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

FORM 8-K

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

Date of Report (Date of earliest event reported): December 17, 2025

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	001-39717	20-2903526
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

433 Plaza Real, Suite 275
Boca Raton, Florida 33432
(Address of principal executive offices)

(631) 830-7092
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (See General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act of 1933 (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(e) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

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 whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry Into a Material Definitive Agreement

On December 17, 2025, Lixte Biotechnology Holdings, Inc., a Delaware corporation (the "Company"), entered into Amendment No.2 ("Amendment No.2") to the GSK & LIXTE Supported Collaborative Study (the "Collaborative Study") by and between the Company, GlaxoSmithKline LLC ("GSK") and the University of Texas M.D. Anderson Cancer Center, a government agency of the State of Texas and a member of the University of Texas System (the "Anderson Cancer Center"). The Collaborative Study was originally entered into on September 18, 2023, and amended on April 4, 2025 ("Amendment No.1"). The Collaborative Study is conducted under protocol 219582 entitled "Safety and Efficacy of Targeting PP2A in Ovarian Clear Cell Carcinoma (OCCC) using dostarlimab and LB-100 (the "Original Study").

Amendment No.2, modifies the Collaborative Study as follows: (i) Appendix A in the Agreement is updated to reflect the following: (a) Number of Study Subjects of 21 (twenty-one) is deleted in its entirety and replaced with ""forty-two (42)"; (b) Other than the cost of Study drugs, Institution will be responsible for Study costs for patients 22-42. GSK's and Lixte's obligations in Agreement shall extend to patients 22-42, including, but not limited to, provision of their respective drugs to Institution at no cost to Institution. (c) The SAF included in Appendix A of the Agreement is updated to reflect the following: (i) Quantity number of vials to be provided by GSK to Institution is increased from 400 to 800. (d) LIXTE to provide sufficient quantity to Institution of LIXTE IP to support 2 times points per cycle at 42 Study Subjects (projected 3x from original amount).

Appendix B, Subsection 1 in the Agreement is deleted in its entirety and replaced with the following:

"1. Enrolment of Study Subjects:

Institution will enroll (which, for clarity, does not include any screening failures) a maximum of forty-two (42) Study Subjects (includes Study Subjects at Northwestern) on the Protocol and use reasonable efforts to achieve an expected rate of 2 Study Subjects per month". GSKs payments are based at the original number of Study Subjects of 21. For clarity, GSK will not make any additional payments for the increase in Study Subjects.

Appendix B.1 in Amendment No. 1 is deleted in its entirety and replaced with Appendix B.2 under Amendment No.2.

All other terms and conditions of the Collaborative Study, as amended by Amendment No. 1 to the Collaborative Study dated April 4, 2025, remain unchanged and in full force and effect. A copy of Amendment No. 2 is attached as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Concurrently, On December 17, the Company entered into a Collaborative Research Agreement with the Anderson Cancer Center (the "Research Agreement"). Pursuant to Amendment No.2, the participants in the Original Study has expanded from 21 patients to 42 patients (the "Expanded Study"). The Company and the Anderson Cancer Center will conduct the Expanded Study utilizing the Company's LB-100 and personnel, expertise and resources of the Anderson Cancer Center to complete the deliverables under Amendment No.2. The Expanded Study shall continue until the later of the completion of the Expanded Study or the Collaborative Study. The Research Agreement may not be terminated without the written consent of the Company and the Anderson Cancer Center.

In consideration of the Anderson Cancer Center conducting the Expanded Study at its costs, the Company will pay the Anderson Cancer Center milestone payments ("Milestone Payments") related to the Expanded Study as follows; (i) $500,000 upon Initiation of the first Pivotal Clinical Trial; (ii) $500,000 upon achievement of Breakthrough Therapy designation or upon achievement of Accelerated Approval designation; and (iii) $500,000 upon U.S. Food and Drug Administration ("FDA") approval in clear cell ovarian cancer (each a "Milestone Event"). In addition to the Milestone Payments, the Company will pay the Anderson Cancer Center a 3.75% royalty, on a Product-by-Product and country-by country basis, based on annual Net Profit of each Product. Royalties will begin to accrue upon FDA approval for LB-100 or any Product in clear cell ovarian cancer. The royalty payments will continue until the later of, the expiration of PCT/US2017/065270 or December 8, 2037. Milestone Payments and royalties are payable to the Anderson Cancer Center regardless of the Company, an Affiliate, licensee or a sublicensee achieving the Milestone Event or generating the revenue.

Amendment No. 2 To Agreement for GSK & Lixte Supported Collaborative Study Agreement, and the Collaborative Research Agreement are being filed as exhibits to this Current Report on Form 8-K and are incorporated herein by reference. The foregoing descriptions do not purport to be complete and are qualified in their entirety by reference to the full text of each agreement, which are filed herewith as Exhibits 10.1 and 10.2.

