intellectual property rights, including possible efforts to enforce rights against us.

We might not have rights under some patents or patent applications that cover technologies that we use in our research, drug targets that we select, product candidates and particular uses thereof that we seek to develop and commercialize, as well as synthesis of our product candidates. Third parties might own or control these patents and patent applications in the United States and elsewhere. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore might choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses might not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights might be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product or product candidate or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

Periodic maintenance fees on issued U.S. patents are due to be paid to the USPTO, and periodic maintenance fees on issued non-U.S. patents and pending non-U.S. patent applications are due to be paid to non-U.S. patent offices. Patent offices require compliance with many procedural, documentary, fee payment and other requirements during the patent application process and after a patent issues or grants. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance, for example, caused by geopolitical events such as civil or political unrest (including the ongoing conflict between Ukraine and Russia), can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to patent office actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, a foreign filing license is required before certain patent applications are filed outside that country. The foreign filing license requirements can vary by country. In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

There has been substantial litigation and other legal proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference or derivation proceeding declared or instituted before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our intended products, our product candidates and our technology, it is possible that we might become one in the future. We are not currently aware of any actual or reasonably foreseeable third-party infringement claim involving our product candidates. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the dispute forum, demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical and biotechnology related patent cases that might turn on the testimony of experts as to technical facts upon which experts might reasonably disagree. Some of our competitors might be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we might be encouraged by researching, developing, manufacturing or commercializing our intended products or our product candidates without a license from the other party and we might be held liable for significant damages. We might not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation or other proceedings might also absorb significant management time.

If we are unable to protect our intellectual property rights, our competitors might develop and market products with similar or identical features that might reduce demand for our potential products.

The following factors are important to our success:

- receiving patent protection for our product candidates;
- preventing others from infringing our intellectual property rights; and
- maintaining our patent rights and trade secrets.

We will be able to protect our intellectual property rights in patents and trade secrets from unauthorized use by third parties only to the extent that such intellectual property rights are covered by valid and enforceable patents or are effectively maintained as trade secrets and we enforce these rights.

Because issues of patentability involve complex legal and factual questions, the issuance, scope or enforceability of patents cannot be predicted with certainty. Patents can be challenged, invalidated, found unenforceable, or circumvented. United States patents and patent applications can be subject to interference or derivation proceedings. United States patents can also be subject to post grant proceedings, including re-examination, derivation, *Inter Partes* Review and Post Grant Review, in the United States Patent and Trademark Office. Foreign patents can be subject to opposition or comparable proceedings in corresponding foreign patent offices. Any of these challenges might result in loss of the patent, rejection of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, these proceedings can be costly. Thus, any patents that we own or license from others might not provide any protection against competitors. Furthermore, an adverse decision in an interference or derivation proceeding can result in a third party receiving the patent rights sought by us, which in turn could affect our ability to market a potential product to which that patent filing was directed. Our pending patent applications, those that we might file in the future, or those that we might license from third parties might not result in patents being issued. If issued, they might not provide us with proprietary protection or competitive advantages against competitors with similar or identical technology. Furthermore, others might independently develop similar technologies or duplicate any technology that we have developed. Some countries have compulsory licensing laws under which a patent owner might be compelled to grant licenses to third parties. For example, compulsory licenses might be required in cases such as where the patent owner has failed to "work" the invention in that country or where a third party has patented improvements. In addition, some countries might limit the enforceability of patents against government agencies or government contractors. In these countries, we might have limited infringement remedies, which could materially diminish the value of our patents. Moreover, the legal systems of some countries are less supportive of enforcement of patents, trade secrets and other intellectual property protection, than the United States, which might make it difficult to stop infringement in these countries.

In addition, our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise or otherwise promote the compounds that are used in their products. Any litigation to enforce or defend our patent rights, even if we prevail, could be costly and time-consuming and would divert the attention of management and key personnel from business operations.

We will also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We will seek to protect this information by entering into confidentiality agreements with parties that have access to it, such as strategic partners, collaborators, employees, contractors and consultants. Any of these parties might breach these agreements and misappropriate or disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Commercialization of Our Current Product Candidate and Future Product Candidates

Our commercial success depends upon attaining significant market acceptance of our current product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and cancer treatment centers.

Even if we obtain regulatory approval for our lead product candidate or any future product candidates, the products might not gain market acceptance among physicians, healthcare payors, patients or the medical community, including cancer treatment centers. Market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;

- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major cancer treatment centers and patients of the drug as safe and effective treatment;
- the adoption of novel immunotherapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including our use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our intended product as well as competitive products;
- the development of manufacturing and distribution processes for commercial scale manufacturing for our lead product candidate and any future product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from third party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If our lead product candidate and any future product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or cancer treatment centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our lead product candidate or any future product candidates, the products might not receive coverage or adequate reimbursement from third party payors in the United States and in other countries in which we seek to commercialize our intended products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from third party payors, including government health administration authorities, private health insurers and other organizations.

Third party payors determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Third party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third party payors might also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefit and value in specific patient populations before covering our intended product for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement might impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we might not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There might be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage might be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, might also not be sufficient to cover our costs and might only be temporary. Reimbursement rates might vary according to the use of the drug and the clinical setting in which it is used, might be based on reimbursement levels already set for lower cost drugs and might be incorporated into existing payments for other services. Net prices for drugs might be reduced by mandatory discounts or rebates required by third party payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they might be sold at lower prices than in the United States. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third party payors can rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved product that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize our intended product and overall financial condition.

Healthcare legislative measures aimed at reducing healthcare costs might have a material adverse effect on our business and results of operations.

Third party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain international jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our intended product profitably. In particular, in 2010, the Affordable Care Act ("ACA") was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that might be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls might adversely affect:

- the demand for our lead product candidate, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our intended product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that might be adopted in the future, might result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs might result in a similar denial or reduction in payments from private payors, which might prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidate, if approved.

Price controls might be imposed in foreign markets, which might adversely affect our future profitability.

In some countries, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments might further complicate pricing negotiations, and pricing negotiations might continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices.

In some countries, we or our collaborators might be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or authorities might lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our intended product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Our performance depends on successful improvements to our existing products and services, commercialization of new products and services and increasingly on our ability to anticipate emerging trends in oncology diagnosis, treatment and management.

Our Liora LiGHT system products require intensive planning, design, development, testing and capital commitment. Because of the large footprint and high price of many proton therapy systems, there is increasing demand for the development of smaller, more compact proton therapy systems. Although we have introduced our Liora Light machine proton therapy solution, other companies have more experience offering smaller, less expensive proton therapy systems. Our competitiveness will depend on our ability to continue to timely develop new technologies to reduce the size and price of our system or provide additional features and functionality that our competitors do not.

We may need to spend more time and money than anticipated to develop and introduce new products, product enhancements or services. We may not be able to recover all or a meaningful part of our investments. New products may adversely impact orders and sales of our existing products or make them less desirable or even obsolete. In addition, certain costs, including installation and warranty costs, associated with new products may be disproportionately greater than the costs associated with existing products, and if we are unable to lower these costs over time, our operating results could be adversely affected.

Risks Related to Healthcare Compliance Regulations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we might become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third party payors and customers might expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that might constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our intended product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that might affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment might be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of drugs, devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which might apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and might require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices might not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that might apply to us, we might be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they might be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees might engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity might not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we might develop.

We face an inherent risk of product liability exposure related to the testing of our lead product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we might develop. Product liability claims might be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our intended product. If we cannot successfully defend ourselves against claims that our lead product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims might result in:

- decreased demand for any product candidates or products that we might develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we might develop.

Prior to engaging in clinical trials, we obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we might be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we might not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that might arise and such insurance might not be adequate to cover all liabilities that we might incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our lead product candidate in development, but we might be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to our Business Operations

We face substantial competition, which might result in others discovering, developing or commercializing products before or more successfully than we do.

We will face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our lead product candidate. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we might develop. Competition could result in reduced sales and pricing pressure on our lead product candidate, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our lead product candidate could allow our competitors to bring products to market before we do and impair our ability to commercialize our lead product candidate. The biotechnology industry, including the cancer immunotherapy market, is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the United States and worldwide are numerous and include pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors might develop and commercialize products that compete directly with those incorporating our technology or might introduce products to market earlier than our intended product or on a more cost-effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We might face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our lead product candidate could result in our having limited prospects for establishing market share or generating revenue.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result might have a competitive advantage over us. Mergers and acquisitions in the pharmaceutical and biotechnology industries might result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies might also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or potentially advantageous to our business.

As a result of these factors, these competitors might obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our lead product candidate. Our competitors might also develop drugs that are safer, more effective, more widely used and cheaper than ours, and might also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our lead product candidate obsolete or non-competitive before we can recover the expenses of development and commercialization.

Significant disruptions of information technology systems, computer system failures or breaches of information and cyber security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we might contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Our internal computer systems, and those of our CROs, our CMOs, and other business vendors on which we might rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or misappropriation or disclosure of confidential or proprietary information, we could incur liability, the further development of our lead and future product candidates could be delayed and our business could be otherwise adversely affected.

We might need to grow the size of our organization in the future, and we might experience difficulties in managing this growth.

As of March 31, 2026, we had three officer/employees, our Chief Executive Officer, our Chief Financial Officer, and our Chief Scientific Officer. The Company relies to a significant extent on outside consultants and advisors with various technical skills and expertise that the Company can draw on as necessary to conduct its research and development and clinical trial programs. We might need to grow the size of our organization in order to support our continued development and potential commercialization of our lead product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources might increase. Our management, personnel and systems currently in place might not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will likely also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our lead product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

Mr. Pursglove's simultaneous service as our Chief Executive Officer and member of our Board of Directors, and as Chief Executive Officer and member of the Board of Directors of Powell Max Ltd., may create conflicts of interest and may adversely affect management attention, financial reporting and decision-making.

Geordan Pursglove currently serves as our Chief Executive Officer and as a member of our Board of Directors, while also serving as Chief Executive Officer and a director of Powell Max Ltd. ("PMAX"). These dual roles may from time to time create actual or potential conflicts of interest, including with respect to the allocation of Mr. Pursglove's time and attention, the evaluation of strategic, commercial or financing opportunities, relationships with counterparties, the handling of confidential information, compliance with blackout and other securities-law restrictions, and the timing and content of public disclosures. Because Mr. Pursglove serves as our Chief Executive Officer, any reduction in his availability or any required recusal from deliberations involving PMAX could also adversely affect financial management, internal-control oversight, capital-markets activities and the speed of management decision-making. If actual or perceived conflicts of interest are not resolved effectively, or if Mr. Pursglove is unable to devote sufficient time to our business, our business, financial condition, results of operations and stock price could be materially adversely affected.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business might rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations might rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies might also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times for various periods of time, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflationary pressures and interest rate changes, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, between Israel and Gaza, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Future adverse developments with respect to financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plans and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to conduct our business plans on schedule and on budget.

Risks Related to Owning our Securities

Provisions of certain warrants could discourage a change-in control transaction involving a third party.

Some of our warrants contain provisions that could make it more difficult or expensive for a third party to make an investment in us acquire us in a change-in-control transaction. Under certain transactions constituting a “fundamental transaction”, the Company could be required to redeem the warrants for a cash payment calculated pursuant to the Black-Scholes option-pricing model. These and other provisions of the warrants could prevent or deter a third party from acquiring us or investing in us in a change-in control transaction, even where the acquisition could be beneficial to you.

The following warrants issued by the Company and outstanding at December 31, 2025, contain a “fundamental transaction” provision whereby in the event of a fundamental transaction (including a sale or transfer of assets or ownership of the Company as defined in the warrant agreement) within the Company’s control, the holder of the unexercised common stock warrants would be entitled to receive, in exchange for extinguishment of the warrants, cash consideration equal to a Black-Scholes valuation, as defined in the warrant agreement. If such fundamental transaction is not within the Company’s control, the warrant holder would only be entitled to receive the same form of consideration (and in the same proportion) as the holders of the Company’s common stock.

Issued	Number of warrants
July 2023	583,334
February 2025	414,784
February 2025	32,609
July 2, 2025	6,355,214
December 22, 2025	1,051,342

In the event of a change in control of the Company or a sale or transfer of all or substantially all of the Company’s assets, as defined, to the extent that the warrants are outstanding at the effective date that such a transaction is closed, this “fundamental transaction” provision would entitle the holder to substantial cash consideration, thus reducing the amounts to be retained by the Company or potentially distributable to the Company’s stockholders.

Our management has broad discretion over the use of the proceeds from any stock offerings we may conduct in the future and we may apply it to uses that do not improve our operating results or the value of our common stock.

Our management will have broad discretion in the application of the net proceeds from any stock offerings, and investors will be relying solely on the judgment of our management regarding the application of these proceeds. Although we expect to use the net proceeds from an offering for working capital and general corporate purposes, including the ongoing clinical development of our lead compound LB-100, we have not allocated these net proceeds for specific purposes. Investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our business prospects or increase the value of our common stock.

As part of the Company's ongoing process of evaluating various alternatives to obtain the capital required to fund its operations and maintain its listing on Nasdaq, management may decide to consider a wide variety of strategic alternatives, and there can be no assurances that any such transaction, if implemented, would enhance stockholder value, and could be highly dilutive to existing stockholders.

The Company is evaluating various alternatives to obtain the capital required to fund its operations and maintain its listing on Nasdaq, including merger or acquisition opportunities (including reverse mergers) and funding transactions involving a change in control. There can be no assurances that the evaluation process will result in the identification of an appropriate transaction, the negotiation and execution of a definitive agreement to effect such a transaction, or that any such transaction will ultimately be approved by the Company's stockholders and then be consummated. Depending on various factors, many of which are outside the control of the Company, our failure to enter into and consummate a strategic transaction could have a material adverse effect on our ability to continue to operate and finance our business, and on the market price of our common stock. Even if such a strategic transaction is consummated, there can be no assurances that it will enhance stockholder value, and it may result in substantial dilution to existing stockholders. Any potential transaction would be dependent on a number of factors that may be outside of our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with the Company, and the availability of appropriate financing for such a transaction. If we are unable to raise the required capital to fund our operations, or to enter into a strategic transaction in the near future, we may need to curtail or cease operations, which could result in a total loss of stockholders' investment.

The price of our common stock might fluctuate substantially.

You should consider an investment in our common stock to be risky. Some factors that might cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors," are:

- sale of our common stock by our stockholders, executives, and directors and our stockholders;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our lead product candidate or any future clinical trials we might conduct;
- changes in the development status of our lead product candidate;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our lead product candidate;
- unanticipated safety concerns related to the use of our lead product candidate;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that might emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;

- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which might be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and might expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Risks Related to the Company's Common Stock

Nasdaq Compliance.

The Company's common stock are traded on The Nasdaq Capital Market under the symbols "LIXT".

On June 2, 2023, the Company effected a 1-for-10 reverse split of its outstanding shares of common stock in order to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq. However, there can be no assurances that the Company will be able to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq over time. In addition, Nasdaq has other continued listing requirements, one of which is maintaining a minimum net stockholders' equity of $2,500,000.

On August 23, 2024, the Company received a letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") on August 19, 2024 indicating that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b) (the "Stockholders' Equity Requirement").

On October 3, 2024, the Company submitted a plan to the Staff to regain compliance with the Stockholders' Equity Requirement, which outlined the Company's proposed initiatives to regain compliance by raising equity capital through various registered equity offerings.

On October 21, 2024, the Staff provided notice (the "Notice") to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement, which required that the Company complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Requirement through filing a Current Report on Form 8-K with the Securities and Exchange Commission (the "SEC") providing certain required information.

As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. Accordingly, on February 19, 2025, the Company received a Staff determination letter from the Staff stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance.

The Company did not meet the terms of the extension and, on February 19, 2025, received a Staff determination letter. The Company timely requested a hearing before the Nasdaq Hearings Panel, staying any suspension or delisting pending the Panel's decision.

Following an April 3, 2025 hearing, the Panel granted the Company a further extension through July 3, 2025 to regain compliance.

On July 2, 2025, the Company closed a $5.05 million private placement and, on July 8, 2025, completed a $1.5 million registered direct offering (see Note 6). On July 15, 2025, Nasdaq notified the Company that it had regained compliance with the stockholders' equity requirement.

The Company remains subject to a Panel Monitor under Nasdaq Listing Rule 5815(d)(4)(B) through July 15, 2026. During this period, any future deficiency in stockholders' equity would require the Company to request a hearing before the Panel rather than submit a new compliance plan.

A sale or perceived sale of a substantial number of shares of our common stock might cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to short our common stock. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Market and economic conditions might negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy might be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it might make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume might decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage might adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and might also impair our ability to expand our business with existing customers and attract new customers.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

In the future, we will need to issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our stockholders. We may also issue additional common stock, warrants or other securities that are convertible into or exercisable for common stock in connection with future mergers or acquisitions, future sales of securities for capital raising purposes, or for other business purposes, in one or more transactions at prices and in a manner that we determine from time to time. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurances that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, and the new investors could gain rights superior to our existing stockholders in any such transactions.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We might be at risk of securities class action litigation.

We might be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Our Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law might have anti-takeover effects that could discourage, delay or prevent a change in control, which might cause our stock price to decline.

Our Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10,000,000 shares of preferred stock. This preferred stock might be issued in one or more series, the terms of which might be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock might include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions might also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the Board of Directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the Board of Directors might be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company". In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we might fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under Sarbanes-Oxley related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we might not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information and email systems that may result in adverse effects on the confidentiality, integrity, or availability of our information and email systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we intend to take any steps necessary to redesign, implement, and maintain reasonable safeguards to minimize identified risks; to reasonably address any identified gaps in existing safeguards; and to regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with an IT consultant, who reports to our Chief Executive Officer and Chief Financial Officer, to manage the risk assessment and mitigation process. As part of our overall risk management system, we monitor and periodically evaluate our safeguards.

We may engage consultants, or other third parties in connection with our risk assessment processes. These service providers can assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards.

To date, we have not encountered cybersecurity challenges that have materially impaired our operations or financial condition. Additional information regarding risks from cybersecurity threats is provided at "Item 1A. Risk Factors".

Governance

One of the functions of our Board of Directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our Board of Directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks that we face. Our Board of Directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our Chief Executive Officer and Chief Financial Officer are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Chief Executive Officer and Chief Financial Officer interact with our IT consultant and oversee our cybersecurity policies and processes, including those described above at "Risk Management and Strategy". The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our Chief Executive Officer and Chief Financial Officer provide periodic briefings to the audit committee regarding the Company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and similar issues.

ITEM 2. PROPERTIES

We do not own any real property.

As a part of the asset acquisition that we completed on November 21,2025 with Liora Technologies Europe Ltd, we assumed a lease with United Kingdom Research and Innovation ("UKRI") for Part of the Tower at Daresbury Laboratory, Daresbury Cheshire within ground and first floor as part of the Department for Science, Innovation and Technology whose principal office is at Polaris House, North Star Avenue, Swindon SN2 1FL.

We believe that our facilities are generally in good condition and suitable to operate our business.

ITEM 3. LEGAL PROCEEDINGS

On November 19, 2025, the Company received a written demand from FX Group Inc. and certain related parties ("FX"), asserting that FX was entitled to consulting fees in connection with capital offerings completed by the Company during June and July 2025. The Company denied the allegations, and negotiations continued after year-end. On January 22, 2026, the Company entered into a settlement agreement, under which the Company agreed to pay a one-time settlement amount of $100,000 to FX in exchange for mutual releases of all claims. As of December 31, 2025, management recorded an accrual of $100,000 for the settlement expense.

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of December 31, 2025 and 2024, the Company was not subject to any other threatened or pending lawsuits, legal claims or legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

The Company's common stock has traded on The Nasdaq Capital Market under the symbol "LIXT" and "LIXTW", respectively, since November 25, 2020. The stock market in general has experienced significant price fluctuations in the past few years. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies have experienced dramatic volatility in the market prices of their common stock. The Company believes that a number of factors, both within and outside its control, could cause the price of the Company's common stock to fluctuate, perhaps substantially.

The following table sets forth the range of reported closing prices of the Company's common stock during the periods presented. Such quotations reflect prices between dealers in securities and do not include any retail mark-up, markdown, or commissions, and may not necessarily represent actual transactions.

	Low	High
Year Ended December 31, 2024		
First Quarter	$ 1.73	$ 3.52
Second Quarter	$ 2.11	$ 3.70
Third Quarter	$ 1.65	$ 2.53
Fourth Quarter	$ 1.31	$ 2.38

	Low	High
Year Ended December 31, 2025		
First Quarter	$ 1.02	$ 3.00
Second Quarter	$ 0.64	$ 1.62
Third Quarter	$ 0.90	$ 6.08
Fourth Quarter	$ 3.50	$ 5.53

Holders

As of December 31, 2025, the Company had 29 stockholders of record holding 8,790,102 shares of the Company's common stock outstanding, including 7,695,980 shares of common stock held by an indeterminate number of beneficial owners of securities whose shares are held in the names of various depository accounts, brokerage firms and clearing agencies.

Dividends

The Company's dividend policy is determined by its Board of Directors and will depend upon a number of factors, including the Company's financial condition and performance, its cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws and any credit or other contractual arrangements may then impose. The Company has not paid any cash dividends on its common stock to date and at the current time the Company does not anticipate paying cash dividend on its common stock in the foreseeable future.

Securities Authorized For Issuance Under Equity Incentive Plans

Set forth in the table below is information regarding awards made through compensation plans or arrangements through December 31, 2025, the most recently completed fiscal year.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted average price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance under compensation plans (excluding securities reflected in column 1) (3)
Equity Compensation Plans Approved by Security Holders	729,309(1)	$ 428.750	2,770,691(2)
Equity Compensation Plans Not Approved by Security Holders	N/A	$ N/A	N/A

(1) Does not include 428,750 shares issuable that were not issued pursuant to a plan.

(2) 2,770,691 shares that remain available are pursuant to the Company's 2020 Stock Incentive Plan, which was adopted on July 14, 2020 and amended on October 7, 2022, November 27, 2023, and on December 8, 2025 (see "ITEM 11. EXECUTIVE COMPENSATION").

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

Overview

The Company is a clinical-stage biopharmaceutical company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company is the majority shareholder of Liora Technologies Europe Ltd., which is pioneering the development of electronically controlled proton therapy systems for treating tumors in various types of cancers. The Company's corporate office is located in Boca Raton, Florida.

The Company's product pipeline is primarily focused on inhibitors of protein phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity.

Liora's proprietary technology, known as LiGHT System (Linac for Image Guided Hadron Therapy), has significant advantages over currently available technologies for treating tumors with proton therapy. Liora is an excellent complement to the pharmaceutical side of the Company's business and ongoing clinical trials with LB-100 for Ovarian Clear Cell Carcinoma and Metastatic Colon Cancer, The Company's strategy for the LiGHT system is to position it as a functional prototype asset (rather than a turnkey clinical system), valued primarily for its intellectual property, accelerator hardware configuration, and accumulated engineering work, without immediate clinical operability. It will be saleable as a functional unlicensed prototype to be copied and licensed at locations closer to large patient populations.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, relies on stock-based compensation for a substantial portion of employee and consultant compensation, and is dependent on periodic access to equity capital to fund its operating requirements.

Recent Significant Developments

Issuance of News Releases

February 25, 2025-

The Company announced that it had added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer.

March 10, 2025 –

The Company announced online publication of new pre-clinical data in BioXriv and International Journal of Pharmaceutics demonstrating how the Company's lead clinical compound, LB-100, is converted into its active form, endothall, a protein phosphatase (PP2A) inhibitor that has been found to be effective in cancer treatment in combination with immunotherapy.

As published in BioXriv, scientists at the Netherlands Cancer Institute have discovered an enzyme that mediates the conversion of LB-100 into the active metabolite endothall. Accordingly, this protein represents a potential biomarker to identify patients who are most likely to respond to LB100. The biomarker discovery study was performed in the laboratories of Professor Rene Bernards, group leader at the Netherlands Cancer Institute and LIXTE board member.

As published in the International Journal of Pharmaceutics, Dr. Hans Rollema and colleagues, medicinal chemists and biochemists at BioPharmaWorks LLC, a consultant to LIXTE, studied how LB-100 can spontaneously convert into the active metabolite endothall by hydrolysis. Their data indicate that this conversion is slow under physiological conditions. The enzymatic conversion of LB-100 identified by the Bernards laboratory expedites the activation of LB-100 inside the cell.

Other Significant Developments:

Effective March 11, 2025, the Company entered into Amendment No. 1 to the Collaboration Agreement between the Company and GEIS that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000, as more fully described below at Principal Commitments – Clinical Trial Agreements - GEIS.

Going Concern

For the year ended December 31, 2025, the Company incurred a net loss of $6,009,520 and used cash in operations of $3,070,618. As of December 31, 2025, the Company had cash of $5,106,872 available to fund its operations. The Company has not generated recurring revenues since inception and has incurred negative operating cash flows as it advances its clinical development programs.

The Company is currently engaged in early-stage clinical trials for its lead product candidate, LB-100. These activities require substantial research, development, regulatory, and clinical expenditures, and the Company does not expect to generate sustainable operating revenues for several years, if ever. At March 31, 2026, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements aggregated approximately $496,000, which are expected to be incurred through December 31, 2027.

In addition, through the acquisition of Liora Technologies Europe Ltd. in November 2025, the Company assumed responsibility for the non-clinical LiGHT proton therapy prototype located at the Daresbury Laboratory in the United Kingdom. The Company expects to incur approximately $2 million over the next twenty-four months to recommission and update the system, together with annual lease obligations of approximately $787,278 under an operating lease with the United Kingdom Research and Innovation. Liora currently has no revenues, and the Company will require additional capital to fund these activities.

Management is actively evaluating and pursuing additional financing alternatives, including equity and debt financings and potential strategic transactions. However, there can be no assurance that additional funding will be available on acceptable terms, in sufficient amounts, or at all. If the Company is unable to obtain the necessary funding, it may be required to delay, scale back, or eliminate its clinical development programs; curtail expenditures related to the LiGHT system; or pursue strategic alternatives, including potential asset sales or the cessation of operations.

As a result, management has concluded, and our independent registered public accounting firm has agreed with our conclusion, that there is a substantial doubt regarding the Company's ability to continue as a going concern for a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. As a result, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2025, includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern.

Nasdaq Compliance

The Company's common stock is traded on the Nasdaq Capital Market under the symbol "LIXT".

On June 2, 2023, the Company effected a 1-for-10 reverse split of its outstanding shares of common stock in order to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq. However, there can be no assurances that the Company will be able to remain in compliance with the $1.00 minimum closing bid price requirement of Nasdaq over time. In addition, Nasdaq has other continued listing requirements, one of which is maintaining a minimum net stockholders' equity of $2,500,000.