Item 7.01 Regulation FD Disclosure

On December 23, 2025, the Company issued a press release announcing it is expanding its collaboration with The University of Texas MD Anderson Cancer Center, Northwestern University, and pharmaceutical manufacturer GSK on an ongoing clinical trial with its proprietary compound, LB-100, to treat ovarian clear cell cancer.

A copy of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 7.01 disclosure, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section. In addition, the information in this Item 7.01 disclosure, including Exhibits 99.1, shall not be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits. The following exhibits are filed herewith.

Exhibit Number	**Description**
10.1	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.
10.2	Collaborative Research Agreement, dated December 17, 2025, by and between the Company, and The University of Texas M.D. Anderson Cancer Center.
99.1	Press Release Dated December 23, 2025
104	Cover Page Interactive Data File (embedded within the inline XBRL Document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 23, 2025

LIXTE BIOTECHNOLOGY HOLDINGS, INC.
(Registrant)

By: */s/ Geordan Pursglove*
Geordan Pursglove
Chairman of the Board and Chief Executive Officer

Exhibit 10.1

AMENDMENT NO. 2 TO AGREEMENT FOR GSK & LIXTE SUPPORTED COLLABORATIVE STUDY

THIS AMENDMENT Number 2 to Agreement for GSK, LIXTE Supported Collaborative Study ("Amendment No. 2") is effective as of last signature date given below ("Effective Date") and is made by and between **GlaxoSmithKline LLC,** with offices at 1250 S. Collegeville Road, Collegeville, PA., 19426-0989 ("GSK"), **LIXTE Biotechnology Holdings, Inc**., having offices at 433 Plaza Real, Suite 275, Boca Raton, FL 33432 ("LIXTE") and **The University of Texas, M. D. Anderson Cancer Center**, a government agency of the State of Texas and a member institution of the University of Texas System ("System") having an address at 1515 Holcombe Blvd, Houston, TX., 77030 ("Institution").

GSK, LIXTE and Institution collectively referred to as "**Parties**" or in the singular "**Party**," under the following terms and conditions collectively referred to as "Parties" or in the singular "Party".

BACKGROUND

WHEREAS, the Parties entered into an Agreement For GSK & LIXTE Supported Collaborative Study with an effective date of 18 September 2023 ("Agreement") and Amendment No.1 with an effective date of 04 April 2025 ("Amendment No.1") relating to the clinical study conducted under Protocol 219582 entitled "Safety and Efficacy of Targeting PP2A in Ovarian Clear Cell Carcinoma (OCCC) using Dostarlimab and LB-100 ("Study"); and

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and other good and valuable consideration, the receipt, adequacy, and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Identification of Changes

1.1 Appendix A in the Agreement is updated to reflect the following:

(a) Number of Study Subjects of 21 (twenty-one) is deleted in its entirety and replaced with ""forty-two (42)".

(b) Other than the cost of Study drugs, Institution will be responsible for Study costs for patients 22-42. GSK's and Lixte's obligations in Agreement shall extend to patients 22-42, including, but not limited to, provision of their respective drugs to Institution at no cost to Institution.

(c) The SAF included in Appendix A of the Agreement is updated to reflect the following:

(i) Quantity number of vials to be provided by GSK to Institution is increased from 400 to 800.

PSS-219582-MDA-LIXTE-DR.JAZAERI-SCS

(d) LIXTE to provide sufficient quantity to Institution of LIXTE IP to support 2 times points per cycle at 42 Study Subjects (projected 3x from original amount).

1.2 Appendix B, Subsection 1 in the Agreement is deleted in its entirety and replaced with the following:
"1. Enrolment of Study Subjects:
Institution will enroll (which, for clarity, does not include any screening failures) a maximum of forty-two (42) Study Subjects (includes Study Subjects at Northwestern) on the Protocol and use reasonable efforts to achieve an expected rate of 2 Study Subjects per month". GSKs payments are based at the original number of Study Subjects of 21. For clarity, GSK will not make any additional payments for the increase in Study Subjects.

1.3 Appendix B.1 in Amendment No. 1 is deleted in its entirety and replaced with Appendix B.2 under this Amendment No.2.

2. Effect of Amendment

2.1 Except as modified herein, all other terms, provisions, conditions, and covenants of the Agreement, as amended, continue in full force and effect.

2.2 In the event of a conflict between or among the Agreement and this Amendment No. 2, the documents shall govern in this order: (1) this Amendment No.2; (2) Amendment No. **1**, and (3) the Agreement.

3. Counterparts and Signatures

3.1 This Amendment No. 2 may be signed (including electronic signatures, including PDF signatures) in counterparts, each executed by at least one (1) or more of the Parties. Each counterpart will be an original of this Amendment No. 2 and all counterparts taken together will constitute one (1) instrument.