On August 23, 2024, the Company received a letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") on August 19, 2024 indicating that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b) (the "Stockholders' Equity Requirement").

On October 3, 2024, the Company submitted a plan to the Staff to regain compliance with the Stockholders' Equity Requirement, which outlined the Company's proposed initiatives to regain compliance by raising equity capital through various registered equity offerings.

On October 21, 2024, the Staff provided notice (the "Notice") to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement, which required that the Company complete its capital raising initiatives and evidence compliance with the Stockholders' Equity Requirement through filing a Current Report on Form 8-K with the Securities and Exchange Commission (the "SEC") providing certain required information.

As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. Accordingly, on February 19, 2025, the Company received a Staff determination letter from the Staff stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance.

The Company did not meet the terms of the extension and, on February 19, 2025, received a Staff determination letter. The Company timely requested a hearing before the Nasdaq Hearings Panel, staying any suspension or delisting pending the Panel's decision.

Following an April 3, 2025 hearing, the Panel granted the Company a further extension through July 3, 2025 to regain compliance.

On July 2, 2025, the Company closed a $5.05 million private placement and, on July 8, 2025, completed a $1.5 million registered direct offering (see Note 5). On July 15, 2025, Nasdaq notified the Company that it had regained compliance with the stockholders' equity requirement.

The Company remains subject to a Panel Monitor under Nasdaq Listing Rule 5815(d)(4)(B) through July 15, 2026. During this period, any future deficiency in stockholders' equity would require the Company to request a hearing before the Panel rather than submit a new compliance plan.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact the Company's consolidated financial statements, including their presentation and related disclosures, is provided in Note 2 to consolidated financial statements included elsewhere in this document.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken, as a whole, under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience, and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. Actual results could differ from those estimates. Significant estimates include those related to assumptions used in the calculation of accruals for clinical trial costs and other potential liabilities, and valuing equity instruments issued for services.

The following critical accounting policies affect the more significant judgements and estimates used in the preparation of the Company's consolidated financial statements.

Asset Acquisitions

The Company assesses whether an acquisition is a business combination or an asset acquisition. If substantially all of the gross assets acquired are concentrated in a single asset or group of similar assets, then the acquisition is accounted for as an asset acquisition, where the purchase consideration is allocated on a relative fair value basis to the assets acquired. An asset acquisition does not result in the recognition of goodwill and transaction costs are capitalized as part of the cost of the asset or group of assets acquired. The Company uses its best estimates and assumptions to assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date. The acquisitions costs are allocated to the assets acquired on a relative fair value basis.

Digital Assets

The Company periodically holds certain digital assets, consisting of Bitcoin and Ethereum cryptocurrencies. Digital assets are initially recorded at cost and subsequently measured at fair value as of each reporting period. The Company determines the fair value of its digital assets in accordance with FASB ASC 820, Fair Value Measurement, based on quoted prices on the active exchange(s) that it has determined is the principal market for Bitcoin and Ethereum (Level 1). Changes in fair value are included in unrealized gain (loss) on digital assets in other income (expense) in the Company's consolidated statements of operations. Realized gains and losses on the sale of digital assets are included in other income (expense) in the Company's consolidated statements of operations. The Company tracks its cost basis of digital assets in accordance with the first-in-first-out method of accounting. The Company's digital assets are reasonably expected to be realized in cash or sold or consumed during the Company's normal operating cycle and as such have been classified as current assets in the Company's consolidated balance sheets.

Property and Equipment

The Company property and equipment consists of Liora's Light machine. Property and equipment are recorded at cost. The Light machine requires recommissioning and updates and is not yet ready for its intended use. Accordingly, it is treated as an asset under construction, and depreciation will not begin until the asset is placed into service.

Long – Lived Assets

Long-lived assets, which include property, plant and equipment and operating lease right-of-use assets, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

Recoverability of long-lived assets to be held and used is measured by comparing the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the assets. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. In conducting its long-lived asset impairment analyses, the Company groups assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluates the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group asset group exceeds its fair value based on discounted cash flow analysis or appraisals. There was no impairment of long-lived assets for the periods ended December 31, 2025 and 2024.

Research and Development

Research and development costs are charged to expense as incurred. The costs of equipment that are acquired or constructed for research and development activities, and have alternative future uses, are classified as property and equipment and depreciated over their estimated useful lives. Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the negotiation, design, development, conduct and management of clinical trials with respect to the Company's clinical compound and product candidate. Research and development costs also include the costs to manufacture compounds used in research and clinical trials, which are charged to operations as incurred. The Company's inventory of LB-100 for clinical use has been manufactured separately in the United States and in the European Union in accordance with the laws and regulations of such jurisdictions.

Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, the termination of an agreement, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Obligations incurred with respect to mandatory scheduled payments under agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the respective agreement. Obligations incurred with respect to mandatory scheduled payments under agreements without milestone provisions are accounted for when due, are recognized ratably over the appropriate period, as specified in the respective agreement.

Payments made pursuant to contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and are then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its various clinical trial and research and development contracts on a quarterly basis.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, employees, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, employees, contractors, and consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date. The expected dividend yield is based on the Company's expectation of dividend payouts and is assumed to be zero.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all of the criteria for equity classification, the warrants are required to be liability-classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each reporting date. Effective November 28, 2025, the Company delisted its public warrants that traded under the symbol "LIXTW". At December 31, 2025 and 2024, the Company did not have any liability-classified warrants.

Summary of Business Activities and Plans

Company Overview

The Company is a clinical-stage biopharmaceutical and proton cancer therapy company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company's product pipeline is primarily focused on inhibitors of protein phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity.

The Company is the majority shareholder of Liora Technologies Europe Ltd., which is pioneering the development of electronically controlled proton therapy systems for treating tumors in various types of cancers. Liora's proprietary technology, known as LiGHT System (Linac for Image Guided Hadron Therapy), has significant advantages over currently available technologies for treating tumors with proton therapy. Liora is an excellent complement to the pharmaceutical side of the Company's business and ongoing clinical trials with LB-100 for Ovarian Clear Cell Carcinoma and Metastatic Colon Cancer,

LB-100

The Company believes that the mechanism by which LB-100 affects cancer cell growth is different from cancer agents currently approved for clinical use. LB-100 is currently being tested in clinical trials in Ovarian Clear Cell Carcinoma, Metastatic Micro Satellite Stable (MSS) Colon Cancer, and Advanced Soft Tissue Sarcoma. LB-100 has shown anti-cancer activity in animal models of glioblastoma multiforme, neuroblastoma, and medulloblastoma, all cancers of neural tissue. LB-100 has also been shown to enhance the effectiveness of commonly used anti-cancer drugs in animal models of melanoma, breast cancer and sarcoma. The enhancement of anti-cancer activity of these anti-cancer drugs occurs at doses of LB-100 that do not significantly increase toxicity in animals. It is therefore hoped that, when combined with standard anti-cancer regimens against many tumor types, LB-100 will improve therapeutic benefit.

As a compound moves through the FDA-approval process, it becomes an increasingly valuable property, but at a cost of additional investment at each stage. As the potential effectiveness of LB-100 has been documented at the clinical trial level, the Company has allocated resources to expand the breadth and depth of its patent portfolio. The Company's approach has been to operate with a minimum of overhead, moving compounds forward as efficiently and inexpensively as possible, and to raise funds to support each of these stages as certain milestones are reached. The Company's longer-term objective is to secure one or more strategic partnerships or licensing agreements with pharmaceutical companies with major programs in cancer.

LIORA TECHNOLOGIE EUROPE LTD..

The Company's strategy for the LiGHT system is to position it as a functional prototype asset (rather than a turnkey clinical system), valued primarily for its intellectual property, accelerator hardware configuration, and accumulated engineering work, without immediate clinical operability. It will be saleable as a functional unlicensed prototype to be copied and licensed at locations closer to large patient populations.

Specific Risks Associated with the Company's Business Activities

Serious Adverse Events

The Company's lead drug candidate, LB-100, is currently undergoing various clinical trials, and there is a risk that one or more of these trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to the Company's drug candidate or to another company's drug used in combination in one of the Company's clinical trials. It is possible that the SAEs could be attributable to the Company's drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level, that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

If an SAE or a pattern of SAEs is observed during the course of a clinical trial involving the Company's drug candidate, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory authorities may issue a clinical hold, requiring the Company to pause or discontinue further enrollment and dosing in its clinical trial. It is also possible that the clinical trial could be terminated. Any of these actions could delay or halt the development of the Company's drug candidate, increase development costs, and negatively impact the Company's ability to ultimately achieve regulatory approval. Additionally, if an SAE is confirmed to be drug-related, the Company may be required to conduct additional studies, modify the study design, or abandon further development of the drug candidate altogether, which could materially impact the Company's business, financial condition, and prospects.

The occurrence of an SAE and any resulting clinical hold could also harm the Company's reputation with patients, physicians, health institutions, and investors, diminish its ability to attract clinical trial participants, and damage its ability to interest investors and obtain financing in the future. There can be no assurance that the Company will not experience such SAEs in the future or that any related clinical hold will be lifted in a timely manner, or at all.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. The Institutional Review Board (the "IRB") of the Netherlands Cancer Institute ("NKI") has put the colorectal cancer study on hold. The adverse reactions that developed in the two patients were dyspnea (shortness of breath) due to lung toxicity possibly or probably related to the combination of LB-100 and atezolizumab in one patient and fever and aphasia possibly or probably related to the combination of LB-100 and atezolizumab in the second patient. The patient who developed lung toxicity deceased due to the combination of lung metastases of colorectal cancer and dyspnea. The patient with fever and aphasia fully recovered from the adverse events with supportive medication.

Given the identified adverse events in the two patients in the clinical trial, the IRB requested from the principal investigator of the study at the NKI information as to whether the adverse events could have been caused by the combination of LB-100 and atezolizumab and information about the mode of action of the combination of LB-100 and atezolizumab. The principal investigator has prepared a response to the IRB detailing the safety experience with LB-100 given alone and in combination with other cancer drugs, especially doxorubicin and dostarlimab. Doxorubicin is a well-known chemotherapy, and dostarlimab is a well-known immunotherapy of which the mode of action is closely related to that of atezolizumab.

The reported adverse events in the colorectal cancer study have not been seen in any other patients thus far treated with LB-100 alone or in combination with other cancer drugs. Through February 2025, a total of 78 patient have received or are receiving experimental treatment with LB-100. The investigators have completed the IRB review in Q4 2025 and the trial is open again for enrolment Q1 2026.

External Risks Associated with the Company's Business Activities

Inflation and Interest Rate Risk. The Company does not believe that inflation or increasing interest rates have had a material effect on its operations to date, other than their impact on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary and interest rate pressures in the future, which would have the effect of increasing the Company's operating costs (including, specifically, clinical trial costs), and which would put additional stress on the Company's working capital resources.

Supply Chain Issues. The Company does not currently expect that supply chain issues will have a significant impact on its business activities, including its ongoing clinical trials in the US. Our current batch of LB-100 in Europe expires by European Law after 5 years, which will be Q4 2026. We are looking to extend the shelf life with an additional 12 months until Q4 2027. If we do not manage to extend the shelf life or are not able to manufacture a new batch we might not be able to complete the enrollment in the Colon Cancer Trail at the NKI.

Potential Recession. There are some indications that the United States economy may be at risk of entering a recessionary period. Although unclear at this time, an economic recession would likely impact the general business environment and the capital markets, which could, in turn, affect the Company.

Geopolitical Risk. The geopolitical landscape poses inherent risks that could significantly impact the operations and financial performance of the Company. In the event of a military conflict, supply chain disruptions, geopolitical uncertainties, and economic repercussions may adversely affect the Company's ability to conduct research, develop, test and manufacture products, and distribute them globally. This could lead to delays in product development, interruptions in the supply of critical materials, and delays in clinical trials, thereby impeding the Company's clinical development and commercialization plans. Furthermore, the impact of a conflict on global financial markets may result in increased volatility and uncertainty in the capital markets, thereby affecting the valuation of the Company's publicly-traded shares. Investor confidence, market sentiment, and access to capital could all be negatively influenced. Such geopolitical risks are outside the control of the Company, and the actual effects on the Company's business, financial condition and results of operations may differ from current estimates.

Cybersecurity Risks. The Company has established policies and processes for assessing, identifying and managing material risk from cybersecurity threats, and has integrated these processes into its overall risk management systems and processes. The Company routinely assesses material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through its information and email systems that may result in adverse effects on the confidentiality, integrity, or availability of the Company's information and email systems or any information residing therein. The Company conducts periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in the Company's business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems and safeguards in place to manage such risks. The Company has not encountered any cybersecurity challenges to date that have materially impaired its operations or financial condition.

The Company is continuing to monitor these matters and will adjust its current business and financing plans as more information becomes available.

Results of Operations

At December 31, 2025, the Company had not yet commenced any revenue-generating operations, does not have any positive cash flows from operations, and is dependent on its ability to raise equity capital to fund its operating requirements.

The Company's consolidated statements of operations as discussed herein are presented below.

	Years Ended December 31,	
	2025	2024
Revenues	$ —	$ —
Costs and expenses:		
General and administrative costs	4,852,702	2,846,557
Research and development costs	254,919	726,232
Total costs and expenses	5,107,621	3,572,789
Loss from operations	(5,107,621)	(3,572,789)
Interest income	7,388	7,048
Interest expense	(9,158)	(16,821)
Realized loss on digital asset	(904,394)	-
Foreign currency gain (loss)	525	(3,403)
Other income	3,740	
Net loss	(6,009,520)	(3,585,965)
Series B convertible	(69,073)	-
Non-controlling interest	-	-
Net loss attributable to common stockholders	$ (6,078,593)	(3,585,965)
Net loss per common share – basic and diluted	$ (1.26)	$ (1.59)
Weighted average common shares outstanding – basic and diluted	4,840,731	2,249,290

Years Ended December 31, 2025 and 2024

Revenues. The Company did not have any revenues for the years ended December 31, 2025 and 2024.

Research and Development Costs. For the years ended December 31, 2025 and December 31, 2024, research and development costs were $254, 919 and $726,232, respectively. These costs consisted of clinical and related oversight costs of $57,193 and $377,958, respectively, regulatory service costs of $9,050 and $18,836, respectively and preclinical research focused on development of additional novel anti-cancer compounds of 188,675 and $329,438, respectively, for the years ended December 31, 2025 and December 31, 2024.

Included in clinical and related oversight costs for the year ended December 31, 2024 is $207,004 for the cost of patients enrolled in the City of Hope clinical trial prior to its termination on July 8, 2024.

Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b/2 clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with metastatic colon cancer. NKI employs Dr. René Bernards, a director of the Company since June 15, 2022 until his resignation from the Board on August 18, 2025. Dr. Bernards was then appointed as Chairman of the Company's Scientific Advisory Committee. The Company has no financial contractual commitment associated with this clinical trial.

Included in preclinical research costs for the years ended December 31, 2024 and 2023 were $210,362 and $226,150, respectively, of costs paid to the Netherlands Cancer Institute, On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam, one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, to identify the most promising drugs to be combined with LB-100, and potential LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with the Netherlands Cancer Institute, which provided for additional research activities, extended the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and added 500,000 Euros to the operating budget being funded by the Company.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year commencing upon the dosing of the first patient in the clinical trial at a project cost of 100,000 Euros (see "Principal Commitments – Other Significant Agreements and Contracts – Netherlands Cancer Institute" below).

Research and development costs decreased by $471,313, or 64.9%, in 2025 as compared to 2024, primarily as a result of a decrease in preclinical research focused on development of additional novel anti-cancer compounds to add to the Company's clinical pipeline of $133,655.

General and Administrative Costs. For the year ended December 31, 2025, general and administrative costs were $4,852,702 which consisted of the fair value of vested stock options issued to directors and officers of $1,527,855 (including quarterly director and board committee fees of $55,000), lease expense of $61,695, patent and licensing legal and filing fees and costs of $112,092, other consulting and professional fees of $1,431,118, insurance expense of $257,478, officer salaries and related costs of $694,827, cash-based director and board committee fees of $27,500, legal settlement of $100,000, licensing and royalties of $30,000, shareholder reporting costs of $68,939, litigation settlement of $100,000, listing fees of $73,000, filing fees of $23,559, investor relations of $372,387, rent of $2,093, and other operating costs of $97,656.

For the year ended December 31, 2024, general and administrative costs were $2,846,557, which consisted of the fair value of vested stock options issued to directors and officers of $418,422 (including quarterly director and board committee fees of $55,000), patent and licensing legal and filing fees and costs of $243,186, other consulting and professional fees of $735,021, insurance expense of $434,444, officer salaries and related costs of $691,244, cash-based director and board committee fees of $38,819, shareholder reporting costs of $41,488, listing fees of $49,500, filing fees of $28,012, investor relations of $59,588, rent of $16,435, conference fees of $14,475 and other operating costs of $45,830, offset by a state franchise tax credits of $45,550.

General and administrative costs increased by $2,006,145, or 70.0%, in 2025 as compared to 2024, primarily as a result of an increase in the fair value of vested stock options issued to directors and officers of $1,054,443, an increase in other consulting and professional fees $696,097, an increase in other costs and expenses of $280,172, offset by decreases in insurance expense of $176,964, decrease in patent and licensing legal and filing fees and costs of $131,094 and decrease in board fees by $11,319.

Interest Income. For the year ended December 31, 2025, the Company had interest income of $7,388, as compared to interest income of $7,048 for the year ended December 31, 2024, related to the investment of the Company's cash resources.

Interest Expense. For the year ended December 31, 2025, the Company had interest expense of $9,158, as compared to interest expense of $16,821 for the year ended December 31, 2024, related to the financing of the premium for the Company's directors and officers liability insurance policy.

Realized loss on digital assets. During the year ended December 31, 2025, the Company recorded a realized loss related to the disposal of certain digital assets (BTC and ETH) that were transferred to Orbit as part of the consideration for the LiGHT equipment acquired in the Liora transaction. This loss reflects the difference between the carrying value of the digital assets and their fair value at the time of transfer.

Foreign Currency Gain (Loss). For the year ended December 31, 2025, the Company had a foreign currency gain of $525, as compared to a foreign currency loss of $3,403 for the year ended December 31, 2024, from foreign currency transactions.

Net Loss. For the year ended December 31, 2025, the Company incurred a net loss of $6,009,520, as compared to a net loss of $3,585,965 for the year ended December 31, 2024.

Liquidity and Capital Resources – December 31, 2025

The Company's consolidated statements of cash flows as discussed herein are as follows:

	Years Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (3,070,618)	$ (3,164,536)
Net cash used in investing activities	(3,172,462)	—
Net cash provided by financing activities	10,311,000	—
Net increase (decrease) in cash	$ 4,067,920	$ (3,164,536)

At December 31, 2025, the Company had working capital of $3,845,268, as compared to working capital of $827,219 at December 31, 2024, reflecting an increase in working capital of $3,018,049 for the year ended December 31, 2025. The increase in working capital during the year ended December 31, 2025 was primarily the result of the Company's completed securities offerings on February 13, July 8, and December 22, 2025 and private placement completed on July 2, 2025 that generated gross proceeds of $10,311,000, net after deducting the placement agent's fees and related offering expenses during 2025.

Going Concern

The Company has no recurring source of revenues and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements through the recurring sale of its equity securities.

As a result, management has concluded, and our independent registered public accounting firm has agreed with our conclusion, that there is a substantial doubt regarding the Company's ability to continue as a going concern for a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. As a result, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2025, includes an explanatory paragraph regarding the existence of substantial doubt about our ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to raise additional equity capital to fund its research and development activities and to ultimately achieve sustainable operating revenues and profitability. The amount and timing of future cash requirements depends on the pace, design, and results of the Company's clinical trial program, which, in turn, depends on the availability of operating capital to fund such activities.

For the year ended December 31, 2025, the Company incurred a net loss of $6,009,520 and used cash in operations of $3,070,618. As of December 31, 2025, the Company had cash of $5,106,872 available to fund its operations. The Company has not generated recurring revenues since inception and has incurred negative operating cash flows as it advances its clinical development programs.

The Company is currently engaged in early-stage clinical trials for its lead product candidate, LB-100. These activities require substantial research, development, regulatory, and clinical expenditures, and the Company does not expect to generate sustainable operating revenues for several years, if ever. At March 31, 2026, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements aggregated approximately $496,000, which are expected to be incurred through December 31, 2027.

In addition, through the acquisition of Liora Technologies Europe Ltd. in November 2025, the Company assumed responsibility for the non-clinical LiGHT proton therapy prototype located at the Daresbury Laboratory in the United Kingdom. The Company expects to incur approximately $2 million over the next twenty-four months to recommission and update the system, together with annual lease obligations of approximately $787,278 under an operating lease with the United Kingdom Research and Innovation. Liora currently has no revenues, and the Company will require additional capital to fund these activities.

Management is actively evaluating and pursuing additional financing alternatives, including equity and debt financings and potential strategic transactions. However, there can be no assurance that additional funding will be available on acceptable terms, in sufficient amounts, or at all. If the Company is unable to obtain the necessary funding, it may be required to delay, scale back, or eliminate its clinical development programs; curtail expenditures related to the LiGHT system; or pursue strategic alternatives, including potential asset sales or the cessation of operations.

The consolidated financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

At December 31, 2025, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Operating Activities. For the year ended December 31, 2025, operating activities utilized cash of $3,070,618, as compared to utilizing cash of $3,164,536 for the year ended December 31, 2024, to fund the Company's ongoing research and development activities and to fund its other ongoing operating expenses, including maintaining and developing its patent portfolio.

Investing Activities. For the year ended December 31, 2025, the Company had investing activities for the cash portion of the purchase of Liora in the amount of $440,000 and purchase of digital assets $2,637,360, that were transferred to the third party seller for the Investment in Liora. In addition, capitalized transaction costs totaled $95,102. For the year ended December 31, 2024, the Company had no investing activities.

Financing Activities. For the year ended December 31, 2025, financing activities consisted primarily of the gross proceeds from the sale of securities in the Company's registered direct offering of $11,900,000, reduced by offering costs of $1,634,801 and $45,801 from the exercise of common stock options.. For the year ended December 31, 2024, the Company had no financing activities.

Principal Commitments

Clinical Trial Agreements

At December 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $496,000, including clinical trial agreements of $293,000 and clinical trial monitoring agreements of $203,000, which, based on current estimates, are currently scheduled to be incurred through approximately December 31, 2027. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data is obtained and analyzed, and is frequently modified, suspended or terminated, in part based on receipt or lack of receipt of an indication of clinical benefit or activity, before the clinical trial endpoint is reached. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions and are typically subject to significant modifications and revisions over time.

Additional information with respect to the conduct of the Company's clinical trial programs is provide at "ITEM 1A. RISK FACTORS - Risks Related to the Development and Regulatory Approval of Our Product Candidates".

The following is a summary of the Company's ongoing contractual clinical trials described below as of December 31, 2025:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Number of Patients in Trial	Study Objective	Clinical Update	Expected Date of Preliminary Efficacy Signal	NCT No.	Remaining Financial Contractual Commitment
LB-100 combined with atezolizumab in microsatellite stable metastatic colorectal cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2026	37	Determine RP2D with atezolizumab	First patient entered August 2024, in total two patients entered	December 2027	NCT06012734	(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Enrollment completed September 2024	9 to 18	Determine MTD and RP2D	Fourteen patients entered	March 2026	NCT05809830	$ 293,000
Doxorubicin with or without LB-100 in advanced soft tissue sarcoma (Randomized Phase 2)	GEIS	TBD	TBD	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	TBD	NCT05809830	$ (1)
LB-100 combined with dostarlimab in ovarian clear cell carcinoma (Phase 1b/2)	MD Anderson	January 2024	December 2027	42	Determine the OS of patients with recurrent ovarian clear cell carcinoma	Twenty one patients entered	December 2027	NCT06065462	(1)
Total									$ 293,000

(1) The Company has no financial contractual commitment associated with this clinical trial at December 31, 2025.

Netherlands Cancer Institute. Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") to conduct a Phase 1b clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with microsatellite stable metastatic colorectal cancer. Under the agreement, the Company will provide its lead compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. The Company has no obligation to and will not provide any reimbursement of clinical trial costs. Pursuant to the agreement and the protocol set forth in the agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The agreement provides for the protection of the respective intellectual property rights of each of the Company, NKI and Roche.

This Phase 1b clinical trial will evaluate safety, optimal dose and preliminary efficacy of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the preliminary efficacy, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial opened in August 2024 with the enrollment of the first patient. A total of two patients have been enrolled to date. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab has completed the investigation into two Serious Adverse Events ("SAEs") observed in the clinical trial (see "Specific Risks Associated with the Company's Business Activities – Serious Adverse Events" above for additional information).

The Company has no financial contractual commitment associated with this clinical trial.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement (the "Agreement") with the City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with an FDA-approved standard regimen for treatment of untreated extensive-stage disease small cell lung cancer ("ED-SCLC"). LB-100 was given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved standard of care regimen, to previously untreated ED-SCLC patients. The LB-100 dose was to be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose ("RP2D"). Patient entry was to be expanded so that a total of 12 patients would be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free survival, and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. Because patient accrual was slower than expected, effective March 6, 2023, the Company and City of Hope added the Sarah Cannon Research Institute ("SCRI"), Nashville, Tennessee, to the ongoing Phase 1b clinical trial. The Company and City of Hope continued efforts to increase patient accrual by adding additional sites and by modifying the protocol to increase the number of patients eligible for the clinical trial. The impact of these efforts to increase patient accrual and to decrease time to completion was evaluated in subsequent quarters.

After evaluating patient accrual through June 30, 2024, the Company and City of Hope agreed to close the clinical trial. Pursuant to the terms of the Agreement, the Company provided notice to City of Hope of the Company's intent to terminate the Agreement effective as of July 8, 2024. Upon closure, the Company incurred a prorated charge of $207,004 for the cost of patients enrolled to date, which is included in accounts payable and accrued expenses at December 31, 2025 and 2024.

During the year ended December 31, 2025 and 2024, the Company incurred costs of $0 and $285,019, respectively, pursuant to this Agreement. As of December 31, 2025, total costs of $732,532 had been incurred pursuant to this Agreement.

GEIS. Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information with respect to the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little improvement in survival from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter approximately 150 to 170 patients in this clinical trial over a period of two to four years. The Phase 1 portion of the study began in the quarter ended June 30, 2023 to determine the recommended Phase 2 dose of the combination of doxorubicin and LB-100. As advanced sarcoma is a very aggressive disease, the design of the Phase 2 portion of the study assumes a median progression-free survival ("PFS"), no evidence of disease progression or death from any cause, of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These standards were adopted subsequent to the production of the Company's existing LB-100 inventory.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks included the synthesis under good manufacturing practice (GMP) of the active pharmaceutical ingredient (API), with documentation of each of the steps involved by an independent auditor. The API was then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product was then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use was submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

As of December 31, 2024, this program to provide new inventory of the clinical drug product for the Spanish Sarcoma Group study, and potentially for subsequent multiple trials within the European Union, had cost approximately $1,144,000.