This Amendment No. **2** has been entered into:

For and on behalf of **GSK LLC** by:

Signature: Electronically signed by: marc harris Reason: I am signing this document as author and attest to its accuracy, completeness and integrity. Date: Nov 24, 2025 08:50:33 EST

Name: Marc Harris
Title: Associate Director
Date: 24-Nov-2025

For and on behalf of **LIXTE Biotechnology Holdings, Inc** by:

Signature: Geordan Pursglove Electronically signed by: Geordan Pursglove Reason: I am signing for the reasons as stated in the document. Date: Dec 4, 2025 13:44:39 EST

Name: Geordan Pursglove
Title: CEO
Date: 04-Dec-2025

For and on behalf of **THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER** by:

Signature: DocuSigned by: Amy M Moritz 62S7A58CD91941A...

Name: Amy M Moritz
Title: Associate Director, ORA
Date: 12/11/2025

Read and Acknowledged:
INVESTIGATOR

DocuSigned by: Amir A Jazaeri 998CFD7843E14D9...

Name: Dr. Amir Jazaeri

Appendix B.2

GSK agrees to provide Funding to Institution in support of the conduct of the Study in the total amount of $1,512,519.40 USD.

1. GSKs final payment to occur when 21 Study Subjects have completed the Study and receipt of the initial report.
2. Institution and GSK agree and acknowledge that the GSK payment amounts are not impacted by the additional Study Subjects or number of drug vials as amended under this Amendment No 2 . For clarity, GSK payment amounts have not changed due to this increased number of Study Subjects or number of vials.
3. Payments by GSK and status is as follows:

Milestone	$ Payment USD-Payment Status
Upon receipt by GSK of (i) the final and fully executed Agreement, (ii) all required documentation, and, (iii) confirmation that the summary Protocol has been posted on clinicaltrials.gov or other public register in accordance with the Agreement.	160,345.04 - Paid
Upon execution of this Amendment No 1, Start-up fees for Social Media Platform/Campaign & Search Engine Optimization	19,500.00- Paid
Upon enrollment of 1 (one) Study subject.	172,345.08 - Paid
Upon enrollment of 4 additional (four) Study subjects (total 5).	172,345.08- Paid
Upon enrollment of 4 additional (four) Study Subjects (total 9).	172,345.08 - Paid
Upon enrollment of 4 additional (four Study Subjects (total 13).	172,345.08- Paid
Upon enrollment of 4 additional (four) Study Subjects (total 17).	172,345.08- Paid
Upon enrollment of 4 additional (four) Study Subjects (total 21).	172,345.08
Upon receipt of documentation that (i) 21 Study Subjects have completed the Study; and (ii) GSK's receipt of an initial report on the first 21 Study Subjects.	298,603.88
TOTAL	**1,512,519.40**

GSK4057190A (Dostarlimab) Supplies Agreement Form: GSK Supply for Supported Studies (Investigator Initiated Study (IIS) and Supported Collaborative Study (SCS))

Refer to VQD-SOP-004991 and VQD-SOP-070869 for use of this form

Supplies Agreement Form Version *1.0, 14-Oct-2025*

Materials Supplied for GSK eTrack ref no. (Internal Study ID) *219582*

GlaxoSmithKline Research & Development will supply Dr. Amir Jazaeri of MD Anderson Cancer Center, 1515 Holcombe Blvd, Houston, Texas 77030, with supplies as described below for Clinical Trial Use only.

Product Name:	Dostarlimab (GSK4057190A)
Product Code:	AA
Item Code	DP282453
Type of Material:	Full Clinical Labelled Clinical Trial Supplies
Dosage Form/Strength:	Solution, 50 mg/mL (10mL vial)
Quantity:	800 vials (approximate quantity that will be sent to cover the duration of the studies)
Technical Storage Conditions:	Store refrigerated, 2°C - 8°C (36°F to 46°F)
Technical Shelf Life: **Technical Storage Conditions and Shelf Life are established through Product Stability.**	36 Months
Packaging Components:	10 mL of solution (extractable volume) filled into a 10 mL Type I borosilicate clear glass vial with a 20 mm West 4432/50 gray chlorobutyl elastomeric stopper laminated with a fluropolymer (FluroTec®) and a 20 mm aluminum overseal with a flip-off cap.
Reference Documents:	Certificate of Conformance (C of C), Certificate of Analysis (C of A)
GSK Cross-referenced Letter Available? **If yes, enter the GSK Cross-referenced Study e-Track reference number and applicable countrie(s):**	Yes 213346 [GARNET] United States

Corresponding GSK IND No/ PIND No / Eudract No (if Europe):	US IND: 126 472
Corresponding Sponsor IND No/ PIND No / Eudract No (if Europe):	US IND: 168 122

Receipt and Storage

Upon receipt of the Investigational Medicinal Product (IMP), the site must check the contents of the consignment against the shipping slip provided. In addition, the staff must confirm the contents have not been tampered with, are not damaged, and any temperature monitoring devices are compliant with required storage conditions.