On October 13, 2022, the Company announced that the Spanish Agency for Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or "AEMPS") had authorized a Phase 1b/randomized Phase 2 study of LB-100, the Company's lead clinical compound, plus doxorubicin, versus doxorubicin alone, the global standard for initial treatment of ASTS. Consequently, this clinical trial commenced during the quarter ended June 30, 2023 and is expected to be completed and a report prepared by December 31, 2026. In April 2023, GEIS completed its first site initiation visit in preparation for the clinical trial at Fundación Jiménez Díaz University Hospital (Madrid). Up to 170 patents will be entered into the clinical trial. The recruitment for the Phase 1b portion of the protocol was extended with two patients and was completed during the quarter ended September 30, 2024. The Company expects to have data on toxicity and preliminary efficacy from this portion of the clinical trial during the quarter ending March 31, 2026.

Given the focus on the combination of LB-100 with immunotherapy in ovarian clear cell carcinoma and colorectal cancer and the availability of capital resources, the Company entered into Amendment No. 1 to the Collaboration Agreement effective March 11, 2025 that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000. As a result, the Phase 2 portion of this clinical trial will not proceed, and the trial will be closed after completion of the first phase in Q1 2026.

The Company's agreement with GEIS provided for various payments based on achieving specific milestones over the term of the agreement. During the years ended December 31, 2025 and 2024, the Company incurred costs of $0 and $268,829, respectively, pursuant to this agreement.

The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $293,000 for the Phase 1b portion of this clinical trial as of December 31, 2025, which is scheduled to be incurred Q1, 2026. As the work is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro. Such fluctuations are recorded in the consolidated statements of operations as foreign currency gain or loss, as appropriate, and have not been significant.

MD Anderson Cancer Center Clinical Trial. On September 20, 2023, the Company announced an investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). The study objective is to determine the overall survival ("OS") of patients with OCCC. The clinical trial is being sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") and is being conducted at The University of Texas - MD Anderson Cancer Center. The Company is providing LB-100 and GSK is providing dostarlimab-gxly and financial support for the clinical trial. On January 29, 2024, the Company announced the entry of the first patient into this clinical trial. The Company currently expects that this clinical trial will be completed by December 31, 2027.

On February 25, 2025, the Company announced that it has added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer. Patient recruitment is underway, and the first patient has been dosed.

On December 23, 2025 we announced that we are going to expand the enrollment of the trial from 21 to 42 patients in collaboration with GSK, MD Anderson and Northwestern University. We completed the enrollment of the first 21 patients in Q4, 2025 and expect patient 22 to be enrolled in Q1 2026.

Clinical Trial Monitoring Agreements

MD Anderson Cancer Center Clinical Trial. On May 15, 2024, the Company signed a letter of intent with Theradex to monitor the MD Andersen investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). On August 19, 2024, the Company signed a work order agreement with Theradex to monitor the MD Anderson clinical trial. The study oversight is expected to be completed by January 31, 2027.

Costs under this letter of intent and related work order agreement are estimated to be approximately $95,000. During the year ended December 31, 2025 and 2024, the Company incurred costs of $21,706 and $26,763, respectively, pursuant to this letter of intent and subsequent work order. As of December 31, 2025, total costs of $46,598 have been incurred pursuant to this letter of intent and subsequent work order.

The Company's aggregate commitment pursuant to this letter of intent, less amounts previously paid to date, totaled approximately $48,000 as of December 31, 2025, which is expected to be incurred through December 31, 2027.

City of Hope. On February 5, 2021, the Company signed a new work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. Costs under this work order agreement were estimated to be approximately $335,000. During the years December 31, 2025 and 2024, the Company incurred costs of $0 and $10,642, respectively, pursuant to this work order. As of December 31, 2025, total costs of $89,323 had been incurred pursuant to this work order agreement. As a result of the closure of the Agreement with City of Hope effective July 8, 2024, the work order was terminated on July 8, 2024.

GEIS. On June 22, 2023, the Company finalized a work order agreement with Theradex, to monitor the GEIS investigator-initiated clinical Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma. The study oversight is expected to be completed by December 31, 2026.

Costs under this work order agreement are estimated to be approximately $153,000, with such payments expected to be allocated approximately 72% to Theradex for services and approximately 28% for payments for pass-through software costs. During the years ended December 31, 2024 and 2023, the Company incurred costs of $34,593 and $14,862, respectively, pursuant to this work order.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $104,000 as of December 31, 2024, which is expected to be incurred through December 31, 2026.

Netherlands Cancer Institute. On August 27, 2024, the Company finalized a work order agreement with Theradex, to monitor the NKI Phase 1b clinical trial of LB-100 combined with atezolizumab, a PD-L1 inhibitor, for patients with microsatellite stable metastatic colorectal cancer. The study oversight is expected to be completed by May 31, 2027.

Costs under this work order agreement are estimated to be approximately $106,380, with such payments expected to be allocated approximately 47% to Theradex for services and approximately 53% for payments for pass-through software costs. During the year ended December 31, 2024, the Company incurred costs of $20,191 pursuant to this work order. As of December 31, 2024, total costs of $20,191 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $88,000 as of December 31, 2024, which is expected to be incurred through May 31, 2027.

Patent and License Agreements

National Institute of Health. Effective February 23, 2024, the Company entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, the Company has licensed on an exclusive basis the NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, estimated at twenty years, unless sooner terminated.

The License Agreement contemplates that the Company will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet certain benchmarks. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, the Company would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

The Company paid NIH a non-creditable, non-refundable license issue royalty of $50,000. The first minimum annual royalty of $25,643 was prorated from the effective date of the License Agreement to the next subsequent January 1. Thereafter, the minimum annual royalty of $30,000 is due each January 1 and may be credited against any earned royalties due for sales made in that year. The second minimum annual royalty for 2025 of $30,000, was paid in December 2024 and is included in other prepaid expenses at December 31, 2024 in the accompanying consolidated balance sheet.

The Company is obligated to pay the NIH, on a country-by-country basis, earned royalties of 2% on net sales of each royalty-bearing product and process, subject to reduction by 50% under certain circumstances relating to royalties paid by the Company to third parties, but not less than 1%. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first commercial sale of a royalty-bearing product or process and expires on the date on which the last valid claim of the licensed product or licensed process expires in such country.

The Company is obligated to pay the NIH benchmark royalties, on a one-time basis, within sixty days from the first achievement of each such benchmark. The License Agreement defines four such benchmarks, which the Company is required to pursue based on "commercially reasonable efforts" as defined in the License Agreement, with deadlines of October 1, 2024, 2027, 2029 and 2031, respectively, each with a different specified benchmark payment amount payable within thirty days of achieving such benchmark. The October 1, 2024 benchmark of $100,000 was defined as the dosing of the first patient with a licensed product in a Phase 2 clinical study of such licensed product in the licensed fields of use. The Company had not commenced a Phase 2 clinical study as of December 31, 2025. The total of all such benchmark payments is $1,225,000.

The Company is obligated to provide annual reports to the NIH on its progress toward the development and commercialization of products under the licensed patents. These reports, due within sixty days following the end of each calendar year, must include updates on research and development activities, regulatory submissions, manufacturing efforts, sublicensing, and sales initiatives. If any deviations from the established commercial development plan or agreed-upon benchmarks occur, the Company is obligated to provide explanation and may amend the commercial development plan and the benchmarks, which, subject to certain conditions, the NIH shall not unreasonably withhold, condition, or delay approval of any request of the Company to amend the commercial development plan and/or the benchmarks and to extend the time periods of the benchmarks.

The Company is obligated to pay the NIH sublicensing royalties of 5% on sublicensing revenue received for granting each sublicense within sixty days of receipt of such sublicensing revenue.

During the years ended December 31, 2025 and 2024, the Company incurred costs of $30,000 and $75,643 in connection with its obligations under the License Agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,765,000 as of December 31, 2025, which is expected to be incurred over approximately the next nineteen years.

Other Significant Agreements and Contracts

NDA Consulting Corp. On December 24, 2013, the Company entered into a consulting agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the consulting agreement, NDA also agreed to cause its president, Dr. Daniel D. Von Hoff, M.D., to serve on the Company's Scientific Advisory Committee during the term of such consulting agreement. The term of the consulting agreement was for one year and provided for a quarterly cash fee of $4,000. The consulting agreement had been automatically renewed for additional one-year terms on its anniversary date, most recently on December 24, 2023, but was subsequently terminated effective September 30, 2024. Consulting and advisory fees charged to operations pursuant to this consulting agreement were $12,000 and $16,000 for the years ended December 31, 2024 and 2023, respectively

BioPharmaWorks. Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services included, among other things, assisting the Company to commercialize its products and strengthen its patent portfolio; identifying large pharmaceutical companies with a potential interest in the Company's product pipeline; assisting in preparing technical presentations concerning the Company's products; consultation in drug discovery and development; and identifying providers and overseeing tasks relating to clinical development of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000. Effective March 1, 2024, the compensation payable under the Collaboration Agreement was converted to an hourly rate structure.

The Company recorded charges to operations pursuant to this Collaboration Agreement of $59,600 and $39,200 during the years ended December 31, 2025 and 2024, respectively, which were included in research and development costs in the consolidated statements of operations.

Netherlands Cancer Institute. On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam ("NKI"), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, for a term of three years. The Development Collaboration Agreement was subsequently modified by Amendment No. 1 thereto. The Development Collaboration Agreement is a preclinical study intended to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company agreed to fund the preclinical study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the preclinical study.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with NKI, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and added 500,000 Euros to the operating budget being funded by the Company.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year and starts upon the dosing of the first patient in the clinical trial at a project cost of 100,000 Euros.

During the years ended December 31, 2025 and 2024, the Company incurred charges in the amount of $0 and $210,362, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company's consolidated statements of operations. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $118,000 as of December 31, 2025, which is expected to be incurred through October 2026. As the work is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

MRI Global. As amended, the Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. During the years ended December 31, 2025 and 2024, the Company incurred costs of $750 and $23,308, respectively, pursuant to this contract.

Trends, Events and Uncertainties

Research and development of new pharmaceutical compounds is, by its nature, unpredictable. Although we will undertake research and development efforts with commercially reasonable diligence, there can be no assurance that our cash position will be sufficient to enable us to develop our pharmaceutical compounds to the extent needed to create future sales to sustain operations as contemplated herein.

There can be no assurance that our pharmaceutical compound will obtain the regulatory approvals and market acceptance to achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurance that we will be able to achieve operating profitability or positive operating cash flows. There can be no assurance that we will be able to secure additional financing, to the extent required, on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash requirements, we would be required to reduce or discontinue our research and development programs, or attempt to obtain funds, if available, through strategic alliances, joint ventures or other transaction structures that could require the Company to relinquish rights to and/or control of LB-100, or to discontinue operations entirely.

Other than as discussed above, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Company's consolidated financial statements and notes thereto and the related report of its independent registered public accounting firm are attached to this Annual Report on Form 10-K beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that is designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported, within the time periods specified in the rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive officer(s) and principal financial officer(s), or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In accordance with Exchange Act Rules 13a-15 and 15d-15, an evaluation was completed under the supervision and with the participation of the Company's management, including its Chief Executive Officer and its Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of the fiscal year ended December 31, 2025, the end of the most recent fiscal year covered by this report. Based on that evaluation, the Company's management concluded that the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed in the Company's reports filed or submitted under the Exchange Act was recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission ("SEC").

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management, including its Chief Executive Officer and its Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process, including policies and procedures, designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. The Company's internal control over financial reporting is designed to ensure that material information regarding the Company's operations is made available to management and the Board of Directors to provide them reasonable assurance that the published financial statements are fairly presented.

The Company's management assessed the Company's internal control over financial reporting based on the Internal Control—Integrated Framework (2013 Framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company's system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Furthermore, smaller reporting companies face additional limitations. Smaller reporting companies employ fewer individuals and can find it more difficult to properly segregate duties. Smaller reporting companies also tend to utilize general accounting software packages that lack a rigorous set of software controls.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or deterred on a timely basis.

Based on the Company's evaluation under the framework in COSO, the Company's management, with the participation of its Chief Executive Officer and its Chief Financial Officer, concluded that the Company's internal control over financial reporting was effective as of December 31, 2025.

Management believes that the consolidated financial statements included in this report fairly present, in all material respects, the Company's financial condition, results of operations and cash flows as of and for the period ended December 31, 2025.

Auditor's Report on Internal Control Over Financing Reporting

This report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this report.

Changes in Internal Control Over Financial Reporting

The Company's management, including its Chief Executive Officer and its Chief Financial Officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the period ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Plans

During the quarter ended December 31, 2025, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" as such term is defined in Item 408(a) of Regulation S-K. As of December 31, 2025, the Company did not have a "Rule 10b5-1 trading arrangement" in effect with respect to its securities.

Insider Trading Policy

The Company has adopted insider trading policies and procedures governing the purchase, sale, and other disposition of its securities, which has been included as an exhibit to this report and has been posted to the investor information/governance section of the Company's corporate website (www.lixte.com).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table and text set forth the names of all of our directors and executive officers as of March 31, 2026. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. The brief descriptions of the business experience of each director and executive officers and an indication of directorships held by each director in other companies subject to the reporting requirements under the Federal securities laws are provided below. Also provided are the biographies of the members of the Scientific Advisory Committee and our consultants.

Our directors and executive officers are as follows:

Name	Age	Position(s) Held with Company
Geordan Pursglove	37	President, Chief Executive Officer, and Chairman of the Board of Directors
Bastiaan van der Baan	54	Chief Scientific Officer
Peter Stazzone	74	Chief Financial Officer
Jason Sawyer	54	Director
Dr. Michael Holloway	63	Director
Lourdes Felix	57	Director
Guy Primus	56	Director

Biographies of Directors and Executive Officers

Geordan Pursglove

Effective June 16, 2025. Mr. Pursglove was appointed as the Company's Chairman of the Board and Chief Executive Officer, and effective September 1, 2025, as President. Prior to joining the Company, he served as President, Chief Executive Officer and Chairman of the Board of Beyond Commerce, Inc. (OTC PINK: BYOC). He was also President of Service 800 Inc., a leading phone and online customer satisfaction survey service that provided actionable customer feedback to Fortune 500 companies globally in which he led operations, scaled revenue and oversaw the company's strategic vision. He held a board position at SemiCab Holdings, an emerging leader in the global logistics and distribution industry that is a subsidiary of Algorhythm Holdings (NASDAQ: RIME). Mr. Pursglove also serves as Chief Executive Officer and a director of Powell Max Ltd (Nasdaq: PMAX). Additionally, he serves as the managing director of 2GP Group LLC where he built multiple businesses in sports, sales, marketing and logistics. Mr. Pursglove has over a decade of experience in M&A, public market space, capital raising, funding growth, scaling businesses and driving innovation.

Bastiaan van der Baan

Bastiaan ("Bas") van der Baan was appointed to the Company's Board of Directors effective June 17, 2022. Effective September 26, 2023, Mr. van der Baan replaced the Company's founder, Dr. John S. Kovach, as President and Chief Executive Officer. Dr. Kovach passed away on October 5, 2023. Effective October 6, 2023, as a result of the passing of Dr. Kovach, Mr. van der Baan was appointed as Chairman of the Board of Directors.

Mr. van der Baan has over 20 years of experience in the biotechnology industry, with a key focus on oncology and diagnostics. He has extensive know-how in the process of managing a compound from clinical development to reimbursement and commercialization, as well as the establishment of partnerships with the pharmaceutical industry, academic collaborators, distributors, insurance companies and governments to successfully launch new oncology products. Mr. van der Baan was most recently the Chief Clinical Officer of Agendia, an oncology molecular diagnostic company based in Irvine, California and Amsterdam, Netherlands through July 15, 2023. Mr. van der Baan is an independent director of Tethis S.p.A., a Milan, Italy-based developer of a novel platform for liquid biopsy testing. Mr. van der Baan was co-founder of ThromboDx, a liquid biopsy company that was acquired in 2016, Qameleon Therapeutics, a company developing synthetic lethal drug combinations for cancer treatment, and Oncosence, an oncology drug development company using senescence as target for drug development. Mr. van der Baan started his career in 1997 at a specialty chemicals division of Unilever that was acquired by ICI. In 2002, Mr. van der Baan joined Kreatech, a biotechnology company acquired by Leica that specialized in life science reagents for gene expression, DNA and protein analysis. Mr. van der Baan holds a Masters Degree in Molecular Sciences from the Wageningen University in the Netherlands.

Peter Stazzone

Effective September 1, 2025, the Company appointed Peter Stazzone as Chief Financial Officer. Mr. Stazzone is a senior finance and business development executive with over 20 years of experience in finance and operations management within start-ups, high-growth and multi-billion-dollar organizations. He is an experienced board member in both public and non-profit sectors. He earned his Master of Business Administration (Finance) from DePaul University and his Bachelor of Science (Accounting) from the University of Illinois. He is also a member of the American Institute of Certified Public Accountants. From 2021 to his appointment with the Company, he acted as the Chief Financial Officer of Beyond Commerce, Inc., a publicly traded company operating in the Business-to-Business Internet Marketing Technology and Services, electric vehicles and logistics markets. From 2016 to 2021, he was the Chief Financial Officer of Strainz, Inc., a leading cannabis brand and manufacturing company operating in Colorado, Washington and Nevada.

Jason Sawyer

Mr. Jason Sawyer is a 30-year veteran of the alternative investment industry and General Manager of Access Alternative Group S.A. (AAG), a Nassau-based venture investment and advisory firm. Based in Cancún, Mexico, he has led over $200 million in early and growth-stage investments across sectors including fintech, biotech, software, energy, and consumer products, partnering with leading family offices and institutions. Previously a Principal at Crane Capital (sold to Bear Stearns), he co-founded Candlebrook Capital and has raised over $3.5 billion for top-tier managers including Blackstone and Gottex. He has also co-founded and financed companies such as Caary Capital, Pacific West Stone, Sanna Health, and California Fitness, with successful exits and institutional backing. He currently leads finance and M&A for Quantum BioPharma (Nasdaq: QNTM) and serves on the board of The FUTR Corp (TSX.V: FTRC).

Dr. Michael Holloway

Dr.Holloway is an accomplished Emergency Medicine Physician and Medical Affairs executive. He has extensive experience spanning diverse healthcare environments across British Columbia, Alberta and Ontario. He has demonstrated leadership and medical innovation at Vice President level. He has a proven track record in policy development, board governance and strategic consulting in healthcare and other fields. He also has extensive exposure to early-stage companies in multiple fields, including med-tech.

Since 1999, Dr. Holloway has served as an Emergency Medicine Physician at Fraser and Vancouver Coastal Health Authorities. From 2016 to the present, he has served as the Vice President of Medical Affairs and Director at Life 360 Innovations, Inc. a medical device company in Vancouver, British Columbia. He served as an advisor for Emergency Medicine services for the province of British Columbia from 2000-2019. Dr. Holloway has a Doctor of Medicine, Family Practice Residency, Emergency Medicine Specialty from the University of Alberta, University of Calgary. He obtained an Honors Bachelor of Arts in Business Administration from the Richard Ivey School of Business, University of Western Ontario.

Lourdes Felix

Lourdes Felix is a Hispanic entrepreneur and seasoned executive with over 30 years of experience in management, corporate finance, capital markets, public accounting, and the private sector—including 15 years in executive leadership. She currently serves as CEO, CFO, and Director of BioCorRx Inc. (OTCQB: BICX), a biotechnology company specializing in addiction treatment solutions.

A founding member and President of BioCorRx Pharmaceuticals Inc., she oversees commercialization and development of addiction and related disorder treatments, regulatory recruitment, strategic planning, and M&A activities. Lourdes led the launch of UnCraveRx, a weight-loss program introduced in 2019, and in 2025, negotiated the company's acquisition of its first FDA-approved drug, LUCEMYRA® (lofexidine).

Known for her strategic financial leadership, she has secured over $40 million in equity and non-dilutive funding, and has extensive experience in SEC reporting, compliance, and risk management. Prior to BioCorRx, she worked in public accounting and the private sector, with deep expertise in GAAP, SEC, and SOX compliance, financial operations, and internal controls.

Since 2023 to the present, Ms. Felix has served as a Board Member and Compensation Committee Chair of Avalon GloboCare Corporation (NASDAQ: ALBT), and from 2024 to the present as a Board Member and Audit Committee Chair of La Rosa Holdings Corp. (NASDAQ: LRHC).

Fluent in Spanish and active in the Hispanic community, Lourdes holds a B.S. in Accounting with a concentration in Business Management from the University of Phoenix.

Guy Primus

Mr. Primus is an accomplished executive and investor with extensive experience leading innovation across technology, media, and applied engineering. Mr. Primus is currently Managing Director of Thrillerdome, a consultancy focused on innovation strategy, intellectual property development, and commercialization.

From 2020 to 2023, Mr. Primus was Chief Executive Officer of Valence Enterprise, a technology platform leveraging analytics and data intelligence to enhance business connectivity. From 2014 to 2020, Mr. Primus was Chief Executive Officer of The Virtual Reality Company, a pioneer in cinematic virtual and augmented reality as well as Chief Operating Officer of Overbrook Entertainment, a diversified media company. Mr. Primus also previously was a consultant with Keanry Management Consultants.

Mr. Primus is an inventor credited with multiple patents related to emotion-based data and user experience systems. He previously served as Chairman of the Advisory Board for the Georgia Tech School of Industrial and Systems engineering. Mr. Primus earned both his Bachelors and Masters Degree in Industrial Engineering from Georgia Tech and an MBA from Harvard Business School.

Family Relationships

Eric Forman, the Company's Vice President and Chief Operating Officer during the year ended December 31, 2024, was the son of board member Dr. Stephen Forman and the son-in-law of former board member Gil Schwartzberg, who passed away on October 30, 2022. Julie Forman, the wife of Eric Forman and the daughter of the late Gil Schwartzberg, is Vice President of Morgan Stanley Wealth Management, where the Company's cash is deposited and managed, and the Company maintains a continuing banking relationship. Eric Forman resigned as Vice President and Chief Operating Officer of the Company effective December 31, 2024.

Committees of Our Board of Directors

Our Board of Directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the Board of Directors and its standing committees. We have a standing audit committee and compensation committee. The Board of Directors serves in place of a nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the Board of Directors when necessary to address specific issues.

Audit Committee

Our audit committee is responsible for, among other things:

- approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our audit committee currently consists of Lourdes Felix, Jason Sawyer, and Guy Primus, with Mrs. Felix serving as Chair. Our Board of Directors has determined that each of the committee members meet the definition of an "independent director," as defined under Nasdaq rules, and that they each meet the independence standards under Rule 10A-3 of the Exchange Act. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our Board of Directors has determined that Ms. Brown qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our Board of Directors has adopted a written charter for the audit committee, which is available on our corporate website at www.lixte.com.

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for executive management;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our compensation committee currently consists of Jason Sawyer, Lourdes Felix, and Guy Primus, with Mr. Sawyer serving as Chair. Our Board of Directors has determined that each of the three committee members meet the definition of an "independent director", as defined under Nasdaq rules. Our Board of Directors has adopted a written charter for the compensation committee, which is available on our corporate website at www.lixte.com.

Nominating and Corporate Governance

Although our Board of Directors serves in place of a nominating and corporate governance committee, our independent directors on the Board of Directors are responsible for, among other things:

- nominating members of the Board of Directors;
- developing a set of corporate governance principles applicable to the Company; and
- overseeing the evaluation of our Board of Directors.

Our Board of Directors may adopt resolutions addressing, among other things, the nomination process, as may be necessary in the future.

Code of Ethics

Our Board of Directors has adopted a code of ethics covering all of our executive officers and key employees. A copy of our code of ethics will be furnished without charge to any person upon written request. Requests should be sent to: Secretary, Lixte Biotechnology Holdings, Inc.,433 Plaza Real, Suite 275, Boca Raton, Florida 33432.

Limitations on Liability and Indemnification Matters

Our Certificate of Incorporation contains provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Certificate of Incorporation provides that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of their actions in that capacity, regardless of whether we would otherwise be permitted to indemnify them under the provisions of Delaware law. Our Amended and Restated Bylaws also provide our Board of Directors with discretion to indemnify our other officers and employees when determined appropriate by our Board of Directors. We have entered into agreements to indemnify our directors, executive officers and other employees as determined by the Board of Directors. With certain exceptions, these agreements provide for indemnification for related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We have obtained customary directors and officers liability insurance.

The limitation of liability and indemnification provisions in our Certificate of Incorporation and Amended and Restated Bylaws may discourage stockholders from bringing a lawsuit against our directors for an alleged breach of their fiduciary duty. These provisions may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Furthermore, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Compliance with Section 16(a) of the Securities Exchange Act of 1934, as Amended

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's directors and executive officers and persons who own more than 10% of a registered class of the Company's equity securities to file various reports with the Securities and Exchange Commission concerning their holdings of, and transactions in, securities of the Company. Copies of these filings are required to be furnished to the Company.

To the Company's knowledge, based solely on its review of the copies of the Section 16(a) reports furnished to the Company and any written representations to the Company that no other reports were required, the Company believes that all individual filing requirements applicable to a director, officer, or beneficial owner of more than 10% of the Company's common stock were complied with under Section 16(a) of the Exchange Act during the year ended December 31, 2025, except as follows: Rene Bernards was late in filing his Form 4 in connection with the grant of stock options on June 30, 2024, and Rene Bernards, Yun Yen, Regina Brown and Stephen Forman were late in filing their Form 4's in connection with the grant of stock options on September 30, 2024.

ITEM 11. EXECUTIVE COMPENSATION

OFFICER AND DIRECTOR COMPENSATION

The table set forth below presents the compensation awarded to, earned by, or paid to our named executive officers for the years ended December 31, 2025, 2024 and 2023.

OFFICER COMPENSATION TABLE

Executive	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Bas van der Baan (6)	2025	174,000	-	-	-	-	-	-	174,000
	2024	153,495	-	-	-	-	-	-	153,495
	2023	40,639	-	-	403,066	-	-	-	443,705
John S. Kovach (2)	2025	-	-	-	-	-	-	-	-
	2024	-	-	-	-	-	-	-	-
	2023	190,860	-	-	-	-	-	-	190,860
James S. Miser (3)	2025	-	-	-	-	-	-	-	-
	2024	102,083	-	-	-	-	-	-	102,083
	2023	175,000	-	-	-	-	-	-	175,000
Robert N. Weingarten (4)	2025	116,667	-	-	-	-	-	-	116,667
	2023	175,000	-	-	-	-	-	-	175,000
	2023	175,000	-	-	-	-	-	-	175,000
Eric J. Forman (5)	2025	-	-	-	-	-	-	-	-
	2024	200,000	-	-	-	-	-	-	200,000
	2023	200,000	-	-	-	-	-	-	200,000
Jan H.M. Schellens (7)	2025	-	-	-	-	-	-	-	-
	2024	56,226	-	-	29,074	-	-	-	85,300
	2023	-	-	-	-	-	-	-	-
Geordan G. Pursglove (8)	2025	120,000	80,000	-	728,671	-	-	10,000	938,671
	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-
Peter M. Stazzone (9)	2025	50,000	12,000	-	173,070	-	-	-	235,070
	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-

(1) Consists of grant date fair value of option award calculated pursuant to the Black-Scholes option-pricing model.

(2) John S. Kovach was the President and Chief Executive Officer from inception through September 26, 2023. Effective July 15, 2020, the Company entered into an employment agreement with Dr. Kovach. On November 6, 2022, Dr. Kovach was awarded an option grant for 20,000 shares of common stock, exercisable for a period of five years at $20.00 per share and valued at $3.282 per share. The employment agreement with Dr. Kovach terminated upon his death on October 5, 2023.

(3) James S. Miser was appointed as Chief Medical Officer on August 1, 2020. In connection with his employment agreement, Dr. Miser was awarded an option grant for 8,334 shares of common stock, exercisable for a period of five years at $71.40 per share and valued at $68.718 per share. On November 6, 2022, Dr. Miser was awarded an option grant for 20,000 shares of common stock, exercisable for a period of five years at $20.00 per share and valued at $3.282 per share. On May 29, 2024, the Company elected not to renew its employment agreement with Dr. Miser, as a result of which such employment agreement expired on July 31, 2024.

(4) Robert N. Weingarten was appointed as Vice President and Chief Financial Officer on August 12, 2020. In connection with his employment agreement, Mr. Weingarten was awarded an option grant for 5,833 shares of common stock, exercisable for a period of five years at $71.40 per share and valued at $68.718 per share. On November 6, 2022, Mr. Weingarten was awarded an option grant for 20,000 shares of common stock, exercisable for a period of five years at $20.00 per share and valued at $3.282 per share.

(5) Eric J. Forman was Chief Administrative Officer from July 15, 2020 through November 6, 2020. In connection with his employment agreement, Mr. Forman was awarded an option grant for 5,833 shares of common stock, exercisable for a period of five years at $71.40 per share and valued at $68.718 per share. Effective November 6, 2022, Mr. Forman was appointed as Vice President and Chief Operating Officer. On November 6, 2022, Mr. Forman was awarded an option grant for 20,000 shares of common stock, exercisable for a period of five years at $20.00 per share and valued at $3.282 per share. The employment agreement with Mr. Forman terminated upon his resignation as an officer of the Company effective December 31, 2024.

(6) Bas van der Baan was appointed as President and Chief Executive Officer on September 26, 2023. In connection with his employment agreement, Mr. van der Baan was awarded an option grant for 250,000 shares of common stock exercisable for a period of five years at $1.95 per share and valued at $1.612 per share. The compensation information provided herein excludes compensation as a Director received before his appointment as President and Chief Executive Officer.

(7) On May 31, 2024, the Company entered into a consulting agreement with Dr. Jan H.M. Schellens, M.D., Ph.D., Pursuant to the agreement, effective July 1, 2024, the Company engaged Dr. Schellens as a consultant, and, effective August 1, 2024, as the Company's Chief Medical Officer. In connection with his employment agreement, Mr. Schellens was awarded an option grant for 15,000 shares of common stock exercisable for a period of five years at $2.39 per share and valued at $1.938 per share. Effective as of July 31, 2025, the Company agreed to accept the resignation of Dr. Schellens and to terminate his consulting agreement to allow Dr. Schellens to pursue other employment opportunities.

(8) Geordan Pursglove was appointed as Chief Executive Officer effective as of July 3, 2025. In connecrrion with his employment agreement, Mr. Pursglove was granted a stock option to purchase 350,000 shares of the Company's common stock at an exercise price of $2.83 per share for a period of five years, exercisable on a cashless basis and valued at $2.0819 per share.

(9) Peter Stazzone was appointed as Chief Financial Officer on September 1,2025. In connection with his employment agreement, Mr. Stazzone was awarded an option grant for 50,000 shares of common stock, exercisable for a period of five years at $4.45 per share and valued at $3.4614 per share.

There were no option exercises by officers during the years ended December 31, 2025, 2024 or 2023.

Outstanding Equity Awards at December 31, 2025

The table set forth below presents information regarding outstanding stock options held by our named executive officers as of December 31, 2025.

NAME	GRANT DATE	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS EXERCISABLE (#)	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS UNEXERCISABLE (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Geordan Pursglove	July 3, 2025	July 3, 2025	350,000	-	2.08	July 3, 2030
Bas van der Baan	June 17, 2022 (1)	June 17, 2022	25,000	-	7.40	June 17, 2027
	June 30, 2023 (1)	September 30, 2023	10,000	-	5.88	June 30, 2028
	September 26, 2023	December 31, 2023	250,000	-	1.95	September 26, 2028
Peter Stazzone	September 1, 2025	September 1, 2025	25,000	25,000	3.46	September 1, 2030

(1) Granted in his capacity as a Director before date of officer appointment on September 26, 2023.

Based on a fair market value of $3.93 per share on December 31, 2025, the intrinsic value attributed to exercisable but unexercised common stock options held by our named executive officers was approximately $1,154,000 at December 31, 2025.

Employment Agreements; Compensation

During July and August 2020, the Company entered into one-year employment agreements with its executive officers, consisting of Dr. John S. Kovach, Eric J. Forman, Dr. James S. Miser, and Robert N. Weingarten, payable monthly, as described below. The employment agreements were automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, or by death, or by termination for cause. These employment agreements were automatically renewed for additional one-year periods in July and August 2021, 2022, 2023 and 2024.

Dr. John Kovach. On July 15, 2020, the Company entered into an employment agreement with Dr. John Kovach to continue to act as the Company's President, Chief Executive Officer and Chief Scientific Officer, with an annual salary of $250,000, payable monthly. His responsibilities included the oversight of the Company's entire operations and strategic planning, and to act as the primary contact between the Company's executive team and the Board of Directors, to whom he reported. Dr. Kovach supervised all scientific endeavors, providing guidance to the Chief Medical Officer. He was the principal spokesperson for the Company. The effective date of the agreement was October 1, 2020 and remained in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. The employment agreement with Dr. Kovach terminated upon his death on October 5, 2023.

Eric Forman. On July 15, 2020, as amended on August 12, 2020, the Company entered into an employment agreement with Eric Forman, to act as the Company's Chief Administrative Officer, reporting directly to the Company's Chief Executive Officer, with an annual salary of $120,000, payable monthly. Effective May 1, 2021, Mr. Forman's annual salary was increased to $175,000. Effective November 6, 2022, Mr. Forman was promoted to Vice President and Chief Operating Officer, with an annual salary of $200,000. Mr. Forman's primary function was to oversee the Company's internal operations, including IT, licensing, legal, personnel, marketing, and corporate governance. Mr. Forman was also granted stock options to acquire 5,833 shares of the Company's common stock. The effective date of the employment agreement was October 1, 2020 and remained in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. The employment agreement with Mr. Forman terminated upon his resignation as an officer of the Company effective December 31, 2024.

Dr. James Miser. On August 1, 2020, the Company entered into an employment agreement with Dr. James Miser, M.D., pursuant to which Dr. Miser was appointed as the Company's Chief Medical Officer, with an annual salary of $150,000. Effective May 1, 2021, Dr. Miser's annual salary was increased to $175,000. Dr. Miser was required to devote at least 50% of his business time to the Company's activities. Dr. Miser was also granted stock options to acquire 8,334 shares of the Company's common stock. The effective date of the agreement was August 1, 2020 and remained in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. On May 29, 2024, the Company elected not to renew its employment agreement with Dr. Miser, as a result of which such employment agreement expired on July 31, 2024.

Dr. Jan H.M. Schellens, M.D., Ph.D. On May 31, 2024, the Company entered into a consulting agreement with Dr. Jan H.M. Schellens, M.D., Ph.D. Pursuant to the agreement, effective July 1, 2024, the Company engaged Dr. Schellens as a consultant, and, effective August 1, 2024, as the Company's Chief Medical Officer. The term of the agreement is in effect from July 1, 2024 until the earliest of (i) termination by either party upon sixty days' notice, (ii) Dr. Schellens' death or disability, or (iii) termination by the Company for breach as provided in the agreement. Under the agreement, Dr. Schellens provides his services for two days per week with the specific days in each week based on arrangements agreed to from time to time between Dr. Schellens and the Company's Chief Executive Officer. The Company pays Dr. Schellens an annual compensation of 104,000 Euros (approximately $108,000 as of December 31, 2024), payable on a monthly basis. On July 1, 2024, in connection with the consulting agreement, Dr. Schellens was granted stock options to purchase 15,000 shares of the Company's common stock. Effective as of July 31, 2025, the Company agreed to accept the resignation of Dr. Schellens and to terminate his consulting agreement, to allow Dr. Schellens to pursue other employment opportunities.

Robert N. Weingarten. On August 12, 2020, the Company entered into an employment agreement with Robert N. Weingarten pursuant to which Mr. Weingarten was appointed as the Company's Vice-President and Chief Financial Officer, with an annual salary of $120,000. Effective May 1, 2021, Mr. Weingarten's annual salary was increased to $175,000. Mr. Weingarten was also granted stock options to acquire 5,833 shares of the Company's common stock. The effective date of the agreement was August 12, 2020 and remained in effect until the earlier of (i) one year from the effective date, automatically renewable for additional one-year periods unless terminated by either party upon 60 days written notice prior to the end of the applicable one-year period, (ii) his death, or (iii) termination for cause. The employment agreement with Mr. Weingarten terminated upon his resignation as an officer of the Company effective August 31, 2025.

Bas van der Baan. Effective September 26, 2023, the Company entered into an employment agreement with Bas van der Baan to act as the Company's President and Chief Executive Officer and as Vice Chairman of the Board of Directors, with an annual salary of $150,000. Effective October 6, 2023, Mr. van der Baan was appointed as Chairman of the Board of Directors upon the death of Dr. Kovach on October 5, 2023. Mr. van der Baan's annual salary may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. van der Baan will be eligible to receive an annual bonus as determined at the sole discretion of the Board of Directors. Mr. van der Baan was also granted stock options to acquire 250,000 shares of the Company's common stock. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination provisions as described in the employment agreement. Effective September 1, 2025, Mr. van der Bann resigned as President, but remained as the Company's Chief Scientific Officer. The term of the employment agreement was for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination provisions as described in the employment agreement.

Geordan Pursglove. Effective June 16, 2025, the Company entered into an employment agreement with Mr. Pursglove to act as the Company's Chairman of the Board and Chief Executive Officer, and effective September 1, 2025, as President with an annual salary of $240,000. Mr. Pursglove's annual salary may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. Pursglove will be eligible to receive an annual bonus as determined at the sole discretion of the Board of Directors. Mr. Pursglove was also granted stock options to acquire 350,000 shares of the Company's common stock. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination provisions as described in the employment agreement.

Peter Stazzone. Effective September 1, 2025, the Company appointed Peter Stazzone as Chief Financial Officer with an annual salary of $150,000. Mr. Stazzone's annual salary may be increased from time to time at the sole discretion of the Board of Directors. In addition, Mr. Stazzone will be eligible to receive an annual bonus as determined at the sole discretion of the Board of Directors. Mr. Stazzone was also granted stock options to acquire 50,000 shares of the Company's common stock. The term of the employment agreement is for one years and is automatically renewable for additional one-year periods unless terminated by either party, subject to early termination provisions as described in the employment agreement.

Policies and Practices – Option Grants

Directors. The Company has a comprehensive compensation program for its non-officer directors for their service on the Board of Directors. This program, as amended, has been in place since April 9, 2021. The Company, with the input and advice of its Compensation Committee, has issued only stock options to its officers and directors.

Equity compensation for directors under this compensation program is as follows:

Appointment of new directors – The Company grants options to purchase 25,000 shares of common stock, exercisable for a period of five years, at the closing market price on the date of grant, vesting 50% on the grant date and the remaining 50% vesting 12.5% on the last day of each calendar quarter beginning in the quarter immediately subsequent to the date of the grant until fully vested, subject to continued service. At the discretion of the Board of Directors, for a nominee to the Board of Directors who is restricted by their respective institution or employer from receiving equity-based compensation, in lieu of the grant of such stock options, the Company may elect to pay a one-time cash fee of $100,000 to such director, payable upfront.

Annual grant of options to directors – Effective on the last business day of the month of June, the Company grants options to purchase 10,000 shares of common stock, exercisable for a period of five years, at the closing market price on the date of grant, vesting 12.5% on the last day of each calendar quarter beginning in the quarter immediately subsequent to the date of grant until fully vested, subject to continued service. If any director has served for less than 12 full calendar months on the grant date, the amount of such stock option grant is prorated based on the length of service of such director. At the discretion of the Board of Directors, for a nominee to the Board of Directors who is restricted by their respective institution or employer from receiving equity-based compensation, in lieu of the grant of such stock options, the Company may elect to pay an annual cash fee of $40,000 to such director, payable quarterly.

Officers. The Company has no specific policy or program with respect to the discretionary grant of options to its officers. The Company granted options to its officers concurrent with their respective appointments during the year ended December 31, 2020. The Company also granted discretionary stock options to its officers during the year ended December 31, 2022. It is the Company's policy that any such option grants take into account the existence of material non-public information when determining the timing of such a grant and the specific terms of such award.

Compensation Clawback Policy

The Board of Directors believes that it is in the best interests of the Company and its stockholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board of Directors has therefore adopted a compensation recoupment policy, which provides for the recovery of erroneously awarded incentive compensation from the Company's executive officers in the event of a triggering event, and which has been filed as an exhibit to this report and has been posted to the investor information/governance section of the Company's corporate website (www.lixte.com).

Board of Directors Compensation

The table set forth below presents the compensation awarded to, earned by or paid to our named directors for the years ended December 31, 2025, 2024 and 2023.

DIRECTOR COMPENSATION TABLE

Name and Principal Position (2)	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Stephen J. Forman (6)	2025	-	-	-	10,000	-	-	978	10,978
Director	2024	-	-	-	28,494	-	-	5,495	33,989
	2023	-	-	-	48,131	-	-	22,500	70,631
Yun Yen (2)	2025	-	-	-	15,000	-	-	1,467	16,467
Director	2024	-	-	-	33,494	-	-	7,500	40,994
	2022	-	-	-	63,340	-	-	30,000	93,340
Regina Brown	2025	-	-	-	16,250	-	-	5,564	21,814
Director (3)	2024	-	-	-	34,744	-	-	7,630	42,374
	2023	-	-	-	48,131	-	-	30,000	78,131
René Bernards	2025	-	-	-	13,750	-	-	4,708	18,458
Director (4)	2024	-	-	-	32,244	-	-	18,194	50,438
	2023	-	-	-	-	-	-	62,500	62,500
Bas van der Baan	2025	-	-	-	-	-	-	-	-
Director (5)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	48,131	-	-	18,478	66,609
Geordan Pursglove:	2025	-	-	-	728,665	-	-		728,665
Director (7)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-
Jason Sawyer	2025	-	-	-	68,360	-	-	13,436	81,796
Director (8)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-
Michael Holloway	2025	-	-	-	68,360	-	-	9,022	77,382
Director (8)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-
Lourdes Felix	2025	-	-	-	78,650	-	-	10,539	89,189
Director (9)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-
Guy Primus	2025	-	-	-	78,650	-	-	8,917	87,567
Director (9)	2024	-	-	-	-	-	-	-	-
	2023	-	-	-	-	-	-	-	-

(1) Consists of grant date fair value of option award calculated pursuant to the Black-Scholes option-pricing model.

(2) Appointed as a director of the Company effective August 4, 2018 and resigned effective July 18, 2025.

(3) Appointed as a director of the Company effective May 11, 2021 and resigned effective September 1, 2025.

(4) Appointed as a director of the Company effective June 15, 2022. Dr. Bernards received all of his compensation from June 15, 2022 through March 31, 2025 in the form of cash. On August 18, 2025, Dr. Bernards resigned from the board and was appointed Chairman of the Scientific Advisory board.

(5) Appointed as a director of the Company effective June 17, 2022, and as Chairman of the Board of Directors on October 6, 2023. Excludes compensation received after appointment as President and Chief Executive Officer on September 26, 2023; and resigned as a director effective September 1, 2025.

(6) Appointed as a director of the Company effective May 13, 2016 and resigned effective July 18, 2025.

(7) Appointed as a director of the Company and Chairman effective June 16, 2025.

(8) Appointed as a director of the Company effective August 15, 2025.

(9) Appointed as a director of the Company effective September 1, 2025.

Scientific Advisory Committee; Compensation

The Scientific Advisory Committee was established to advise the Company's management in three areas: human molecular pathology; the clinical management of human brain tumors; and medicinal chemistry. Members of the Scientific Advisory Committee do not serve in any management capacity with the Company. During the year ended December 31, 2025, the Scientific Advisory Committee consisted of one member, Dr. Rene Bernards, and the years ended December 31, 2024 and 2023, the Scientific Advisory Committee consisted of one member Dr. Daniel D. Von Hoff, M.D.

2020 Stock Incentive Plan

Summary

On July 14, 2020, the Board of Directors of the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan"), which was subsequently approved by the stockholders of the Company. The 2020 Plan provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates, initially for a total of 233,333 shares of the Company's common stock, under terms and conditions as determined by the Company's Board of Directors. On October 7, 2022, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 180,000 shares, to a total of 413,333 shares. On November 27, 2023, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 336,667 shares, to a total of 750,000 shares. On December 8, 2025, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 2,750,000 shares, to a total of 3,500,000 shares.

As of December 31, 2025, unexpired stock options for 729,309 shares were issued and outstanding under the 2020 Plan and 2,770,691 shares were available for issuance under the 2020 Plan.

Having an adequate number of shares available for future equity compensation grants is necessary to promote our long-term success and the creation of stockholder value by:

- Enabling us to continue to attract and retain the services of key service providers who would be eligible to receive grants;
- Aligning the interests of participants with the interests of stockholders through incentives that are based upon the performance of our common stock;
- Motivating participants, through equity incentive awards, to achieve long-term growth in our business, in addition to short-term financial performance; and
- Providing a long-term equity incentive program that is competitive as compared to other companies with whom we compete for talent.

The 2020 Plan permits the discretionary award of incentive stock options ("ISOs"), non-statutory stock options ("NQSOs"), restricted stock, restricted stock units ("RSUs"), stock appreciation rights ("SARs"), other equity awards and/or cash awards to selected participants. The 2020 Plan will remain in effect until July 14, 2030.

The 2020 Plan provides for the reservation of 3,500,000 shares of common stock for issuance thereunder (the "Share Limit"), and provides that the maximum number of shares that may be issued pursuant to the exercise of ISOs is 3,500,000 shares (the "ISO Limit").

Key Features of the 2020 Plan

Certain key features of the 2020 Plan are summarized as follows:

- If not terminated earlier by our Board of Directors, the 2020 Plan will terminate on July 14, 2030.
- Up to a maximum aggregate of 3,500,000 shares of common stock may be issued under the 2020 Plan. The maximum number of shares that may be issued pursuant to the exercise of ISOs is also 3,500,000.
- The 2020 Plan is administered by the Compensation Committee, which is comprised solely of independent members of our Board of Directors. The Board of Directors may designate a separate committee to make awards to employees who are not officers subject to the reporting requirements of Section 16 of the Exchange Act.

- Employees, consultants and board members are eligible to receive awards, provided that the Compensation Committee has the discretion to determine (i) who shall receive any awards, and (ii) the terms and conditions of such awards.

- Awards may consist of ISOs, NQSOs, restricted stock, RSUs, SARs, other equity awards and/or cash awards.

- Stock options and SARs may not be granted at a per share exercise price below the fair market value of a share of our common stock on the date of grant.

- Stock options and SARs may not be repriced or exchanged without stockholder approval.

- The maximum exercisable term of stock options and SARs may not exceed ten years.

- Awards are subject to recoupment of compensation policies adopted by us.

Eligibility to Receive Awards. Employees, consultants and members of our Board of Directors are eligible to receive awards under the 2020 Plan. The Compensation Committee determines, in its discretion, the selected participants who will be granted awards under the 2020 Plan.

Shares Subject to the 2020 Plan. The maximum number of shares of common stock that can be issued under the 2020 Plan is 3,500,000 shares.

The shares underlying forfeited or terminated awards (without payment of consideration), or unexercised awards become available again for issuance under the 2020 Plan. No fractional shares may be issued under the 2020 Plan. No shares will be issued with respect to a participant's award unless applicable tax withholding obligations have been satisfied by the participant.

Administration of the 2020 Plan. The 2020 Plan is administered by the Compensation Committee of the Board of Directors, which consists of independent board members. With respect to certain awards issued under the 2020 Plan, the members of the Compensation Committee also must be "Non-Employee Directors" under Rule 16b-3 of the Exchange Act. Subject to the terms of the 2020 Plan, the Compensation Committee has the sole discretion, among other things, to:

- Select the individuals who will receive awards;

- Determine the terms and conditions of awards (for example, performance conditions, if any, and vesting schedule);

- Correct any defect, supply any omission, or reconcile any inconsistency in the 2020 Plan or any award agreement;

- Accelerate the vesting, extend the post-termination exercise term or waive restrictions of any awards at any time and under such terms and conditions as it deems appropriate, subject to the limitations set forth in the 2020 Plan;

- Permit a participant to defer compensation to be provided by an award; and

- Interpret the provisions of the 2020 Plan and outstanding awards.

The Compensation Committee may suspend vesting, settlement, or exercise of awards pending a determination of whether a selected participant's service should be terminated for cause (in which case outstanding awards would be forfeited). Awards may be subject to any policy that the Board of Directors may implement on the recoupment of compensation (referred to as a "compensation clawback" policy). The members of the Board of Directors, the Compensation Committee and their delegates shall be indemnified by us to the maximum extent permitted by applicable law for actions taken or not taken regarding the 2020 Plan.

Types of Awards.

Stock Options. A stock option is the right to acquire shares at a fixed exercise price over a fixed period of time. The Compensation Committee determines, among other terms and conditions, the number of shares covered by each stock option and the exercise price of the shares subject to each stock option, but such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant of the stock option. The exercise price of each stock option granted under the 2020 Plan must be paid in full at the time of exercise, either with cash, or through a broker-assisted "cashless" exercise and sale program, or net exercise, or through another method approved by the Compensation Committee. Stock options granted under the 2020 Plan may be either ISOs or NQSOs. In order to comply with Treasury Regulation Section 1.422-2(b), the 2020 Plan provides that no more than 750,000 shares may be issued pursuant to the exercise of ISOs.

SARs. A SAR is the right to receive, upon exercise, an amount equal to the difference between the fair market value of the shares on the date of the SAR's exercise and the aggregate exercise price of the shares covered by the exercised portion of the SAR. The Compensation Committee determines the terms of SARs, including the exercise price (provided that such per share exercise price cannot be less than the fair market value of a share of our common stock on the date of grant), the vesting and the term of the SAR. Settlement of a SAR may be in shares of common stock or in cash, or any combination thereof, as the Compensation Committee may determine. SARs may not be repriced or exchanged without stockholder approval.

Restricted Stock. A restricted stock award is the grant of shares of our common stock to a selected participant and such shares may be subject to a substantial risk of forfeiture until specific conditions or goals are met. The restricted shares may be issued with or without cash consideration being paid by the selected participant as determined by the Compensation Committee. The Compensation Committee also will determine any other terms and conditions of an award of restricted stock.

RSUs. RSUs are the right to receive an amount equal to the fair market value of the shares covered by the RSU at some future date after the grant. The Compensation Committee will determine all of the terms and conditions of an award of RSUs. Payment for vested RSUs may be in shares of common stock or in cash, or any combination thereof, as the Compensation Committee may determine. RSUs represent an unfunded and unsecured obligation for us, and a holder of a stock unit has no rights other than those of a general creditor.

Other Awards. The 2020 Plan also provides that other equity awards, which derive their value from the value of our shares or from increases in the value of our shares, may be granted. In addition, cash awards may also be issued. Substitute awards may be issued under the 2020 Plan in assumption of or substitution for or exchange for awards previously granted by an entity which we may acquire.

Limited Transferability of Awards. Awards granted under the 2020 Plan generally are not transferrable other than by will or by the laws of descent and distribution. However, the Compensation Committee may in its discretion permit the transfer of awards other than ISOs.

Change in Control. In the event that we are a party to a merger or other reorganization or similar transaction, outstanding 2020 Plan awards will be subject to the agreement pertaining to such merger or reorganization. Such agreement may provide for (i) the continuation of the outstanding awards by us if we are a surviving corporation, (ii) the assumption or substitution of the outstanding awards by the surviving entity or its parent, (iii) full exercisability and/or full vesting of outstanding awards, or (iv) cancellation of outstanding awards either with or without consideration, in all cases with or without consent of the selected participant. The Compensation Committee will decide the effect of a change in control of us on outstanding awards.

Amendment and Termination of the 2020 Plan. The Board of Directors generally may amend or terminate the 2020 Plan at any time and for any reason, except that it must obtain stockholder approval of material amendments to the extent required by applicable laws, regulations or rules.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The table set forth below presents certain information regarding beneficial ownership of our common stock (the only class of our voting equity securities issued and outstanding) as of March 31, 2026 by (i) each person or entity who is known by us to own beneficially more than 5% of our outstanding shares of common stock, (ii) each of our directors, and (iii) all of our directors and executive officers as a group. As of March 31, 2026, there were 11,617,944 shares of our common stock issued and outstanding. In computing the number and percentage of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of March 31, 2026 pursuant to stock options, warrants, convertible preferred stock or other rights are counted as outstanding, while these shares are not counted as outstanding for computing the percentage ownership of any other person. This table is based upon information supplied by our directors, officers and principal stockholders and reports filed with the Securities and Exchange Commission. Except as noted, the Company's executive office is reflected as the address of all officers, directors and other stockholders owning more than 5%.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percent of Class
Officers and Directors		
Bas van der Baan 433 Plaza Real, Suite 275 Boca Raton, Florida 33432	168,498(2)	1.5%
All officers and directors as a group (1 persons)	168,498	1.5%
Other Stockholders Owning More Than 5%		
Orbit Capital P.O. Box 822 George Town Grand Cayman KY1-1003 Cayman Islands	700,000(1)	6.0%

(1) Includes 11,000 shares of common stock and stock options to purchase 157,498 shares of common stock owned by Bas van der Baan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

(a) Related Party Transactions

During the years ended December 31, 2025, 2024, and 2023, there were no transactions, either directly or indirectly, between the Company and any of its officers, directors or affiliates, including their family members, except as described elsewhere in this document.

(b) Director Independence

The Company considers that Dr. Jason Sawyer, Michael Holloway, Lourdes Felix, and Guy Primus are each an "independent director," as defined under Nasdaq rules and by Rule 10A-3 of the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Weinberg & Company, P.A. acted as the Company's independent registered public accounting firm for the fiscal years ended December 31, 2025 and 2024 and for the interim periods in such fiscal years. The following table shows the fees that were incurred by the Company for audit and other services provided by Weinberg & Company, P.A. for the years ended December 31, 2025 and 2024.

	Years Ended December 31,	
	2025	**2024**
Audit Fees[1]	$ 121,783	$ 104,205
Audit-Related Fees[2]	—	—
Tax Fees[3]	21,458	13,718
Other Fees[4]	33,600	25,695
Total	$ 176,841	$ 143,618

(1) Audit fees represent fees for professional services provided in connection with the audit of the Company's annual financial statements included in its Annual Reports on Form 10-K and the review of its interim financial statements included in its Quarterly Reports on Form 10-Q and services that are normally provided in connection with statutory or regulatory filings, excluding those fees included in Other Fees.

(2) Audit-related fees represent fees for assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements and not reported above under Audit Fees.

(3) Tax fees represent fees for professional services related to tax compliance, tax advice and tax planning.

(4) Other fees represent fees incurred with respect to the Company's Registration Statements on Form S-1 and Form S-3.

All audit and audit-related services, tax services and other services rendered by Weinberg & Company, P.A. during the fiscal years ended December 31, 2025 and 2024 were pre-approved by either the Company's Audit Committee or by the Company's Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for the Company by its independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

See (b) below.

(b) Exhibits:

A list of exhibits required to be filed as part of this Annual Report on Form 10-K is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None

INDEX TO EXHIBITS

Exhibit Number	Description of Document
1.1	Underwriting Agreement, dated as of November 25, 2020, between the Company and WestPark Capital, Inc. and WallachBeth, LLC, filed as Exhibit 1.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 27, 2020 and incorporated herein by reference.
1.2	Form of Underwriting Agreement, filed as Exhibit 1.1 to the Company's Registration Statement on Form S-1, as filed with the Securities and Exchange Commission on June 18, 2025 and incorporated herein by reference.
2.1	Share Exchange Agreement dated as of June 8, 2006 among the Company , John S. Kovach and Lixte Biotechnology , Inc., filed as Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 7, 2006 and incorporated herein by reference.
3.1	Certificate of Incorporation, as filed with the Delaware Secretary of State on May 24, 2005, filed as Exhibit 3.1 to the Company's Registration Statement on Form 10-SB, as filed with the Securities and Exchange Commission on August 3, 2005 and incorporated herein by reference.
3.2	Certificate of Amendment of Certificate of Incorporation, filed as Appendix A to the Company's Information Statement, as filed with the Securities and Exchange Commission on September 19, 2006 and incorporated herein by reference.
3.3	Certificate of Designations for the Company's Series A Convertible Preferred Stock, filed as Exhibit 4.01 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on March 18, 2015 and incorporated herein by reference.
3.4	Certificate of Amendment of Certificate of Designations of the Series A Convertible Preferred Stock, filed as Exhibit 3.4 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 28, 2016 and incorporated herein by reference.
3.5	Amended and Restated Bylaws, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 10, 2022 and incorporated herein by reference.
3.6	Certificate of Amendment of Certificate of Incorporation, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 27, 2020 and incorporated herein by reference.
3.7	Certificate of Amendment to the Certificate of Incorporation of Lixte Biotechnology Holdings, Inc., filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 6, 2023 and incorporated herein by reference.
3.8	Series B Certificate of Designation, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 3, 2025 and incorporated herein by reference.
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock, filed as Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 25, 2025 and incorporated herein by reference.
4.1	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, filed as Exhibit 4.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 25, 2020 and incorporated herein by reference.
4.2	Form of Public Warrant included in Unit, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 27, 2020 and incorporated herein by reference.
4.3	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023 and incorporated herein by reference.

4.4	Form of Common Stock Purchase Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 13, 2025 and incorporated herein by reference.
4.5	Form of Placement Agent Warrant, filed as Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023 and incorporated herein by reference.
4.6	Form of Placement Agent Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 13, 2025 and incorporated herein by reference.
4.7	Form of Pre-Funded Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 3, 2025 and incorporated herein by reference.
4.8	Form of Common Stock Warrant, filed as Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 3, 2025 and incorporated herein by reference.
4.9	Form of Pre-Funded Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 8, 2025 and incorporated herein by reference.
4.10	Form of Pre-Funded Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 22, 2025 and incorporated herein by reference.
4.11	Form of Common Stock Warrant, filed as Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 22, 2025 and incorporated herein by reference.
10.1	Master Agreement between Lixte Biotechnology Holdings, Inc. and Theradex Systems, Inc. dated January 12, 2010, filed as Exhibit 10.15 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, as filed with the Securities and Exchange Commission on March 15, 2013 and incorporated herein by reference.
10.2	Materials Cooperative Research and Development Agreement between Lixte Biotechnology Holdings, Inc. and the National Institute of Neurological Disorders and Stroke dated October 18, 2013, filed as Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 21, 2014 and incorporated herein by reference.
10.3	Clinical Trial Agreement dated as of June 10, 2024 between the Company and the Netherlands Cancer Institute, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 14, 2024 and incorporated herein by reference.
10.4	Collaboration Agreement between Lixte Biotechnology Holdings, Inc. and BioPharmaWorks LLC effective September 14, 2015, filed as Exhibit 10.01 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 18, 2015 and incorporated herein by reference.
10.5	Collaboration Agreement for an Investigator-Initiated Clinical Trial between Lixte Biotechnology Holdings, Inc. and the Spanish Sarcoma Group as of July 31, 2019 (certain portions of this exhibit have been omitted based on a request for confidential treatment filed by the Company with the Securities and Exchange Commission that was granted on September 19, 2019), filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 6, 2019 and incorporated herein by reference.
10.6	Amendment No. 1 to Collaboration Agreement dated March 11, 2025 for an Investigator-Initiated Clinical Trial between Lixte Biotechnology Holdings, Inc. and the Spanish Sarcoma Group as of July 31, 2019, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on March 14, 2025 and incorporated herein by reference.
10.7	Consulting Agreement between the Company and Dr. Jan Schellens, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 5, 2024 and incorporated herein by reference.+
10.8	Employment Agreement between the Company and Robert N. Weingarten, filed as Exhibit 10.02 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on August 18, 2020 and incorporated herein by reference.+
10.9	Lixte Biotechnology Holdings, Inc. 2020 Stock Incentive Plan, filed as Exhibit 10.1 to the Company Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 17, 2020 and incorporated herein by reference.+

10.10	Lixte Biotechnology Holdings, Inc. 2020 Stock Incentive Plan (as amended) , filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 28, 2023 and incorporated herein by reference.+
10.11	Investigator-Initiated Clinical Research Support Agreement between City of Hope National Medical Center and City of Hope Medical Foundation and Lixte Biotechnology Holdings, Inc., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on January 22, 2021 and incorporated herein by reference.
10.12	Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc. and the Netherlands Cancer Institute, Amsterdam, and Oncode Institute, Utrecht, entered into on October 8, 2021 (certain portions of this Exhibit have been omitted) , filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on November 10, 2021 and incorporated herein by reference.
10.13	Insider Trading Policy , filed as Exhibit 10.21 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on March 29, 2023 and incorporated herein by reference.
10.14	Compensation Clawback Policy , filed as Exhibit 10.16 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission on March 19, 2024, and incorporated herein by reference.+
10.15	Amendment to Contract between Lixte Biotechnology Holdings, Inc. and MRI Global effective April 17, 2022, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, as filed with the Securities and Exchange Commission on May 10, 2023 and incorporated herein by reference.
10.16	Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 20, 2023 and incorporated herein by reference.
10.17	Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 13, 2025 and incorporated herein by reference.
10.18	Employment Agreement between the Company and Bastiaan van der Baan effective September 26, 2023, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on September 27, 2023 and incorporated herein by reference.
10.19	Amendment No. 1 to Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc. and the Netherlands Cancer Institute, Amsterdam, and the Oncode Institute, Utrecht, entered into on October 8, 2021, filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, as filed with the Securities and Exchange Commission on November 9, 2023 and incorporated herein by reference.
10.20	Amendment No. 2 to Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc. and the Netherlands Cancer Institute, Amsterdam, and the Oncode Institute, Utrecht, entered into on October 13, 2023 (certain portions of this Exhibit have been omitted) , filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on October 17, 2023 and incorporated herein by reference.
10.21	Amendment No. 3 to Development Collaboration Agreement by and between Lixte Biotechnology Holdings, Inc. and the Netherlands Cancer Institute, Amsterdam, and the Oncode Institute, Utrecht, entered into on November 29, 2024, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 2, 2024 and incorporated herein by reference.

10.22	Exclusive Patent License Agreement between Lixte Biotechnology , Inc. and the National Institute of Neurological Disorders and Stroke and the National Cancer Institute, each a component of the National Institute of Health, effective as of February 23, 2024, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 26, 2024 and incorporated herein by reference.
10.23	At-the-Market Sales Agreement dated as of January 6, 2025 between Lixte Biotechnology Holdings, Inc. and WallachBeth Capital, LLC, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on January 6, 2025 and incorporated herein by reference.
10.24	Amendment No. 1 to the Clinical Trial Agreement between the Company and GEIS dated March 11, 2025, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on March 14, 2025 and incorporated herein by reference.
10.25	Employment Agreement between the Company and Geordan Pursglove dated as of June 16, 2025, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 17, 2025 and incorporated herein by reference.
10.26	Amendment to Employment Agreement. between the Company and Bastiaan van der Baan dated as of June 16, 2025, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on June 17, 2025 and incorporated herein by reference.
10.27	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 3, 2025 and incorporated herein by reference.
10.28	Form of Placement Agent Agreement, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 3, 2025 and incorporated herein by reference.
10.29	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 8, 2025 and incorporated herein by reference.
10.30	Form of Placement Agent Agreement, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on July 8, 2025 and incorporated herein by reference.
10.31	Share Exchange Agreement, dated November 21, 2025, by and among the Company, Orbit Capital Inc., and Liora Technologies Europe Ltd., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 25, 2025 and incorporated herein by reference.
10.32	Royalty Agreement, dated November 24, 2025, by and among the Company and Orbit Capital Inc., filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on November 25, 2025 and incorporated herein by reference.
10.33	Amendment to the Lixte Biotechnology Holdings, Inc. 2020 Stock Incentive Plan (Incorporated by reference to Annex A to Schedule DEF 14A filed with the SEC on October 27,2025)., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 11, 2025 and incorporated herein by reference.
10.34	Form of Securities Purchase Agreement, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 22, 2025 and incorporated herein by reference.
10.35	Form of Placement Agent Agreement, filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 22, 2025, and incorporated herein by reference.
10.36	Amendment No. 2 To Agreement for GSK & Lixte Supported Collaborative Study Agreement, dated December 17th, 2025, by and among the Company, GlaxoSmithKline LLC and The University of Texas, M.D. Anderson Cancer Center., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 23, 2025, and incorporated herein by reference.
10.37	Collaborative Research Agreement, dated December 17, 2025, by and between the Company, and The University of Texas M.D. Anderson Cancer Center., filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 23, 2025, and incorporated herein by reference.
10.38	Share Exchange Agreement dated December 30, 2025, among Orbit Capital Inc. and Lixte Biotechnology Holdings, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on December 31, 2025, and incorporated herein by reference.

10.39	Allocation Deed dated February 12, 2026, between Sidney Braun, Liora Technologies Europe Ltd, and Lixte Biotechnology Holdings. Inc., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 18, 2026, and incorporated herein by reference.
10.40	Consultancy Agreement dated February 13, 2026, between Liora Technologies Europe Ltd, and Sidney Braun., filed as Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the Securities and Exchange Commission on February 18, 2026, and incorporated herein by reference.
21.1	Subsidiaries of the Registrant, filed as Exhibit 21.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on March 29, 2023 and incorporated herein by reference.
23.1	Consent of Weinberg & Company , P.A., Independent Registered Public Accounting Firm*
31.1	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
32.2	Officer's Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*
101.INS	Inline XBRL Instance Document (does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Scheme Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101.INS)

* Filed herewith.

\+ Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURES

In accordance with Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: March 31, 2026

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ GEORDAN PURSGLOVE*
Name: Geordan Pursglove
Title: President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant in the capacity and on the dates indicated.

Signature	Title	Date
/s/ GEORDAN PURSGLOVE Geordan Pursglove	President and Chief Executive Officer	March 31, 2026
/s/ PETER STAZZONE Peter Stazzone	Vice President and Chief Financial Officer	March 31, 2026
/s/ JASON D. SAWYER Jason D. Sawyer	Director	March 31, 2026
/s/ MICHAEL A. HOLLOWAY Michael A. Holloway	Director	March 31, 2026
/s/ GUY W. PRIMUS Guy W. Primus	Director	March 31, 2026
/s/ LOURDES FELIX Lourdes Felix	Director	March 31, 2026

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
(INCLUDING REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM)

Years Ended December 31, 2025 and 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Lixte Biotechnology Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lixte Biotechnology Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has no recurring source of revenue and has experienced negative operating cash flows since inception. The Company has financed its working capital requirements through the recurring sale of its equity securities. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1 to the financial statements. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which it relates.

Acquisition of Liora

As discussed in Note 4 to the financial statements, the Company acquired an 80% ownership interest in Liora Technologies Europe Ltd. ("Liora"), which owns the LiGHT proton therapy system. Management concluded that the transaction should be accounted for as an asset acquisition because substantially all of the fair value of the gross assets acquired was concentrated in the LiGHT system. As of December 31, 2025, the Company consolidates Liora and presents the remaining 20% ownership interest as noncontrolling interest.

Auditing the accounting for the acquisition of Liora involved especially challenging auditor judgment due to the complexity of the transaction structure, including the sequencing of the transaction and the significant judgement required to determine the appropriate accounting under ASC 805. The acquisition was executed through multiple interrelated agreements, including an initial share exchange agreement, subsequent restructuring transactions, and a later amended and restated agreement intended to reflect the final ownership structure. Significant auditor judgement was required to evaluate whether the appropriate accounting treatment was applied, including evaluating the substance of these interrelated transactions, and whether the acquisition should be viewed as the purchase of a business or the acquisition of a single identifiable asset group. This assessment required significant auditor judgment in evaluating whether substantially all of the fair value of the assets acquired was concentrated in the LiGHT proton therapy system and whether the acquired set included a substantive process or organized workforce sufficient to meet the definition of a business.

Our audit procedures related to the acquisition consisted of the following, among others:

- We obtained and evaluated the original share exchange agreement, the subsequent share exchange agreement, and the amended and restated share exchange agreement, and assessed whether the substance of the arrangements supported accounting for the transaction as a single integrated transaction.
- We evaluated management's analysis under ASC 805, including management's conclusion that the acquisition did not meet the definition of a business acquisition.
- We evaluated the measurement of the consideration transferred.
- We performed a physical observation of the LiGHT proton therapy system at the Daresbury Laboratory facility.
- We assessed the adequacy of the Company's disclosures related to the transaction in the consolidated financial statements.

We have served as the Company's auditor since 2008.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 31, 2026

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash	$ 5,106,872	$ 1,038,952
Prepaid insurance	26,682	20,898
Other prepaid expenses	44,825	85,653
Total current assets	5,178,379	1,145,503
LiGHT proton therapy system equipment	6,582,560	-
Right-of-use lease assets	972,682	-
Total assets	$ 12,733,621	$ 1,145,503
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including $125,959 and $27,500 to related parties at December 31, 2025 and December 31, 2024, respectively	$ 436,482	$ 83,206
Research and development contract liabilities	232,138	235,078
Operating lease obligations, current	595,418	-
Series B Convertible Preferred Stock 8% cumulative dividend payable	69,073	-
Total current liabilities	1,333,111	318,284
Operating lease obligations, long-term	438,959	-
Total liabilities	1,772,070	318,284
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized;		
Series A Convertible Preferred Stock, $10.00 per share stated value – 0 and 350,000 shares issued and outstanding at December 31, 2025 and 2024, respectively	-	3,500,000
Series B Convertible Preferred Stock, $0.7146 per share stated value – 2,423,130 and 0 shares issued and outstanding at December 31, 2025 and 2024, respectively	1,731,569	-
Common stock, $0.0001 par value authorized – 100,000,000 shares; issued and outstanding – 8,790,102 and 2,249,290 shares at December 31, 2025 and 2024, respectively	879	225
Additional paid-in capital	66,008,824	49,394,687
Accumulated deficit	(58,077,213)	(52,067,693)
Total Lixte Biotechnology stockholders' equity	9,664,059	827,219
Non-controlling interest	1,297,492	-
Total stockholders' equity	10,961,551	827,219
Total liabilities and stockholders' equity	$ 12,733,621	$ 1,145,503

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2025	**2024**
Revenues, net	$ -	$ -
Costs and expenses:		
General and administrative costs (includes $1,388,322 and $418,422 of stock-based compensation, respectively)	4,852,702	2,846,557
Research and development costs	254,919	726,232
Total costs and expenses	5,107,621	3,572,789
Loss from operations	(5,107,621)	(3,572,789)
Other income (expenses):		
Interest Income	7,388	7,048
Interest Expense	(9,158)	(16,821)
Realized loss on digital assets	(904,394)	-
Foreign currency gain (loss)	525	(3,403)
Other income	3,740	-
Net loss	$ (6,009,520)	$ (3,585,965)
Series B Convertible Preferred Stock 8% cumulative dividend	(69,073)	$ -
Non-controlling interest	-	$ -
Net loss attributable to common stockholders	$ (6,078,593)	$ (3,585,965)
Net loss per common share – basic and diluted	$ (1.26)	$ (1.59)
Weighted average common shares outstanding – basic and diluted	4,840,731	2,249,290

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid in	Accumulated	Non-controlling	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	interest	Equity
Balance, December 31, 2023	350,000	$ 3,500,000	-	$ -	2,249,290	$ 225	$48,976,265	$(48,481,728)	$ -	$ 3,994,762
Stock-based compensation	-	-	-	-	-	-	418,422	-	-	418,422
Net loss	-	-	-		-	-	-	(3,585,965)		(3,585,965)
Balance, December 31, 2024	350,000	3,500,000	-	-	2,249,290	225	49,394,687	(52,067,693)	-	827,219
Proceeds from sale of securities in February 2025 registered direct offering, net of offering costs	-	-	-	-	434,784	43	914,185	-	-	914,228
Stock options issued to settle accrued payable	-	-	-	-	-	-	27,500	-	-	27,500
Conversion of Series A convertible stock	(350,000)	(3,500,000)	-	-	72,917	8	3,499,992	-	-	-
Proceeds from sale of securities in July 2025 registered private placement, net of offering costs	-	-	3,573,130	2,553,359	59,552	6	1,624,797	-	-	4,178,162
Proceeds from sale of securities in July 2025 registered direct offering, net of offering costs	-	-	-	-	210,675	21	1,330,791	-	-	1,330,812
Proceeds from sale of securities in December 2025 registered direct offering, net of offering costs	-	-	-	-	526,342	53	3,841,944	-	-	3,841,997
Exercise of placement agent warrants	-	-	-	-	221,690	22	(22)	-	-	-
Exercise of pre-funded warrants	-	-	-	-	3,065,362	306	(306)	-	-	-
Exercise of common warrants	-	-	-	-	20,000	2	45,799	-	-	45,801
Common stock issued for services	-	-	-	-	39,181	4	171,607	-	-	171,611
Conversion of Series B Convertible Preferred Stock and related dividend	-	-	(1,150,000)	(821,790)	1,190,309	119	821,671	-	-	-
Series B Convertible Preferred Stock 8% cumulative dividend	-	-	-	-	-	-	(69,073)	-	-	(69,073)
Common stock issued for acquisition of Liora	-	-	-	-	700,000	70	3,016,930	-	-	3,017,000
Liora non-controlling interest	-	-	-	-					1,297,492	1,297,492
Stock-based compensation	-	-	-	-	-	-	1,388,322	-	-	1,388,322
Net loss	-	-	-	-	-	-	-	(6,009,520)		(6,009,520)
Balance, December 31, 2025	-	$ -	2,423,130	$1,731,569	8,790,102	$ 879	$66,008,824	$(58,077,213)	$1,297,492	$ 10,961,551

See accompanying notes to consolidated financial statements.

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,009,520)	$ (3,585,965)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash lease expense for right-of-use asset	61,695	-
Stock-based compensation expense	1,388,322	418,422
Common stock issued for services	171,611	-
Realized loss on digital assets	904,394	-
Changes in operating assets and liabilities:		
Advances on research and development contract services	-	78,016
Prepaid insurance	(5,784)	(3,782)
Other prepaid expenses	40,828	(75,653)
Accounts payable and accrued expenses	380,776	(73,552)
Research and development contract liabilities	(2,940)	77,978
Net cash used in operating activities	(3,070,618)	(3,164,536)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of digital assets	(2,637,360)	
Cash paid for Liora investment	(440,000)	-
Capitalized transaction costs	(95,102)	-
Net cash used in investing activities	(3,172,462)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of securities in registered direct offerings, net of offering costs	6,087,037	-
Proceeds from sale of securities in registered private placement, net of offering costs	4,178,162	
Exercise of common stock warrants	45,801	
Net cash provided by financing activities	10,311,000	-
NET CHANGE IN CASH	4,067,920	(3,164,536)
Cash - Beginning of period	1,038,952	4,203,488
Cash - End of period	$ 5,106,872	$ 1,038,952
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 9,158	$ 16,821
Cash paid for income taxes	$ -	$ -
Non-cash investing and financing activities:		
Options issued to settle accrued Board fees	$ 27,500	-
Exercise of placement agent warrants on a cashless basis	$ 22	-
Exercise of pre-funded warrants	$ 306	-
Conversion of Series A Convertible Preferred Stock into common stock	$ 3,500,000	-
Conversion of Series B Convertible Preferred Stock into common stock	$ 821,790	-
Accrual of Series B Convertible Preferred Stock 8% cumulative dividend	$ 69,073	-
Dividend payable settled in shares	$ 20,075	
Digital assets transferred as consideration for acquisition of Liora (non-cash investing) — FV at transfer	$ 1,732,966	-
Common stock issued for acquisition of Liora	$ 3,017,000	-
Right-of use asset and lease liability - operating lease (UKRI Daresbury)	$ 1,034,377	
Non-controlling interest	$ 1,297,492	
Accrual of deferred offering costs	$ -	$ 6,928

See accompanying notes to consolidated financial statements.

1. Organization and Basis of Presentation

Lixte Biotechnology Holdings, Inc., a Delaware corporation, including its wholly-owned Delaware subsidiary, Lixte Biotechnology, Inc. (collectively, the "Company"), is a clinical-stage biopharmaceutical company focused on identifying new targets for cancer drug development and developing and commercializing cancer therapies. The Company's corporate office is located in Boca Raton, Florrida.

On November 21, 2025, the Company acquired Liora Technologies Europe Ltd. ("Liora"). Liora's principal asset is a proton therapy system known as the Linac Image-Guided Hadron Technology ("LiGHT") machine. The LiGHT machine provides a proton beam allowing the delivery of ultra-high dose rates to deep-seated cancer tumors (see Note 3).

In addition, the Company's product pipeline is focused on inhibitors of protein phosphatase 2A, which is used to enhance cytotoxic agents, radiation, immune checkpoint blockers and other cancer therapies. The Company believes that inhibitors of protein phosphatases have significant therapeutic potential for a broad range of cancers. The Company is focusing on the clinical development of a specific protein phosphatase inhibitor, referred to as LB-100, which has been shown to have clinical anti-cancer activity.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have positive cash flows from operations, relies on stock-based compensation for a substantial portion of employee and consultant compensation, and is dependent on periodic access to equity capital to fund its operating requirements.

Going Concern

For the year ended December 31, 2025, the Company incurred a net loss of $6,009,520 and used cash in operations of $3,070,618. As of December 31, 2025, the Company had cash of $5,106,872 available to fund its operations. The Company has not generated recurring revenues since inception and has incurred negative operating cash flows as it advances its development programs. As a result, management has concluded that there is a substantial doubt regarding the Company's ability to continue as a going concern for a period of at least 12 months beyond the filing of this Annual Report on Form 10-K. The consolidated financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

The Company is currently engaged in early-stage clinical trials for its lead product candidate, LB-100. These activities require substantial research, development, regulatory, and clinical expenditures, and the Company does not expect to generate sustainable operating revenues for several years, if ever. At December 31, 2025, the Company's remaining contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements aggregated approximately $496,000, which are expected to be incurred through December 31, 2027.

In addition, through the acquisition of Liora, the Company expects to incur approximately $2 million over the next 24 months to recommission and update the Light machine. Liora currently has no revenues, and the Company will require additional capital to fund these activities.

Management is actively evaluating and pursuing additional financing alternatives, including equity and debt financings and potential strategic transactions. However, there can be no assurance that additional funding will be available on acceptable terms, in sufficient amounts, or at all. If the Company is unable to obtain the necessary funding, it may be required to delay, scale back, or eliminate its clinical development programs; curtail expenditures related to the LiGHT system; or pursue strategic alternatives, including potential asset sales or the cessation of operations.

Nasdaq Compliance

The Company's common stock are traded on the Nasdaq Capital Market under the symbol "LIXT".

On August 23, 2024, the Company received written notification from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") that the Company was not in compliance with the minimum stockholders' equity requirement of $2,500,000 for continued listing on the Nasdaq Capital Market under Listing Rule 5550(b) (the "Stockholders' Equity Requirement"). On October 3, 2024, the Company submitted a plan to the Staff to regain compliance with the Stockholders' Equity Requirement. On October 21, 2024, the Staff provided written notification to the Company that it had granted an extension through February 18, 2025 to regain compliance with the Stockholders' Equity Requirement. As of February 18, 2025, the Company had not gained compliance with the Stockholders' Equity Requirement. Accordingly, on February 19, 2025, the Company received written notification from the Staff stating that the Company did not meet the terms of the extension because it did not complete its proposed financing initiatives to regain compliance. The Company timely requested a hearing before the Nasdaq Hearings Panel ("Panel"), staying any suspension or delisting pending the Panel's decision. Following an April 3, 2025 hearing, the Panel granted the Company a further extension through July 3, 2025 to regain compliance. On July 2, 2025, the Company closed a $5.05 million private placement and, on July 8, 2025, completed a $1.5 million registered direct offering (see Note 6). On July 15, 2025, Nasdaq notified the Company that it had regained compliance with the stockholders' equity requirement.

The Company remains subject to a Panel Monitor under Nasdaq Listing Rule 5815(d)(4)(B) through July 15, 2026. During this period, any future deficiency in stockholders' equity would require the Company to request a hearing before the Panel rather than submit a new compliance plan.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the financial statements of Lixte Biotechnology Holdings, Inc., its wholly-owned subsidiary, Lixte Biotechnology, Inc., and its 80% owned subsidiary Liora. Liora was acquired on November 21, 2025. The accompanying consolidated financial statements include Liora's assets, liabilities, income and expenses since acquisition. Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. On an ongoing basis, management reviews its estimates and, if appropriate, adjusts them. Significant estimates include those related to assumptions used in the calculation of accruals for clinical trial costs and other potential liabilities, and valuing equity instruments issued for services.

Cash

Cash is held in a cash bank deposit program maintained by Morgan Stanley Wealth Management, a division of Morgan Stanley Smith Barney LLC ("Morgan Stanley"). Morgan Stanley is a FINRA-regulated broker-dealer. The Company's policy is to maintain its cash balances with financial institutions in the United States with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC") and/or by the Securities Investor Protection Corporation (the "SIPC"). The Company periodically has cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of $250,000 and $500,000, respectively. Morgan Stanley Wealth Management also maintains supplemental insurance coverage for the cash balances of its customers. The Company has not experienced any losses to date resulting from this policy.

Asset Acquisitions

The Company assesses whether an acquisition is a business combination or an asset acquisition. If substantially all of the gross assets acquired are concentrated in a single asset or group of similar assets, then the acquisition is accounted for as an asset acquisition, where the purchase consideration is allocated on a relative fair value basis to the assets acquired. An asset acquisition does not result in the recognition of goodwill and transaction costs are capitalized as part of the cost of the asset or group of assets acquired. The Company uses its best estimates and assumptions to assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date. The acquisitions costs are allocated to the assets acquired on a relative fair value basis.

Digital Assets

The Company periodically holds certain digital assets, consisting of Bitcoin and Ethereum cryptocurrencies. Digital assets are initially recorded at cost and subsequently measured at fair value as of each reporting period. The Company determines the fair value of its digital assets in accordance with FASB ASC 820, Fair Value Measurement, based on quoted prices on the active exchange(s) that it has determined is the principal market for Bitcoin and Ethereum (Level 1). Changes in fair value are included in unrealized gain (loss) on digital assets in other income (expense) in the Company's consolidated statements of operations. Realized gains and losses on the sale of digital assets are included in other income (expense) in the Company's consolidated statements of operations. The Company tracks its cost basis of digital assets in accordance with the first-in-first-out method of accounting. The Company's digital assets are reasonably expected to be realized in cash or sold or consumed during the Company's normal operating cycle and as such have been classified as current assets in the Company's consolidated balance sheets.

Property and Equipment

The Company property and equipment consists of Liora's Light machine. Property and equipment are recorded at cost. The Light machine requires recommissioning and updates and is not yet ready for its intended use. Accordingly, it is treated as an asset under construction, and depreciation will not begin until the asset is placed into service.

Long – Lived Assets

Long-lived assets, which include property, plant and equipment and operating lease right-of-use assets, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable.

Recoverability of long-lived assets to be held and used is measured by comparing the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the assets. Fair value is generally determined using the asset's expected future discounted cash flows or market value, if readily determinable.

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. In conducting its long-lived asset impairment analyses, the Company groups assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluates the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group asset group exceeds its fair value based on discounted cash flow analysis or appraisals. There was no impairment of long-lived assets for the periods ended December 31, 2025 and 2024.

Research and Development

Research and development costs are charged to expense as incurred. The costs of equipment that are acquired or constructed for research and development activities, and have alternative future uses, are classified as property and equipment and depreciated over their estimated useful lives. Research and development costs consist primarily of fees paid to consultants and contractors, and other expenses relating to the negotiation, design, development, conduct and management of clinical trials with respect to the Company's clinical compound and product candidate. Research and development costs also include the costs to manufacture compounds used in research and clinical trials, which are charged to operations as incurred. The Company's inventory of LB-100 for clinical use has been manufactured separately in the United States and in the European Union in accordance with the laws and regulations of such jurisdictions.

Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, the termination of an agreement, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Obligations incurred with respect to mandatory scheduled payments under agreements with milestone provisions are recognized as charges to research and development costs in the Company's consolidated statement of operations based on the achievement of such milestones, as specified in the respective agreement. Obligations incurred with respect to mandatory scheduled payments under agreements without milestone provisions are accounted for when due, are recognized ratably over the appropriate period, as specified in the respective agreement.

Payments made pursuant to contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and are then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its various clinical trial and research and development contracts on a quarterly basis.

Patent and Licensing Legal and Filing Fees and Costs

Due to the significant uncertainty associated with the successful development of commercially viable products based on the Company's research efforts and related patent applications, all patent and licensing legal and filing fees and costs related to the development and protection of the Company's intellectual property are charged to operations as incurred. Patent and licensing legal and filing fees and costs were $112,091 and $243,186 for the years ended December 31, 2025 and 2024, respectively. Patent and licensing legal and filing fees and costs are included in general and administrative costs in the Company's consolidated statement of operations.

Leases

Under the guidance of ASC 842, operating lease agreements are required to be recognized on the balance sheet as Right-of-Use ("ROU") assets and corresponding lease liabilities. ROU assets include any prepaid lease payments and exclude any lease incentives and initial direct costs incurred. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. The lease terms may include options to extend or terminate the lease if it is reasonably certain that the Company will exercise that option.

Income Taxes

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax assets, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2025 and 2024. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company had no unrecognized tax benefits as of December 31, 2025 or 2024 and does not anticipate any material amount of unrecognized tax benefits through December 31, 2026.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. The Company had not recorded any liability for uncertain tax positions as of December 31, 2025 or 2024. Subsequent to December 31, 2025, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, employees, contractors and consultants for services rendered. Options vest and expire according to terms established at the issuance date of each grant. Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

The Company accounts for stock-based payments to officers, directors, employees, contractors, and consultants by measuring the cost of services received in exchange for equity awards utilizing the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

The fair value of stock options granted as stock-based compensation is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the expected life of the stock option, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair market value of the common stock is determined by reference to the quoted market price of the Company's common stock on the grant date. The expected dividend yield is based on the Company's expectation of dividend payouts and is assumed to be zero.

The Company recognizes the fair value of stock-based compensation awards in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted when the warrants are issued and at the end each subsequent quarterly period while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all of the criteria for equity classification, the warrants are required to be liability-classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each reporting date. Effective November 28, 2025, the Company delisted its public warrants that traded under the symbol "LIXTW". At December 31, 2025 and 2024, the Company did not have any liability-classified warrants.

Segment Information

The Company's Chief Executive Officer is the Company's Chief Operating Decision Maker ("CODM") and evaluates performance and makes operating decisions about allocating resources based on internal financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it operates in a single reportable segment, which consists of the development of cancer treatments. The CODM uses consolidated net income (loss) as the sole measure of segment profit or loss (see Note 10).

Earnings (Loss) Per Share

The Company's computation of earnings (loss) per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., preferred shares, warrants and stock options) as if they had been converted at the beginning of the respective periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the respective periods. The weighted average number of common shares outstanding utilized for determining basic net loss per common share for the year ended December 31, 2025 includes all pre-funded warrants sold in the July 2, 2025, July 8, 2025, and December 22, 2025 equity financings, aggregating 3,610,883 pre-funded warrants, of which 545,521 pre-funded warrants were unexercised at December 31, 2025. Basic and diluted loss per common share was the same for all periods presented because all preferred shares, warrants (excluding pre-funded warrants) and stock options outstanding were anti-dilutive.

	December 31,	
	2025	**2024**
Series A Convertible Preferred Stock	—	72,917
Series B Convertible Preferred Stock	2,423,130	—
Common stock warrants	8,512,614	808,365
Common stock options, including options issued in the form of warrants	1,158,059	613,232
Total	12,093,803	1,494,514

Foreign Currency Translation

The consolidated financial statements are presented in the United States dollar, which is the functional and reporting currency of the Company.

The Company periodically incurs a cost or expense in a foreign jurisdiction denominated in a local currency. The Company purchases the required foreign currency to pay such cost or expense on an as-needed basis. Such cost or expense is converted into United States dollars for financial statement purposes based on the foreign currency conversion rate in effect on the transaction date. The Company purchases the requisite foreign currency to pay such cost or expense on an as-needed basis. Any gain or loss resulting from the purchase of the foreign currency is included as foreign currency gain (loss) in the consolidated statement of operations.

During the years ended December 31, 2025 and 2024, the Company incurred various costs and expenses denominated in Euros, which were converted into United States dollars at the average rate of 1.1306 and 1.0823 Euros per United States dollar, respectively. As of December 31, 2025 and 2024, the Company did not hold any currencies other than the United States dollar in its bank accounts, and was not a party to any foreign currency forward or exchange contracts.

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers in and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently traded non-exchange-based derivatives and commingled investment funds and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The carrying value of financial instruments, which consists of accounts payable and accrued expenses is considered to be representative of their respective fair values due to the short-term nature of those instruments.

Concentration of Risk

The Company periodically contracts with vendors and consultants to provide services related to the Company's operations. Charges incurred for these services can be for a specific period (typically one year) or for a specific project or task. Costs and expenses incurred that represented 10% or more of general and administrative costs or research and development costs for the years ended December 31, 2025 and 2024 are described below.

General and administrative costs for the years ended December 31, 2025 and 2024 include charges from legal firms and other vendors for general licensing and patent prosecution costs relating to the Company's intellectual properties representing 2.9% and 8.6% of total general and administrative costs, respectively. General and administrative costs for the year ended December 31, 2025 include charges for management compensation, representing 18.5% of total general and administrative costs. December 31, 2024 includes charges from two vendors and consultants representing 15.0% and 13.1%, respectively, of total general and administrative costs. General and administrative costs for the years ended December 31, 2025 and 2024 include charges for the fair value of stock options granted to directors and corporate officers representing 20.9% and 14.7%, respectively, of total general and administrative costs.

Research and development costs for the year ended December 31, 2025 include charges from four vendors and consultants representing 25.6%, 22.0% and 21.4%, and 11.7%, respectively, of total research and development costs. Research and development costs for the year ended December 31, 2024 include charges from three vendors and consultants representing 39.2%, 29.0% and 15.4%, respectively, of total research and development costs.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40). ASU 2024-03 amends the FASB Accounting Standards Codification to require specified information about certain costs and expenses in the notes to the financial statements at each interim and annual reporting period, including disclosure of the amounts of purchases of inventory; employee compensation; depreciation; intangible asset amortization; and depreciation, depletion, and amortization included in each relevant expense caption on the face of the income statement within continuing operations that contains any of the expense categories previously listed. Disclosure will also be required of the total amount of selling expenses and an entity's definition of selling expenses in annual reporting periods. ASU 2024-03 does not change or remove current expense disclosure requirements, but does affect where and how this information is presented in the notes to the financial statements. ASU 2024-03 is effective for annual reporting periods beginning January 1, 2027, and interim periods within annual reporting periods beginning January 1, 2028. Early adoption is permitted. The Company is in the process of evaluating ASU 2024-03 to determine its impact on the Company's consolidated financial statement presentation and related disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company's financial statements, including their presentation and related disclosures.

3. Acquisition of Liora Technologies Europe Ltd.

Background

A.D.A.M. S.A. ("ADAM") was founded in 2007 by the European Council for Nuclear Research ("CERN") to develop proton therapy particle accelerators for cancer treatment. Advanced Oncotherapy Plc ("AVO"), a public company in the United Kingdom, acquired ADAM in 2013. ADAM began development on the Linac Image-Guided Hadron Technology ("LiGHT") machine in 2005, which provides a proton beam allowing the delivery of ultra-high dose rates to deep-seated tumors. After acquisition by AVO, development of the LiGHT machine continued through 2021. AVO was unable to raise sufficient capital to finish its business plan for the LiGHT machine and entered bankruptcy on May 30, 2024. Upon entering bankruptcy, AVO's LiGHT machine was a physically complete prototype, but not clinically certified to be used on patient treatment. The LiGHT machine is located in a leased facility at the Daresbury Laboratory research park in the United Kingdom. Between May 2024 and November 2025, two trustees administrated the AVO bankrupt estate, and there was no activity related to the LiGHT machine other than being stored at Daresbury Laboratory. The Light machine is not currently operational.

Liora and Orbit Capital

Liora was formed October 7, 2025, by issuance of 1,000 shares of capital stock to Medgenesis, a Wyoming Corporation, owned by Sidney Braun ("Braun") and Dr. Asher Schmulewitz. Contemporaneously, Orbit Capital Inc., a Cayman Islands corporation founded by Jason Butcher, entered into a loan agreement pursuant to which Orbit Capital loaned $1 million to Medgenesis. On November 6, 2025, Liora acquired all the assets, as defined, of AVO for total consideration of $5.8 million, of which $800,000 was paid upon closing and $5 million is deferred until two specific milestones are met: (i) $2.5 million of the deferred consideration is due when Liora obtains certification from US/UK regulator to use the LiGHT machine on patients, and (ii) $2.5 million of the deferred consideration is due when Liora's revenue exceeds $30 million. The funds to purchase the assets from AVO were provided to Liora by the loan of $1 million from Orbit Capital to Medgenesis. On November 10, 2025 all 1,000 shares of Liora's capital stock were sold to Orbit Capital by Medgenesis for $1 and the extinguishment of the $1 million loan. During 2025, Braun was a consultant to the Company, and became CEO of Liora on February 13, 2026.

Lixte acquisition of Liora

On November 21, 2025, the Company entered into a share exchange agreement to acquire Liora from Orbit Capital. The acquisition was executed through multiple agreements, including (i) an initial share exchange agreement dated November 21, 2025 (the "Original SEA"); (ii) a subsequent share exchange agreement dated December 30, 2025 (the "Post-Closing SEA"); and (iii) an amended and restated agreement dated March 6, 2026 (the "A&R Agreement"). The Post-Closing SEA finalized the structure such that Lixte owned 80% of Liora and Orbit Capital owned 20% of Liora. In addition there was a royalty agreement between the Company and Orbit dated November 21, 2025, that was terminated on December 16, 2025.

As of December 31, 2025, the Company owns 80% of Liora and consolidates Liora, with the remaining 20% ownership interest presented as noncontrolling interest.

A summary of the transaction agreements are as follows:

(i) Share Purchase Agreement dated November 21, 2025 (the "Original SEA")

On November 21, 2025, the Company agreed to purchase 1,000 shares of Liora from Orbit Capital in exchange for 2,700 shares of Series C preferred stock, convertible into 2.7 million shares of common stock, 10.59 Bitcoin ($901,323), 300.7 Ethereum ($831,643), and $440,000 cash. In addition, Lixte assumed the deferred payment due to AVO of $5 million, and assumed a two-year lease at Daresbury Laboratory.

Royalty Agreement dated November 21, 2025, terminated December 16, 2025

Lixte agreed to a Royalty agreement to pay Orbit 10% of "net revenue" generated from the operation, use, licensing, or sale of the LiGHT machine. This royalty stream is capped at $45 million. On December 16, 2025, the royalty agreement was terminated.

(ii) Share Purchase Agreement dated December 30, 2025 (the "Post-Closing SEA")

Management determined this was a post-closing restructuring of the equity consideration of the November 21 2025, transaction. Orbit Capital agreed to exchange the 2,700 shares of the Lixte's Series C Convertible Preferred stock for 700,000 Shares of Lixte's common shares plus 200 shares of Liora. The December 30, 2025 share exchange agreement finalized that Lixte retained 80% ownership of Liora and Orbit Capital Inc. retained 20% of Liora.

(iii) Amended and Restated Share Exchange Agreement dated March 6, 2026 (the "A&R Agreement")

Management determined that, in substance, the Company, Liora and Orbit intended that the transactions occurring under the Original SEA and the Post-Closing SEA all be given effect as if they all occurred effective November 21, 2025. Accordingly, the Company and Orbit entered into the A&R Agreement to clarify and consolidate the transactions contemplated by the Original SEA and Post-Closing SEA and by such interim arrangements into a single integrated agreement reflecting the parties' intent and agreed upon ownership structure. Management concluded that the Original SEA, Post-Closing SEA, and A&R Agreement represent a single integrated transaction that, in substance, resulted in the Company acquiring an 80% ownership interest in Liora effective November 21, 2025

Accounting for acquisition of Liora as an asset acquisition

The Company evaluated whether the acquisition met the definition of a business. Management determined that substantially all of the fair value of the assets acquired is concentrated in the LiGHT proton therapy system equipment, and that the acquisition of Liora did not include substantive processes or an organized workforce. Accordingly, the acquisition does not meet the definition of a business and is accounted for as an asset acquisition.

The following table summarizes the fair value of the purchase consideration and the fair value of tangible assets and assumed liabilities of Liora on the date of acquisition:

Total consideration transferred and implied fair value of acquired assets		
Cash	$	440,000
Digital assets (10.5925 Bitcoin BTC)		901,323
Digital assets (300.699 Ether ETH)		831,643
Common stock (700,000 shares of common stock at $4.31 per share)		3,017,000
Total consideration transferred for 80% interest		5,189,966
Noncontrolling interest (20%)		1,297,492
The implied total value of the acquired asset (100%)		6,487,458
Capitalized transaction costs		95,102
Total acquisition costs	$	6,582,560
Liora's identifiable assets acquired and liabilities assumed		
LIGHT proton therapy system equipment	$	6,582,560

The LiGHT system is presented as a consolidated asset. The 20% ownership retained by Orbit is presented as noncontrolling interest in equity. The LiGHT system is a tangible long-lived asset. The LIGHT system is currently not operational and requires recommissioning, upgrades, and regulatory clearance. Accordingly, the asset is classified as property and equipment and treated as an asset under construction until it is ready for its intended use.

Contingent consideration

Liora's purchase of the LiGHT system from AVO included deferred milestone-based payments of $5 million, which Lixte assumed with the purchase of the LiGHT system. The deferred consideration is contingent upon specified future milestones. As of December 31, 2025, no amounts have been recognized related to these contingent payments. Accordingly, the deferred consideration should be evaluated under the applicable contingency guidance and recognized when the recognition threshold is met. Until that time, the deferred contingent amounts should be disclosed, as appropriate, but not recorded as part of the initial purchase price allocation.

Lease accounting

The LiGHT machine is located in a leased facility. After the acquisition of the LiGHT machine from AVO, Liora entered into a two year operating lease with the Daresbury Laboratory site on November 17, 2025. The Company assumed the lease obligations and is accounting for the lease under ASC 842, including recognition of a right-of-use asset and lease liability (see Note 4). Currently, the Company expects that the LiGHT machine will continue to be housed at this location on a long-term basis.

Business plan

The LiGHT machine represents a physically complete proton linear accelerator prototype that has demonstrated the capability to generate a proton beam at therapeutic energy levels. The machine reflects the culmination of prior design and engineering activities and does not require further fundamental research and development to establish proof of concept. The Company's current strategy is to position the LiGHT machine as a functional prototype platform to support future replication, licensing, and commercialization. However, the LiGHT machine has been inactive for an extended period prior to acquisition and is not currently operational. Before the LiGHT machine can be placed into service, it must undergo a comprehensive recommissioning process, including:

- safety assessment and certification prior to reactivation;
- replacement and updating of control room hardware and software (including computers, monitors, and operating systems);
- beamline integration, including alignment of accelerator components and synchronization of control systems;
- completion of safety checks and system validation procedures; and
- obtaining required regulatory clearances.

Management estimates that the recommissioning process will require approximately 24 months to complete and will involve incremental expenditures of approximately $2.0 million. The realization of economic benefit from the LiGHT machine is dependent upon the successful completion of recommissioning activities, achievement of regulatory approval, and ultimate commercialization of the technology. There can be no assurance that the LiGHT machine will become operational or generate revenues. As of December 31, 2025, based on management's evaluation of relevant events and circumstances, there are no indicators of impairment related to the LiGHT machine.

4. Leases

On November 21, 2025, the Company assumed as part of the Liora acquisition, a two-year lease agreement between United Kingdom Research and Innovation (the "UKRI Daresbury Lease") as a lessor that is a UK government entity and Liora for the rental of the Daresbury Tower located on premises at UKRI Daresbury that houses the acquired machine. The lease was classified as an operating lease and has a quarterly base rent of GBP 147,596 or approximately $198,500. The lease commencement date was November 17, 2025 and has no renewal option. The Company recognized a right-of-use asset and corresponding lease liability of $1,043,437 for the UKRI Daresbury Lease.

The following tables presents net lease costs and other supplemental lease information:

		Year Ended December 31, 2025
Operating lease cost	$	61,695
Operating lease – operating cash flows (fixed payments)	$	-
Operating lease – operating cash flows (liability reduction)	$	-
Non- Current assets – right of use assets	$	972,682
Current liabilities – operating lease liabilities	$	595,418
Non-current liabilities – operating lease liabilities	$	438,959
Remaining lease term (in years)		1.88
Implicit rate used for lease calculation		9.00

Future minimum payments under the leases at December 31, 2025 are listed in the table below (in thousands):

Fiscal Year		Operating Leases
2026	$	595,418
2027		564,884
Total future minimum lease payments	$	1,160,302
Less: Imputed Interest		(125,925)
Present value of net future minimum lease payments	$	1,034,377

5. Digital assets

As of December 31, 2025, the Company has sold all digital assets that were initially purchased during August 2025. The Company did not have any digital assets at December 31, 2024. The following table represents the activity for digital assets during the year 2025:

	Units	Fair Value at 12/31/24	Cost of Additions	Fair value of digital assets transferred for the acquisition of Liora	Realized Loss	Fair Value at 12/31/25
Etherum (ETH)	300.699	$ -	$ 1,431,820	$ (831,643)	$ (600,177)	$ -
Bitcoin (BTC)	10.5925	-	1,205,540	(901,323)	(304,217)	-
		$ -	$ 2,637,360	$ (1,732,966)	$ (904,394)	$ -

The Company's digital asset holdings in Bitcoin and Ethereum were transferred to Orbit for the acquisition of Liora in November 2025.

6. Stockholders' Equity

Preferred Stock

The Company is authorized to issue a total of 10,000,000 shares of preferred stock, par value $0.0001 per share. On March 17, 2015, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company designated a total of 350,000 shares as Series A Convertible Preferred Stock, which are non-voting.

Each share of Series A Convertible Preferred Stock was convertible into 0.20833 shares of common stock (subject to customary anti-dilution provisions), had a liquidation preference based on its assumed conversion into shares of common stock, did not have any cash liquidation preference rights or any registration rights. The 350,000 outstanding shares of Series A Convertible Preferred Stock were converted into a total of 72,917 shares of common stock pursuant to a notice of conversion dated May 16, 2025. As of December 31, 2025 and 2024, the Company had 10,000,000 and 9,650,000 shares of undesignated preferred stock, respectively, which may be issued with such rights and powers as the Board of Directors may designate.

On October 21, 2025, the Company filed a Certificate of Elimination of Certificate of Designations of Series A Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation to eliminate the 350,000 shares of Preferred Stock associated with the Series A Convertible Preferred Stock classification.

On July 1, 2025, the Company filed a Certificate of Designations, Preferences, Rights and Limitations of its Series B Convertible Preferred Stock with the Delaware Secretary of State to amend the Company's certificate of incorporation. The Company has designated a total of 3,573,130 shares as Series B Convertible Preferred Stock with a stated value of $0.7146 per share. Each Preferred Share was convertible into one share of Common Stock, plus an additional adjustment for an 8% per annum cumulative dividend payable at conversion into shares of Common Stock valued at the conversion rate of $0.7146. The Preferred Shares are non-voting, except that certain actions of the Company may not be taken except upon approval of holders who own a majority in stated value of the Preferred Shares. The Preferred Shares bear an 8% per annum cumulative dividend non-compounding and payable at conversion either in cash or, at the holder's election, in shares of Common Stock valued at the then effective conversion rate. The holders of the Preferred Shares have the right to designate two members to the Company's Board of Directors. During the period October 1, 2025 through December 31, 2025, 1,150,000 shares of Series B Preferred were converted into 1,190,309 shares of common stock.

As of December 31, 2025 and December 31, 2024, the Company had 7,576,870 shares and 9,650,000 shares, respectively, of undesignated preferred stock, which may be issued with such rights and powers as the Board of Directors may designate.

Common Stock

The Company is authorized to issue a total of 100,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2025 and 2024, the Company had 8,790,102 and 2,249,290 shares of common stock issued and outstanding, respectively.

February 13, 2025 registered direct offering

Effective February 13, 2025, the Company closed a registered direct offering with certain investors which resulted in gross proceeds of $1,050,003. After deducting placement agent fees and direct offering expenses of $135,775, the Company received net proceeds of $914,228. The Company sold and issued 434,784 shares of common stock at $2.415 per share. In a concurrent private placement, the Company also issued warrants to purchase 434,784 shares of common stock at an exercise price of $2.29 per share, exercisable immediately and expire five years from the date of issuance. The Company also granted the placement agent warrants to purchase 32,609 shares of common stock at $3.0188 per share, expiring February 11, 2030.

During 2025, 20,000 warrants were exercised, resulting in the receipt of $45,801 and issuance of 20,000 share of common stock.

All warrants issued in the February 2025 equity offering include customary anti-dilution adjustments and a "fundamental transaction" provision. If a qualifying fundamental transaction within the Company's control is consummated, holders may elect cash settlement equal to the Black-Scholes value. For fundamental transactions outside the Company's control, holders are entitled to receive the same consideration as common shareholders. The warrants are classified in permanent equity. Any future cash settlements will be accounted for as equity distributions upon occurrence of the related fundamental transaction.

July 2, 2025 private placement

On July 18, 2025, the Company closed a private placement offering with certain investors which resulted in gross proceeds of $5,050,000. After deducting placement agent fees and direct offering expenses of $871,838, the Company received net proceeds of $4,178,162. The Company sold and issued 3,573,130 shares of the Company's Series B Convertible Preferred Stock; 59,552 shares of the Company's common stock; warrants to purchase 6,355,214 shares of common stock; and pre-funded warrants to purchase 2,322,532 shares of common stock. The offering was priced at-the-market under Nasdaq rules at $0.8396 per common stock unit, with each unit consisting of one share of common stock at a price of $0.7146 and one common stock warrant at a price of $0.125 to acquire one share of common stock at an exercise price of $1.00 per share.

During 2025, 2,302,011 pre-funded warrants exercisable at $0.00001 per share were exercised, resulting in the issuance of 2,302,011 shares of common stock. As of October 31, 2025, 20,521 pre-funded warrants remained unexercised.

The 6,355,214 warrants issued in the offering include customary anti-dilution adjustments and a "fundamental transaction" provision. If a qualifying fundamental transaction within the Company's control is consummated, holders may elect cash settlement equal to the Black-Scholes value. For fundamental transactions outside the Company's control, holders are entitled to receive the same consideration as common shareholders. Accordingly, in the event of a change in control of the Company or a sale or transfer of all or substantially all of the Company's assets, as defined, this fundamental transaction provision would entitle the warrant holders to substantial cash consideration, thus reducing the amounts to be retained by the Company or potentially distributable to the Company's stockholders.

The Company engaged Spartan Capital Securities, LLC ("Spartan") to act as the placement agent, and paid Spartan a cash fee equal to 8.0% of the aggregate gross proceeds raised, a non-accountable expense allowance of 1.0% of the aggregate gross proceeds, plus $125,000 to reimburse Spartan's expenses. The Company also issued Spartan placement agent warrants to purchase up to 315,626 shares of common stock, with an exercise price of 125% of the offering price. On July 15, 2025, the placement agent's warrants were exercised on a cashless basis into 221,690 shares of the Company's common stock

July 8, 2025 equity offering

On July 8, 2025, the Company closed a registered direct offering with certain investors which resulted in gross proceeds of $1,500,000. After deducting placement agent fees and direct offering expenses of $169,188, the Company received net proceeds of $1,330,812. The Company sold and issued 210,675 shares of common stock, and pre-funded warrants to purchase 763,351 shares of common stock, at an offering price of $1.54 per share. During the period from July 8, 2025 through August 18, 2025, all 763,351 pre-funded warrants exercisable at $0.00001 per share that were sold were exercised, resulting in the issuance of 763,351 shares of common stock.

The Company engaged Spartan Capital Securities, LLC ("Spartan") to act as the placement agent, and paid Spartan a cash fee equal to 8.0% of the aggregate gross proceeds raised, plus $40,000 to reimburse Spartan's expenses.

December 22, 2025 equity offering

On December 23, 2025, the Company closed a registered direct offering with certain investors which resulted in gross proceeds of $4,299,997. After deducting placement agent fees and direct offering expenses of $458,000, the Company received net proceeds of $3,841,997. The Company sold and issued 526,342 shares of the Company's common stock, warrants to purchase 1,051,342 shares of common stock at an offering price of $3.96 per share, and pre-funded warrants to purchase 525,000 shares of common stock at an offering price of $4.09 per share (or $4.08999 per pre-funded warrant).

The Company engaged Spartan to act as the placement agent, and paid Spartan a cash fee equal to 6.0% of the aggregate gross proceeds raised, plus $85,000 to reimburse Spartan's expenses.

Shares Issued for Services

In connection with the Market Awareness Agreement with MicroCap Advisory, LLC entered into during August 2025 and terminated in September 2025, the Company issued 9,181 shares of its common stock, valued at $44,711, as settlement of the original 48,000 common share obligation.

Common Stock Warrants

A summary of common stock warrant activity, including warrants to purchase common stock that were issued in conjunction with the Company's private placement and public offerings, during the years ended December 31, 2025 and 2024 is presented below.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2023	803,365	$ 16.407	
Issued	—	—	
Exercised	—	—	
Expired	—	—	
Warrants outstanding at December 31, 2024	808,365	$ 16.407	
Issued	8,189,875	1.46	
Exercised	(335,926)	1.31	
Expired	(149,700)	—	
Warrants outstanding at December 31, 2025	8,512,614	$ 1.914	3.77
Warrants exercisable at December 31, 2024	808,365	$ 16.407	
Warrants exercisable at December 31, 2025	8,512,614	$ 1.914	3.77

At December 31, 2025, the outstanding warrants are exercisable at the following prices per common share:

Exercise Price	Warrants Outstanding (Shares)
$ 1.000	6,355,214
$ 2.290	414,784
$ 3.019	32,609
$ 3.950	1,051,342
$ 6.000	583,334
$ 6.600	35,000
$ 20.000	29,000
$ 37.000	11,331
	8,512,614

During the periods presented, the Company issued pre-funded warrants, each of which is exercisable immediately upon issuance at a de minimis exercise price of $0.00001 per share. Because the holders have already paid substantially all of the purchase price at issuance and the remaining exercise price is nominal, the pre-funded warrants are economically equivalent to outstanding common shares. The pre-funded warrants meet the criteria for equity classification. The warrants are indexed to the Company's own stock, require physical settlement in shares, and do not include features that could require cash settlement.

Due to their economic characteristics, pre-funded warrants function as share-like instruments, rather than traditional warrants with a substantive exercise price or term. Therefore, including them together with standard warrants in the warrant rollforward would significantly distort both the weighted-average exercise price and the weighted-average remaining contractual life, rendering those disclosures not meaningful. As a result, the Company presents pre-funded warrants separately from standard common stock warrants in the tables below. The pre-funded warrants are excluded from weighted-average exercise price and remaining life due to their de-minimis strike price and share-like characteristics.

The following table presents a summary of activities related to pre-funded warrants.

	Number of Pre-funded Warrants
Outstanding at December 31, 2024	-
Issued	3,610,883
Exercised	(3,065,362)
Outstanding at December 31, 2025	545,521

The following table presents a summary of total number of common stock warrants and pre-funded warrants.

Warrant Type	12/31/2025
Common stock warrants	8,512,614
Pre-funded warrants	545,521
Total warrants outstanding	9,058,135

7. Related Party Transactions

Related party transactions include transactions with the Company's officers, directors and affiliates.

Employment Agreements with Officers

Effective June 16, 2025, the Company entered into an employment agreement with Geordan Pursglove pursuant to which Mr. Pursglove was appointed as the Company's Chief Executive Officer and Chairman of the Board of Directors for a term of three years, subject to automatic termination if the Company did not complete a successful financing that would enable it to maintain its listing on the Nasdaq Capital Market by July 3, 2025, which was accomplished on July 2, 2025. Under the employment agreement, Mr. Pursglove will receive an annual salary of $240,000, which was increased to $360,000 effective as of January 1, 2026. During the year ended December 31, 2025, the Company paid $130,000 to Mr. Pursglove. Effective September 1, 2025, the Company appointed Geordan Pursglove as the Company's President as the result of the resignation of Bastiaan ("Bas") van der Baan (see below).

Effective September 1, 2025, the Company entered into an employment agreement with Peter Stazzone to act as the Company's Chief Financial Officer, for a term of one year, with an annual salary of $150,000. During the year ended December 31, 2025, the Company paid $50,000 to Mr. Stazzone.

In 2023, the Company entered into an employment agreement with Bas van der Baan to act as the Company's President, Chief Executive Officer. Effective October 6, 2023, Mr. van der Baan was appointed as Chairman of the Board of Directors. Effective June 16, 2025, the employment agreement was amended to provide that Mr. van der Baan will serve as President and Chief Scientific Officer of the Company. Effective September 1, 2025, Mr. van der Bann resigned as President, but remained as the Company's Chief Scientific Officer. The term of the employment agreement is for three years and is automatically renewable for additional one-year periods. During the years ended December 31, 2025 and 2024, the Company paid $174,000 and $153,495, respectively, to Mr. van der Baan.

Former officers

In 2020, the Company entered into an employment agreement with Robert N. Weingarten to act as the Company's Vice President and Chief Financial Officer. Mr. Weingarten resigned from the Company on September 1, 2025. During the years ended December 31, 2025 and 2024, the Company paid $116,667 and $175,000, respectively, to Mr. Weingarten.

In 2020, the Company entered into an employment agreement with Dr. James S. Miser, M.D., to act as the Company's Chief Medical Officer. On May 29, 2024, the Company elected not to renew its employment agreement with Dr. Miser. During the year ended December 31, 2024, the Company paid $102,083 to Dr. Miser.

In 2020, the Company entered into an employment agreement with Eric J. Forman, to act as the Company's Chief Administrative Officer. The employment agreement with Mr. Forman terminated upon his resignation as an officer of the Company effective December 31, 2024. During the year ended December 31, 2024, the Company paid $200,000 to Mr. Forman.

In 2024, the Company entered into a consulting agreement with Dr. Jan H.M. Schellens, M.D., Ph.D. the Company engaged Dr. Schellens as a consultant, and, effective August 1, 2024, as the Company's Chief Medical Officer. The Company pays Dr. Schellens an annual compensation of 104,000 Euros (approximately $108,000 as of December 31, 2025). Effective as of July 31, 2025, the Company agreed to accept the resignation of Dr. Schellens. During the years ended December 31, 2025 and December 31, 2024, the Company paid $67,494 and $56,226 to Dr. Schellens, respectively.

In 2022, René Bernards was appointed to the Company's Board of Directors as an independent director. and would receive annual compensation for his services on the Board only in the form of cash, in lieu of the annual June 30 grant of stock options as provided to the Company's other non-officer directors. During the years ended December 31, 2025 and 2024, the Company recorded charges of $0 and $10,000, respectively, with respect to his annual cash board compensation. On September 1, 2025 the board accepted his resignation.

Compensatory Arrangements for Members of the Board of Directors

Effective April 9, 2021, the Board of Directors approved a comprehensive cash and equity compensation program for the non-officer directors for their services on the Board of Directors (the "Board Plan"), which was amended effective May 25, 2022 and July 9, 2024.

Cash compensation for directors, payable quarterly, is as follows: Base director compensation - $20,000 per year, Chairman of audit committee – additional $10,000 per year, Chairman of any other committees – additional $5,000 per year, Member of audit committee – additional $5,000 per year, Member of any other committees – additional $2,500 per year.

Total cash compensation paid to non-officer directors was $27,500 and $38,819, respectively, for the years ended December 31, 2025 and 2024. Stock-based compensation granted to members of the Company's Board of Directors, officers and affiliates is described at Note 8.

A summary of related party costs, including compensation under employment and consulting agreements and fees paid to non-officer directors for their services on the Board of Directors, for the years ended December 31, 2025 and 2024, is presented below.

	Years Ended December 31,	
	2025	**2024**
Related party costs:		
Cash-based	$ 817,325	$ 753,124
Stock-based	1,388,322	418,422
Total	$ 2,205,647	$ 1,171,546

8. Stock-Based Compensation

On July 14, 2020, the Company adopted the 2020 Stock Incentive Plan (the "2020 Plan") that provides for the granting of equity-based awards, consisting of stock options, restricted stock, restricted stock units, stock appreciation rights, and other stock-based awards to employees, officers, directors and consultants of the Company and its affiliates. As of December 31, 2024, the 2020 Plan allowed for a total of 750,000 issuable common shares. On December 8, 2025, the stockholders of the Company approved an amendment to the 2020 Plan to increase the number of common shares issuable thereunder by 2,750,000 shares, to a total of 3,500,000 issuable common shares.

Stock Options Issued, Vested and Cancelled

The Company periodically issues stock options as incentive compensation to directors and as compensation for the services of employees, contractors, and consultants of the Company.

As of December 31, 2025, unexpired stock options for 729,309 shares were issued and outstanding under the 2020 Plan and 2,770,691 shares were available for issuance under the 2020 Plan.

During the year ended December 31, 2025, the Company granted stock options to directors and officers to purchase an aggregate of 631,414 shares of common stock. The stock options are exercisable at $0.90 per share to $4.45 per share, expire in five years, vest either immediately or over periods up to two years, with a fair value of approximately $1,150,000 on the date of grant which will be amortized over the vesting period.

The total fair value of options that vested during years ended December 31, 2025 and 2024, was approximately $1,388,000 and $418,000.

The fair value of a stock option award is calculated on the grant date using the Black-Scholes option-pricing model. The risk-free interest rate is based on the U.S. Treasury yield curve in effect as of the grant date. The expected dividend yield assumption is based on the Company's expectation of dividend payouts and is assumed to be zero. The estimated volatility is based on the historical volatility of the Company's common stock, calculated utilizing a look-back period approximately equal to the contractual life of the stock option being granted. Unless sufficient historical exercise data is available, the expected life of the stock option is calculated as the mid-point between the vesting period and the contractual term (the "simplified method"). The fair market value of the common stock is determined by reference to the quoted market price of the common stock on the grant date.

For stock options requiring an assessment of value during the year ended December 31, 2025, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	3.58% to 3.82%
Expected dividend yield	0%
Expected volatility	129% to 139%
Expected life	2.5 to 3.5 years

For stock options requiring an assessment of value during the year ended December 31, 2024, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model with the following assumptions:

Risk-free interest rate	3.55% to 4.29%
Expected dividend yield	0%
Expected volatility	126%
Expected life	2.5 to 3.5 years

A summary of stock-based compensation costs for the years ended December 31, 2025 and 2024 is as follows:

	Years Ended December 31,	
	2025	**2024**
Related parties	$ 1,388,322	$ 418,422
Non-related parties	—	—
Total stock-based compensation costs	$ 1,388,322	$ 418,422

A summary of stock option activity, including options issued in the form of warrants, during the years ended December 31, 2025 and 2024 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Stock options outstanding at December 31, 2023	552,083	$ 15.330	
Granted	92,815	2.259	
Exercised	—	—	
Expired	(31,666)	35,368	
Stock options outstanding at December 31, 2024	613,232	12.317	
Granted	631,494	2.7673	
Exercised	—	—	
Expired	(86,667)	40.071	
Stock options outstanding at December 31, 2025	1,158,059	$ 5.033	3.34
Stock options exercisable at December 31, 2024	409,897	$ 17,100	
Stock options exercisable at December 31, 2025	1,059,311	$ 5.2016	3.23

As of December 31, 2025, 1,059,311 stock options were vested and exercisable. Total deferred compensation expense for the outstanding value of unvested stock options was approximately $230,000 at December 31, 2025, which will be recognized subsequent to December 31, 2025 over a weighted-average period of approximately 9 months.

At December 31, 2025, the outstanding common stock options, including options issued in the form of warrants, are exercisable at the following prices per common share:

Exercise Prices	Options Outstanding (Shares)	Options Exercisable (Shares)
$ 0.905	72,648	50,148
$ 1.210	32,181	32,181
$ 1.870	21,217	21,217
$ 1.950	250,000	250,000
$ 2.330	16,665	16,665
$ 2.370	51,598	44,100
$ 2.390	5,000	5,000
$ 2.830	350,000	350,000
$ 3.590	50,000	31,250
$ 4.050	50,000	25,000
$ 4.450	50,000	25,000
$ 5.025	8,750	8,750
$ 5.880	40,000	40,000
$ 7.400	55,000	55,000
$ 20.000	20,000	20,000
$ 20.600	20,000	20,000
$ 28.000	25,000	25,000
$ 30.300	30,000	30,000
$ 32.100	10,000	10,000
	1,158,059	1,059,311

Based on the closing fair market value of $3.93 per share on December 31, 2025, the intrinsic value attributed to exercisable but unexercised common stock options was approximately $1,276,719 at December 31, 2025.

Outstanding stock options to acquire 98,749 shares of the Company’s common stock had not vested at December 31, 2025.

Upon the exercise of such stock options, the Company expects to satisfy the related stock obligations through the issuance of authorized but unissued shares of common stock.

9. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets as of December 31, 2025 and 2024 are as follows:

	December 31,	
	2025	2024
Research credits	$ 733,000	$ 652,000
Capitalized research and development	720,000	900,000
Stock-based compensation	1,940,000	1,550,000
Net operating loss carryforwards	10,668,000	9,515,000
Other	37,000	
Total deferred tax assets	14,098,000	12,617,000
Valuation allowance	(14,098,000)	(12,617,000)
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. As of December 31, 2025 and 2024, management was unable to determine if it is more likely than not that the Company's deferred tax assets will be realized and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

The Company's effective tax rate for the periods ended 12/31/2025 and 12/31/2024 were 0.0% for each period respectively. For the period ended 12/31/2025, the primary drivers of the variance from the statutory rate were primarily due to the full valuation allowance against deferred tax assets, and other permanent differences. For the period ended 12/31/2024, the primary drivers of the variance from the statutory rate were mainly due to the establishment of a full valuation allowance against deferred tax assets, state income tax effects, and other permanent differences. Due to the Company's pre-tax loss position and valuation allowance, no income tax expense or benefit was recorded for the period.

The following is a reconciliation from the Company's statuary rate to the effective tax rate reported in the financial statements:

	Years Ended December 31,			
	2025		2024	
U. S. federal statutory tax rate	$ (1,276,505)	21.0%	$ (753,053)	21.0%
Effects of:				
State and local income taxes, net of federal benefit of state	1,264	(0.1)%	-	-%
Prior year true ups	(19,668)	0.3%	(40,668)	1.13%
Tax credits	(40,275)	3.2%	-	0.00%
Non-Deductible or Non-Taxable Items	379	0.0%	137,387	(3.83)%
Change in valuation allowance	1,336,405	(24.4)%	656,334	(18.3)%
Effective tax rate	$ 1,600	-%	-	-%

For the period ended 12/31/2025, the Company had federal and states net operating loss carryforwards of approximately $34.8M and $36.8M respectively. Of the federal amount, $14.0 have a limited carryforward period and will begin to expire in 2029 the remaining $20.8M will have an indefinite carryforward period. Of the state post-apportioned amount, $14.1M have a limited carryforward period and will begin to expire in 2038; the remaining $22.7 will have an indefinite carryforward period.

The Company has $732,880 of Federal, R&D tax credit carryforwards as of December 31, 2025.

In accordance with Section 382 and Section 383, utilization of the NOL and tax credit carryforwards may be subject to limitations based on prior or future ownership changes.

Additionally, after weighing up all available positive and negative evidence for the period ending 12/31/2025, the Company has recorded a full valuation allowance.

On July 4th, 2025, the President of the United States of America signed into law significant federal tax legislation, H.R.1 (the "Tax Reform Act of 2025"). The legislation includes numerous changes to U.S. corporate income tax law, including but not limited to permanent 100% bonus depreciation for qualified property, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest expense, increased Section 179 expensing limits, changes to the international tax regime, and expanded limitations on the deductibility of executive compensation under IRC Section 162(m). Most provisions are effective for tax years beginning after December 31, 2024, with certain transition rules and exceptions.

The Company has not recognized any significant impact from the change in the tax law.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change", which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income might be limited.

As the Company's net operating losses have yet to be utilized, all previous tax years since 2006 remain subject to adjustment by Federal authorities and other jurisdictions in which the Company currently operates or has operated in the past.

10. Segment Information

The Company's chief operating decision maker ("CODM") has been identified as the Company's President and Chief Executive Officer ("CEO"). The Company's CODM evaluates performance and makes operating decisions about allocating resources based on financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it has a single operating segment composed of the consolidated financial results of the Company.

The following table presents the significant segment expenses (10% or greater) and other segment items regularly reviewed by the Company's CODM and included in general and administrative costs.

	Years Ended December 31,	
	2025	**2024**
Cash based compensation	751,860	753,124
Stock-based compensation	1,388,322	418,422
Patent and licensing legal and filing fees and costs	112,091	243,186
Other consulting and professional fees	1,431,118	735,021
Insurance expense	257,478	434,444
Other costs and expenses, net	911,833	262,360
Total general and administrative costs	$ 4,852,702	$ 2,846,557

The following table presents the significant segment expenses (10% or greater) and other segment items regularly reviewed by the Company's CODM and included in research and development costs.

	Years Ended December 31,	
	2025	**2024**
Clinical and related oversight costs	$ 57,193	$ 377,958
Preclinical research focused on development of additional novel anti-cancer compounds	188,675	329,438
Regulatory service costs	9,051	18,836
Total research and development costs	$ 254,919	$ 726,232

The following table presents a summary of research and development costs for the years ended December 31, 2025 and 2024 based on the respective geographical regions where such costs were incurred.

	Years Ended December 31,	
	2025	**2024**
United States	$ 193,679	$ 462,566
Spain	61,240	51,022
China	-	2,282
Netherlands	-	210,362
Total	$ 254,919	$ 726,232

The following table presents the Company's total assets by segment at December 31, 2025 and 2024.

	December 31,	
	2025	**2024**
Research and development assets	$ 10,000	$ 39,298
Corporate assets	12,723,621	1,106,205
Total assets	$ 12,733,621	$ 1,145,503

11. Commitments and Contingencies

Legal Claims

On November 19, 2025, the Company received a written demand from FX Group Inc. and certain related parties ("FX"), asserting that FX was entitled to consulting fees in connection with capital offerings completed by the Company during June and July 2025. The Company denied the allegations, and negotiations continued after year-end. On January 22, 2026, the Company entered into a settlement agreement, under which the Company agreed to pay a one-time settlement amount of $100,000 to FX in exchange for mutual releases of all claims. As of December 31, 2025, management recorded an accrual of $100,000 for the settlement expense.

The Company may be subject to legal claims and actions from time to time as part of its business activities. As of December 31, 2025 and 2024, the Company was not subject to any other threatened or pending lawsuits, legal claims or legal proceedings.

Principal Commitments

Clinical Trial Agreements

At December 31, 2025, the Company's remaining financial contractual commitments pursuant to clinical trial agreements and clinical trial monitoring agreements not yet incurred, as described below, aggregated $496,000, including clinical trial agreements of $293,000 and clinical trial monitoring agreements of $203,000, which, based on current estimates, are currently scheduled to be incurred through approximately December 31, 2027. The Company's ability to conduct and fund these contractual commitments is subject to the timely availability of sufficient capital to fund such expenditures, as well as any changes in the allocation or reallocation of such funds to the Company's current or future clinical trial programs. The Company expects that the full amount of these expenditures will be incurred only if such clinical trial programs are conducted as originally designed and their respective enrollments and duration are not modified or reduced. Clinical trial programs, such as the types that the Company is engaged in, can be highly variable and can frequently involve a series of changes and modifications over time as clinical data is obtained and analyzed, and is frequently modified, suspended or terminated, in part based on receipt or lack of receipt of an indication of clinical benefit or activity, before the clinical trial endpoint is reached. Accordingly, such contractual commitments as discussed herein should be considered as estimates only based on current clinical assumptions and conditions and are typically subject to significant modifications and revisions over time.

The following is a summary of the Company's ongoing contractual clinical trials described below as of December 31, 2025:

Description of Clinical Trial	Institution	Start Date	Projected End Date	Number of Patients in Trial	Study Objective	Clinical Update	Expected Date of Preliminary Efficacy Signal	NCT No.	Remaining Financial Contractual Commitment
LB-100 combined with atezolizumab in microsatellite stable metastatic colorectal cancer (Phase 1b)	Netherlands Cancer Institute (NKI)	August 2024	December 2027	37	Determine RP2D with atezolizumab	First patient entered August 2024, in total two patients entered	December 2027	NCT06012734	(1)
LB-100 combined with doxorubicin in advanced soft tissue sarcoma (Phase 1b)	GEIS	June 2023	Recruitment completed September 2024	9 to 18	Determine MTD and RP2D	Fourteen patients entered	March 2026	NCT05809830	$ 293,000
Doxorubicin with or without LB-100 in advanced soft tissue sarcoma (Randomized Phase 2)	GEIS	TBD	TBD	150	Determine efficacy: PFS	Clinical trial not yet begun (subject to completion of Phase 1b GEIS clinical trial)	TBD	NCT05809830	(1)
LB-100 combined with dostarlimab in ovarian clear cell carcinoma (Phase 1b/2)	MD Anderson	January 2024	December 2027	42	Determine the OS of patients with recurrent ovarian clear cell carcinoma	Twenty one patients entered	December 2027	NCT06065462	(1)
Total									$ 293,000

(1) The Company has no financial contractual commitment associated with this clinical trial at December 31, 2025.

Netherlands Cancer Institute. Effective June 10, 2024, the Company entered into a Clinical Trial Agreement with the Netherlands Cancer Institute ("NKI") (see Note 5) to conduct a Phase 1b clinical trial of the Company's protein phosphatase inhibitor, LB-100, combined with atezolizumab, a PD-L1 inhibitor, the proprietary molecule of F. Hoffman-La Roche Ltd. ("Roche"), for patients with microsatellite stable metastatic colorectal cancer. Under the agreement, the Company will provide its lead compound, LB-100, and under a separate agreement between NKI and Roche, Roche will provide atezolizumab and financial support for the clinical trial. The Company has no obligation to and will not provide any reimbursement of clinical trial costs. Pursuant to the agreement and the protocol set forth in the agreement, the clinical trial will be conducted by NKI at NKI's site in Amsterdam by principal investigator Neeltje Steeghs, MD, PhD, and NKI will be responsible for the recruitment of patients. The agreement provides for the protection of the respective intellectual property rights of each of the Company, NKI and Roche.

This Phase 1b clinical trial will evaluate safety, optimal dose and preliminary efficacy of LB-100 combined with atezolizumab for the treatment of patients with metastatic microsatellite stable colorectal cancer. Immunotherapy using monoclonal antibodies like atezolizumab can enhance the body's immune response against cancer and hinder tumor growth and spread. LB-100 has been found to improve the effectiveness of anticancer drugs in killing cancer cells by inhibiting a protein called PP2A on cell surfaces. Blocking PP2A increases stress signals in tumor cells expressing the PP2A protein. Accordingly, combining atezolizumab with LB-100 may enhance treatment efficacy for metastatic colorectal cancer, as cancer cells with heightened stress signals are more vulnerable to immunotherapy.

This study comprises a dose escalation phase and a dose expansion phase. The objective of the dose escalation phase is to determine the recommended Phase 2 dose (RP2D) of LB-100 when combined with the standard dosage of atezolizumab. The dose expansion phase will further investigate the preliminary efficacy, safety, tolerability, and pharmacokinetics/dynamics of the LB-100 and atezolizumab combination. The clinical trial opened in August 2024 with the enrollment of the first patient. A total of two patients have been enrolled to date. Patient accrual is expected to take up to 24 months, with a maximum of 37 patients with advanced colorectal cancer to be enrolled in this study.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab is currently investigating two Serious Adverse Events ("SAEs") observed in the clinical trial. The Investigational Review Board (IRB) of the Netherlands Cancer Institute has requested additional information with respect to these SAEs and the study has been paused for enrollment until the IRB's questions have been satisfactorily addressed (see "Specific Risks Associated with the Company's Business Activities - Serious Adverse Events" below for additional information).

The Company has no financial contractual commitment associated with this clinical trial.

City of Hope. Effective January 18, 2021, the Company executed a Clinical Research Support Agreement (the "Agreement") with the City of Hope National Medical Center, an NCI-designated comprehensive cancer center, and City of Hope Medical Foundation (collectively, "City of Hope"), to carry out a Phase 1b clinical trial of LB-100, the Company's first-in-class protein phosphatase inhibitor, combined with an FDA-approved standard regimen for treatment of untreated extensive-stage disease small cell lung cancer ("ED-SCLC"). LB-100 was given in combination with carboplatin, etoposide and atezolizumab, an FDA-approved standard of care regimen, to previously untreated ED-SCLC patients. The LB-100 dose was to be escalated with the standard fixed doses of the 3-drug regimen to reach a recommended Phase 2 dose ("RP2D"). Patient entry was to be expanded so that a total of 12 patients would be evaluable at the RP2D to confirm the safety of the LB-100 combination and to look for potential therapeutic activity as assessed by objective response rate, duration of overall response, progression-free survival, and overall survival.

The clinical trial was initiated on March 9, 2021, with patient accrual expected to take approximately two years to complete. Because patient accrual was slower than expected, effective March 6, 2023, the Company and City of Hope added the Sarah Cannon Research Institute ("SCRI"), Nashville, Tennessee, to the ongoing Phase 1b clinical trial. The Company and City of Hope continued efforts to increase patient accrual by adding additional sites and by modifying the protocol to increase the number of patients eligible for the clinical trial. The impact of these efforts to increase patient accrual and to decrease time to completion was evaluated in subsequent quarters.

After evaluating patient accrual through June 30, 2024, the Company and City of Hope agreed to close the clinical trial. Pursuant to the terms of the Agreement, the Company provided notice to City of Hope of the Company's intent to terminate the Agreement effective as of July 8, 2024. Upon closure, the Company incurred a prorated charge of $207,004 for the cost of patients enrolled to date, which is included in accounts payable and accrued expenses at December 31, 2025 and 2024.

During the years ended December 31, 2025 and 2024, the Company incurred costs of $0 and $285,019, respectively, pursuant to this Agreement. As of December 31, 2025, total costs of $732,532 had been incurred pursuant to this Agreement.

GEIS. Effective July 31, 2019, the Company entered into a Collaboration Agreement for an Investigator-Initiated Clinical Trial with the Spanish Sarcoma Group (Grupo Español de Investigación en Sarcomas or "GEIS"), Madrid, Spain, to carry out a study entitled "Randomized phase I/II trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma". The purpose of this clinical trial is to obtain information with respect to the efficacy and safety of LB-100 combined with doxorubicin in soft tissue sarcomas. Doxorubicin is the global standard for initial treatment of advanced soft tissue sarcomas ("ASTS"). Doxorubicin alone has been the mainstay of first line treatment of ASTS for over 40 years, with little improvement in survival from adding cytotoxic compounds to or substituting other cytotoxic compounds for doxorubicin. In animal models, LB-100 consistently enhances the anti-tumor activity of doxorubicin without apparent increases in toxicity.

GEIS has a network of referral centers in Spain and across Europe that have an impressive track record of efficiently conducting innovative studies in ASTS. The Company agreed to provide GEIS with a supply of LB-100 to be utilized in the conduct of this clinical trial, as well as to provide funding for the clinical trial. The goal is to enter approximately 150 to 170 patients in this clinical trial over a period of two to four years. The Phase 1 portion of the study began in the quarter ended June 30, 2023 to determine the recommended Phase 2 dose of the combination of doxorubicin and LB-100. As advanced sarcoma is a very aggressive disease, the design of the Phase 2 portion of the study assumes a median progression-free survival ("PFS"), no evidence of disease progression or death from any cause, of 4.5 months in the doxorubicin arm and an alternative median PFS of 7.5 months in the doxorubicin plus LB-100 arm to demonstrate a statistically significant decrease in relative risk of progression or death by adding LB-100. There is a planned interim analysis of the primary endpoint when approximately 50% of the 102 events required for final analysis is reached.

The Company had previously expected that this clinical trial would commence during the quarter ended June 30, 2020. However, during July 2020, the Spanish regulatory authority advised the Company that although it had approved the scientific and ethical basis of the protocol, it required that the Company manufacture new inventory of LB-100 under current Spanish pharmaceutical manufacturing standards. These standards were adopted subsequent to the production of the Company's existing LB-100 inventory.

In order to manufacture a new inventory supply of LB-100 for the GEIS clinical trial, the Company engaged a number of vendors to carry out the multiple tasks needed to make and gain approval of a new clinical product for investigational study in Spain. These tasks included the synthesis under good manufacturing practice (GMP) of the active pharmaceutical ingredient (API), with documentation of each of the steps involved by an independent auditor. The API was then transferred to a vendor that prepares the clinical drug product, also under GMP conditions documented by an independent auditor. The clinical drug product was then sent to a vendor to test for purity and sterility, provide appropriate labels, store the drug, and distribute the drug to the clinical centers for use in the clinical trials. A formal application documenting all steps taken to prepare the clinical drug product for clinical use was submitted to the appropriate regulatory authorities for review and approval before being used in a clinical trial.

On October 13, 2022, the Company announced that the Spanish Agency for Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios or "AEMPS") had authorized a Phase 1b/randomized Phase 2 study of LB-100, the Company's lead clinical compound, plus doxorubicin, versus doxorubicin alone, the global standard for initial treatment of ASTS. Consequently, this clinical trial commenced during the quarter ended June 30, 2023 and is expected to be completed and a report prepared by December 31, 2026. In April 2023, GEIS completed its first site initiation visit in preparation for the clinical trial at Fundación Jiménez Díaz University Hospital (Madrid). Up to 170 patents will be entered into the clinical trial. The recruitment for the Phase 1b portion of the protocol was extended with two patients and was completed during the quarter ended September 30, 2024. The Company expects to have data on toxicity and preliminary efficacy from this portion of the clinical trial during the quarter ending December 31, 2025.

Given the focus on the combination of LB-100 with immunotherapy in ovarian clear cell carcinoma and colorectal cancer and the availability of capital resources, the Company entered into Amendment No. 1 to the Collaboration Agreement effective March 11, 2025 that relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000. As a result, it is uncertain as to whether the Phase 2 portion of this clinical trial will proceed.

The Company's agreement with GEIS provided for various payments based on achieving specific milestones over the term of the agreement. During the years ended December 31, 2025 and 2024, the Company incurred costs of $0 and $268,829, respectively, pursuant to this agreement.

The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $293,000 for the Phase 1b portion of this clinical trial as of March 31, 2026, which is scheduled to be incurred through December 31, 2026. As the work is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro. Such fluctuations are recorded in the consolidated statements of operations as foreign currency gain or loss, as appropriate, and have not been significant.

MD Anderson Cancer Center Clinical Trial. On September 20, 2023, the Company announced an investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). The study objective is to determine the overall survival ("OS") of patients with OCCC. The clinical trial is being sponsored by The University of Texas MD Anderson Cancer Center ("MD Anderson") and is being conducted at The University of Texas - MD Anderson Cancer Center. The Company is providing LB-100 and GSK is providing dostarlimab-gxly and financial support for the clinical trial. On January 29, 2024, the Company announced the entry of the first patient into this clinical trial. The Company currently expects that this clinical trial will be completed by December 31, 2027.

On February 25, 2025, the Company announced that it has added the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University as a second site in a clinical trial combining the Company's proprietary compound LB-100 with GSK's dostarlimab to treat ovarian clear cell cancer. Patient recruitment is underway, and the first patient has been dosed.

Clinical Trial Monitoring Agreements

MD Anderson Cancer Center Clinical Trial. On May 15, 2024, the Company signed a letter of intent with Theradex to monitor the MD Andersen investigator-initiated Phase 1b/2 collaborative clinical trial to assess whether adding LB-100 to a human programmed death receptor-1 ("PD-1") blocking antibody of GSK plc ("GSK"), dostarlimab-gxly, may enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma ("OCCC"). On August 19, 2024, the Company signed a work order agreement with Theradex to monitor the MD Anderson clinical trial. The study oversight is expected to be completed by January 31, 2027.

Costs under this letter of intent and related work order agreement are estimated to be approximately $95,000. During the year ended December 31, 2025 and 2024, the Company incurred costs of $21,706 and $26,763, respectively, pursuant to this letter of intent and subsequent work order. As of December 31, 2025, total costs of $46,598 have been incurred pursuant to this letter of intent and subsequent work order.

The Company's aggregate commitment pursuant to this letter of intent, less amounts previously paid to date, totaled approximately $48,000 as of December 31, 2024, which is expected to be incurred through December 31, 2027.

City of Hope. On February 5, 2021, the Company signed a \work order agreement with Theradex to monitor the City of Hope investigator-initiated clinical trial in small cell lung cancer in accordance with FDA requirements for oversight by the sponsoring party. Costs under this work order agreement were estimated to be approximately $335,000. During the years December 31, 2025 and 2024, the Company incurred costs of $0 and $10,642, respectively, pursuant to this work order. As of December 31, 2025, total costs of $89,323 had been incurred pursuant to this work order agreement. As a result of the closure of the Agreement with City of Hope effective July 8, 2024, the work order was terminated on July 8, 2024.

GEIS. On June 22, 2023, the Company finalized a work order agreement with Theradex, to monitor the GEIS investigator-initiated clinical Phase I/II randomized trial of LB-100 plus doxorubicin vs. doxorubicin alone in first line of advanced soft tissue sarcoma. The study oversight is expected to be completed by December 31, 2026.

Costs under this work order agreement are estimated to be approximately $153,000, with such payments expected to be allocated approximately 72% to Theradex for services and approximately 28% for payments for pass-through software costs. During the years ended December 31, 2025 and 2024, the Company incurred costs of $18,137 and $34,593, respectively, pursuant to this work order.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $86,000 as of December 31, 2025, which is expected to be incurred through December 31, 2027.

Netherlands Cancer Institute. On August 27, 2024, the Company finalized a work order agreement with Theradex, to monitor the NKI Phase 1b clinical trial of LB-100 combined with atezolizumab, a PD-L1 inhibitor, for patients with microsatellite stable metastatic colorectal cancer. The study oversight is expected to be completed by May 31, 2027.

Costs under this work order agreement are estimated to be approximately $106,380, with such payments expected to be allocated approximately 47% to Theradex for services and approximately 53% for payments for pass-through software costs. During the year ended December 31, 2025 and 2024, the Company incurred costs of $0 and $20,191 pursuant to this work order. As of December 31, 2025, total costs of $20,191 have been incurred pursuant to this work order agreement.

The Company's aggregate commitment pursuant to this clinical trial monitoring agreement, less amounts previously paid to date, totaled approximately $118,000 as of December 31, 2025, which is expected to be incurred through May 31, 2027.

National Institute of Health. Effective February 23, 2024, the Company entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, the Company has licensed on an exclusive basis the NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, estimated at twenty years, unless sooner terminated.

The License Agreement contemplates that the Company will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet certain benchmarks. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, the Company would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

The Company paid NIH a non-creditable, non-refundable license issue royalty of $50,000. The first minimum annual royalty of $25,643 was prorated from the effective date of the License Agreement to the next subsequent January 1. Thereafter, the minimum annual royalty of $30,000 is due each January 1 and may be credited against any earned royalties due for sales made in that year. The second minimum annual royalty for 2025 of $30,000, was paid in December 2024.

The Company is obligated to pay the NIH, on a country-by-country basis, earned royalties of 2% on net sales of each royalty-bearing product and process, subject to reduction by 50% under certain circumstances relating to royalties paid by the Company to third parties, but not less than 1%. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first commercial sale of a royalty-bearing product or process and expires on the date on which the last valid claim of the licensed product or licensed process expires in such country.

The Company is obligated to pay the NIH benchmark royalties, on a one-time basis, within sixty days from the first achievement of each such benchmark. The License Agreement defines four such benchmarks, which the Company is required to pursue based on "commercially reasonable efforts" as defined in the License Agreement, with deadlines of October 1, 2024, 2027, 2029 and 2031, respectively, each with a different specified benchmark payment amount payable within thirty days of achieving such benchmark. The October 1, 2024 benchmark of $100,000 was defined as the dosing of the first patient with a licensed product in a Phase 2 clinical study of such licensed product in the licensed fields of use. The Company had not commenced a Phase 2 clinical study as of December 31, 2024. The total of all such benchmark payments is $1,225,000.

The Company is obligated to provide annual reports to the NIH on its progress toward the development and commercialization of products under the licensed patents. These reports, due within sixty days following the end of each calendar year, must include updates on research and development activities, regulatory submissions, manufacturing efforts, sublicensing, and sales initiatives. If any deviations from the established commercial development plan or agreed-upon benchmarks occur, the Company is obligated to provide explanation and may amend the commercial development plan and the benchmarks, which, subject to certain conditions, the NIH shall not unreasonably withhold, condition, or delay approval of any request of the Company to amend the commercial development plan and/or the benchmarks and to extend the time periods of the benchmarks.

The Company is obligated to pay the NIH sublicensing royalties of 5% on sublicensing revenue received for granting each sublicense within sixty days of receipt of such sublicensing revenue.

During the years ended December 31, 2025 and 2024, the Company incurred costs of $30,000 and $75,643 in connection with its obligations under the License Agreement. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $1,765,000 as of December 31, 2025, which is expected to be incurred over approximately the next nineteen years.

Other Significant Agreements and Contracts

NDA Consulting Corp. On December 24, 2013, the Company entered into a consulting agreement with NDA Consulting Corp. for consultation and advice in the field of oncology research and drug development. As part of the consulting agreement, NDA also agreed to have its president, Dr. Daniel D. Von Hoff, M.D., serve on the Company's Scientific Advisory Committee during the term of such consulting agreement. The term of the consulting agreement was for one year and provided for a quarterly cash fee of $4,000. The consulting agreement had been automatically renewed for additional one-year terms on its anniversary date, most recently on December 24, 2023, but was subsequently terminated by mutual agreement effective September 30, 2024. Consulting and advisory fees charged to operations pursuant to this consulting agreement were $0 and $12,000 for the years ended December 31, 2025 and 2024, respectively.

BioPharmaWorks. Effective September 14, 2015, the Company entered into a Collaboration Agreement with BioPharmaWorks, pursuant to which the Company engaged BioPharmaWorks to perform certain services for the Company. Those services included, among other things, assisting the Company to commercialize its products and strengthen its patent portfolio; identifying large pharmaceutical companies with a potential interest in the Company's product pipeline; assisting in preparing technical presentations concerning the Company's products; consultation in drug discovery and development; and identifying providers and overseeing tasks relating to clinical development of new compounds.

BioPharmaWorks was founded in 2015 by former Pfizer scientists with extensive multi-disciplinary research and development and drug development experience. The Collaboration Agreement was for an initial term of two years and automatically renews for subsequent annual periods unless terminated by a party prior to the expiration of the applicable period. In connection with the Collaboration Agreement, the Company agreed to pay BioPharmaWorks a monthly fee of $10,000. Effective March 1, 2024, the compensation payable under the Collaboration Agreement was converted to an hourly rate structure.

The Company recorded charges to operations pursuant to this Collaboration Agreement of $59,600 and $39,200 during the years ended December 31, 2025 and 2024, respectively, which were included in research and development costs in the consolidated statements of operations.

Netherlands Cancer Institute. On October 8, 2021, the Company entered into a Development Collaboration Agreement with the Netherlands Cancer Institute, Amsterdam ("NKI") (see Note 7), one of the world's leading comprehensive cancer centers, and Oncode Institute, Utrecht, a major independent cancer research center, for a term of three years. The Development Collaboration Agreement was subsequently modified by Amendment No. 1 thereto.

The Development Collaboration Agreement is a preclinical study intended to identify the most promising drugs to be combined with LB-100, and potentially LB-100 analogues, to be used to treat a range of cancers, as well as to identify the specific molecular mechanisms underlying the identified combinations. The Company agreed to fund the preclinical study, at an approximate cost of 391,000 Euros and provide a sufficient supply of LB-100 to conduct the preclinical study.

On October 3, 2023, the Company entered into Amendment No. 2 to the Development Collaboration Agreement with NKI, which provides for additional research activities, extends the termination date of the Development Collaboration Agreement by two years to October 8, 2026, and added 500,000 Euros to the operating budget being funded by the Company.

On October 4, 2024, the Company entered into Amendment No. 3 to the Development Collaboration Agreement with NKI, which suspended Amendment No. 2 and provided for a new study term of one year and starts upon the dosing of the first patient in the trial at a project cost of 100,000 Euros.

During the years ended December 31, 2025 and 2024, the Company incurred charges in the amount of $0 and $210,362, respectively, with respect to this agreement, which amounts are included in research and development costs in the Company's consolidated statements of operations. The Company's aggregate commitment pursuant to this agreement, less amounts previously paid to date, totaled approximately $118,000 as of December 31, 2025, which is expected to be incurred through October 2026. As the work is being conducted in Europe and is paid for in Euros, final costs are subject to foreign currency fluctuations between the United States Dollar and the Euro.

MRI Global. As amended, the Company has contracted with MRI Global for stability analysis, storage and distribution of LB-100 for clinical trials in the United States. During the years ended December 31, 2025 and 2024, the Company incurred costs of $750 and $23,308, respectively, pursuant to this contract.

Specific Risks Associated with the Company's Business Activities

Serious Adverse Events

The Company's lead drug candidate, LB-100, is currently undergoing various clinical trials, and there is a risk that one or more of these trials could be placed on hold by regulatory authorities due to serious adverse events (SAEs) related to the Company's drug candidate or to another company's drug used in combination in one of the Company's clinical trials. It is possible that the SAEs could be attributable to the Company's drug candidate and could include, but not be limited to, unexpected severe side effects, treatment-related deaths, or long-term health complications. A dose given could result in non-tolerable adverse events defined as dose-limiting toxicity (DLT). When two DLTs occur at the same dose-level, that dose-level is considered too high and unsafe. Further treatment is only allowed at lower dose-levels that have previously been found safe.

If an SAE or a pattern of SAEs is observed during the course of a clinical trial involving the Company's drug candidate, the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or other regulatory authorities may issue a clinical hold, requiring the Company to pause or discontinue further enrollment and dosing in its clinical trial. It is also possible that the clinical trial could be terminated. Any of these actions could delay or halt the development of the Company's drug candidate, increase development costs, and negatively impact the Company's ability to ultimately achieve regulatory approval. Additionally, if an SAE is confirmed to be drug-related, the Company may be required to conduct additional studies, modify the study design, or abandon further development of the drug candidate altogether, which could materially impact the Company's business, financial condition, and prospects.

The occurrence of an SAE and any resulting clinical hold could also harm the Company's reputation with patients, physicians, health institutions, and investors, diminish its ability to attract clinical trial participants, and damage its ability to interest investors and obtain financing in the future. There can be no assurance that the Company will not experience such SAEs in the future or that any related clinical hold will be lifted in a timely manner, or at all.

The principal investigator of the colorectal study testing LB-100 in combination with atezolizumab (Roche PD-L1 inhibitor) is currently investigating two SAEs observed in the clinical trial that was launched in August 2024. The Netherlands Cancer Institute ("NKI") Institutional Review Board (the "IRB") has put the colorectal cancer study on hold. The adverse reactions that developed in the two patients were dyspnea (shortness of breath) due to lung toxicity possibly or probably related to the combination of LB-100 and atezolizumab in one patient and fever and aphasia possibly or probably related to the combination of LB-100 and atezolizumab in the second patient. The patient who developed lung toxicity deceased due to the combination of lung metastases of colorectal cancer and dyspnea. The patient with fever and aphasia fully recovered from the adverse events with supportive medication.

Given the identified adverse events in the two patients in the clinical trial, the IRB requested from the principal investigator of the study at the NKI information as to whether the adverse events could have been caused by the combination of LB-100 and atezolizumab and information about the mode of action of the combination of LB-100 and atezolizumab. The principal investigator is preparing a response to the IRB detailing the safety experience with LB-100 given alone and in combination with other cancer drugs, especially doxorubicin and dostarlimab. Doxorubicin is a well-known chemotherapy, and dostarlimab is a well-known immunotherapy of which the mode of action is closely related to that of atezolizumab.

The reported adverse events in the colorectal cancer study have not been seen in any other patients thus far treated with LB-100 alone or in combination with other cancer drugs. Through February 2025, a total of 78 patient have received or are receiving experimental treatment with LB-100. It is expected that it will take at least two months to prepare a detailed response to the IRB, during which time the Company intends to update the safety overview of LB-100.

Other Business Risks

Inflation and Interest Rate Risk. The Company does not believe that inflation or increasing interest rates have had a material effect on its operations to date, other than their impact on the general economy. However, there is a risk that the Company's operating costs could become subject to inflationary and interest rate pressures in the future, which would have the effect of increasing the Company's operating costs (including, specifically, clinical trial costs), and which would put additional stress on the Company's working capital resources.

Supply Chain Issues. The Company does not currently expect that supply chain issues will have a significant impact on its business activities, including its ongoing clinical trials.

Potential Recession. There are some indications that the United States economy may be at risk of entering a recessionary period. Although unclear at this time, an economic recession would likely impact the general business environment and the capital markets, which could, in turn, affect the Company.

Geopolitical Risk. The geopolitical landscape poses inherent risks that could significantly impact the operations and financial performance of the Company. In the event of a military conflict, supply chain disruptions, geopolitical uncertainties, and economic repercussions may adversely affect the Company's ability to conduct research, develop, test and manufacture products, and distribute them globally. This could lead to delays in product development, interruptions in the supply of critical materials, and delays in clinical trials, thereby impeding the Company's clinical development and commercialization plans. Furthermore, the impact of a conflict on global financial markets may result in increased volatility and uncertainty in the capital markets, thereby affecting the valuation of the Company's publicly-traded shares. Investor confidence, market sentiment, and access to capital could all be negatively influenced. Such geopolitical risks are outside the control of the Company, and the actual effects on the Company's business, financial condition and results of operations may differ from current estimates.

Cybersecurity Risks. The Company has established policies and processes for assessing, identifying and managing material risk from cybersecurity threats, and has integrated these processes into its overall risk management systems and processes. The Company routinely assesses material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through its information and email systems that may result in adverse effects on the confidentiality, integrity, or availability of the Company's information and email systems or any information residing therein. The Company conducts periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in the Company's business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems and safeguards in place to manage such risks. The Company has not encountered any cybersecurity challenges to date that have materially impaired its operations or financial condition.

The Company is continuing to monitor these matters and will adjust its current business and financing plans as more information becomes available.

12. Subsequent Events

The Company performed an evaluation of subsequent events through the date of filing of these consolidated financial statements with the SEC. Other than as described below or elsewhere in the notes to the consolidated financial statements, there were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements.

Issuance of Common Stock

On January 6, 2026, the Company entered into a consulting agreement with Pillow Hog Ventures, Inc ("PHVC") for marketing and strategic consulting services. The agreement is for a term of six months ending June 30, 2026. The agreement provides for the payment to PHVC of 30,000 shares of the Company's common stock.

Exercise of Preferred Series B Stock

On January 29, 2026, Preferred Series B shareholders converted 112,650 shares into 117,862 shares of the Company's common stock. On February 17, 2026, an additional 2,319,480 shares of Preferred Series B were converted into 2,426,959 shares of the Company's common stock, Each Preferred Share was convertible into one share of Common Stock, plus an additional adjustment for an 8% per annum cumulative dividend payable at conversion into shares of Common Stock valued at the conversion rate of $0.7146. As of March 10, 2026, the outstanding balance of Preferred Series B stock was zero.

Exercise of Pre-Funded Warrants

On January 6, 2026, a warrant holder from the July 2, 2025 private placement exercised 20,521 pre-funded warrants exercisable at $0.00001 per share resulting in the issuance of into 20,521 shares of the Company's common stock. As of March 10, 2026, zero pre-funded warrants remain unexercised from the July 2, 2025 private placement.

On February 6, 2026, a warrant holder from the December 22, 2025 private placement exercised 262,500 pre-funded warrants exercisable at $0.00001 per share resulting in the issuance of into 262,500 shares of the Company's common stock. As of March 31, 2026, 262,500 pre-funded warrants remain unexercised from the December 22, 2025 private placement.

Other Significant Agreements and Contracts

On January 21, 2026, the Company received the final report of the first phase of the Collaboration Agreement between the Company and GEIS that triggered the final milestone payment of Euro 249,141.95, approximately $334,859 USD. This completed all financial obligations of the company of this Collaboration Agreement effective March 11, 2025. The Company entered into Amendment No. 1 to the Collaboration Agreement between the Company and GEIS, which relieved the Company of the financial obligation to support the randomized Phase 2 portion of the clinical trial contemplated in the Collaboration Agreement of approximately $3,095,000.

On February 12, 2026, Liora Technologies Europe Ltd, a subsidiary of the Company, and Sidney Braun ("the Parties"), entered into an Allocation Deed Agreement. Pursuant to the terms of the Deed, if there is a Sale of the shares or business of Liora, Mr. Braun shall be paid an amount equal to twenty percent (20%) of the net purchase price paid for Liora.

On February 13, 2026, the Parties entered into a Consultancy Agreement. Pursuant to the Consultancy Agreement, Mr. Braun will be appointed to the board of directors of Liora and as Liora's Chief Executive Officer. The Consultant will be paid a signing bonus of GBP 50,000 exclusive of VAT, or approximately 67,121 USD, and a monthly retainer of GBP 25,000 exclusive of VAT, or approximately 33,561 USD. The Consultancy Agreement shall continue on a month-to-month basis.

On February 18, 2026, the Company paid in full the contractual clinical trials amount of $293,000.

On March 6, 2026, the Company, Liora Technologies Europe Ltd, a subsidiary of the Company and Orbit Capital Inc., (the "Parties") entered into an Amended and Restated Share Exchange Agreement with an effective date of November 21, 2025 (the "A&R Agreement"). The A&R Agreement amends and restates certain terms of the Share Exchange Agreement entered into among the Company, Liora and Orbit Capital on November 21, 2025 (the "Original SEA").

On March 18, 2026, the Company, and Geordan Pursglove, the Company's Chief Executive Officer, entered into an Amendment to the Employment Agreement. The original employment agreement between the Company and Mr. Pursglove was entered in on June 16, 2025. Pursuant to the Amendment, Mr. Pursglove's annual base salary was increased from $240,000 to $360,000 effective as of January 1, 2026.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-282781), Form S-3 (No. 333-278874), and Form S-8 (333-255407 and No. 333-268860) of our report dated March 31, 2026, relating to the consolidated financial statements of Lixte Biotechnology Holdings, Inc. as of and for the years ended December 31, 2025 and 2024 (which report includes an explanatory paragraph relating to substantial doubt about the Company's ability to continue as a going concern), included in Lixte Biotechnology Holdings, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission. We also consent to the reference to our firm under the heading "Experts" in such Registration Statements and related Prospectuses.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 31, 2026

Exhibit 31.1

CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Geordan Pursglove, Chief Executive Officer of Lixte Biotechnology Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Lixte Biotechnology Holdings, Inc. (the "Annual Report");

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this Annual Report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and I have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this Annual Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this Annual Report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

(d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2026

By: */s/ GEORDAN PURSGLOVE*
Name: Geordan Pursglove
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS OF THE CHIEF FINANCIAL OFFICER
UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Stazzone, Chief Financial Officer of Lixte Biotechnology Holdings, Inc. (the "Registrant"), certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Lixte Biotechnology Holdings, Inc. (the "Annual Report");

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this Annual Report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and I have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this Annual Report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this Annual Report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

(d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2026

By: */s/ PETER STAZZONE*
Name: Peter Stazzone
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF THE CHIEF EXECUTIVE OFFICER
UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (the "Annual Report") with the Securities and Exchange Commission, I, Geordan Pursglove, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 31, 2026

By: */s/ GEORDAN PURSGLOVE*
Name: Geordan Pursglove
Title: President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATIONS OF THE CHIEF FINANCIAL OFFICER
UNDER SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing by Lixte Biotechnology Holdings, Inc. (the "Registrant") of its Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (the "Annual Report") with the Securities and Exchange Commission, I, Peter Stazzone, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

Date: March 31, 2026

By: */s/ PETER STAZZONE*
Name: Peter Stazzone
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)