If the contents of the consignment do not agree with the shipping slip or there is evidence of damage and/or tampering, please notify the Local Depot Shipping department at the phone number on the shipping invoice.

The IMP must be stored in a secure area with restricted access.

Re-supply ordering

Dr. Amir Jazaeri or designee of MD Anderson Cancer Center is responsible for managing site inventory and ordering re-supplies throughout the course of the study as required.

Potential Site Based Temperature Excursion Management

All potential site based temperature excursions must be reported to the selected Almac Clinical Services for assessment and a final disposition decision will be communicated to the Dr. Amir Jazaeri or designee of MD Anderson Cancer Center.

Notifications and Recalls

If during the study, GSK becomes aware of any issue affecting the quality of the material, GSK notifies Dr. Amir Jazaeri or designee of MD Anderson Cancer Center in a timely manner. Dr. Amir Jazaeri or designee of MD Anderson Cancer Center is responsible for the recall of any investigational medicinal products, following consultation with GSK and/or any other company in the case of products supplied by them.

Dr. Amir Jazaeri or designee of MD Anderson Cancer Center must notify GSK of any changes to the protocol that may affect the use of the clinical trial material provided.

Destruction

Dr. Amir Jazaeri or designee of MD Anderson Cancer Center performs the destruction of supplies in accordance with GMP, Good Clinical Practice and with any local or national Regulatory requirements.

Shipping Information

Shipping from	Address	Shipping to	Address
Almac Clinical Services	Almac Clinical Services 25 Fretz Road Souderton Pennsylvania 18964 US	Dr. Amir Jazaeri	MD Anderson Investigational Pharmacy 1515 Holcombe Blvd, Room B1.4392 Houston, Texas 77030

Revision History

Version Number	Changes Made
Version 1	Initial issue

Approval

	GSK CSC (Signature of Author)	Study Delivery Lead (Approval of contents of the SAF on behalf of the IIS/SCS Sponsor, as per VQD-SOP-070869)
Name (Print) & Job Title	Namra Din Supply Chain Study Lead	Tyler Lockard Senior Supported Studies Delivery Lead (Oncology)
Signature	See VQD signature page for approvals	See VQD signature page for approvals
Date	See VQD signature page for approvals	See VQD signature page for approvals

Execution Copy

COLLABORATIVE RESEARCH AGREEMENT

THIS COLLABORATIVE RESEARCH AGREEMENT (this "Agreement") is dated and effective as of December 17, 2025 ("Effective Date") and is made by and between **LIXTE Biotechnology Holdings, Inc.**, having offices at 680 E. Colorado Boulevard, Suite 180, Pasadena, CA 91101 ("**LIXTE**") and **The University of Texas M. D. Anderson Cancer Center**, a government agency of the State of Texas and a member institution of the University of Texas System ("**System**") having an address at 1515 Holcombe Blvd, Houston, TX., 77030 ("**Institution**").

LIXTE and Institution collectively referred to as "**Parties**" or in the singular "**Party**", under the following terms and conditions.

BACKGROUND

WHEREAS, the Parties and GlaxoSmithKline entered into an Agreement for GSK & LIXTE Supported Collaborative Study with an effective date of 18 September 2023, and further amended on April 4, 2025 and on December 11, 2025 (collectively, "**GSK Agreement**") relating to the clinical study ("**Original Study**") conducted under protocol 219582 entitled "Safety and Efficacy of Targeting PP2A in Ovarian Clear Cell Carcinoma (OCCC) using *dostarlimab* and LB-100;

WHEREAS, under GSK Agreement: (a) GSK (as defined therein) provides its *dostarlimab* and LIXTE provides its PP2A inhibitor (LB-100) at their own cost and expense to the Institution to conduct the Original Study at their own expense as provided therein; and (b) the Parties and GSK have now agreed to expand the Original Study from 21 to 42 patients to study the safety and efficacy of the combination of *dostarlimab* in combination with LIXTE's PP2A inhibitor ("**LB-100**") in clear cell ovarian cancer ("**Expanded Study**"); and

WHEREAS, the Parties desire to establish a collaboration to conduct the Expanded Study utilizing LIXTE's LB-100 and the Institution's personnel, expertise and resources to perform the Expanded Study ("Collaboration") and complete the deliverables under the GSK Agreement;

WHEREAS, the Parties desire to clarify the financial arrangement between LIXTE and Institution, as it relates to the Expanded Study**; and**

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and other good and valuable consideration, the receipt, adequacy, and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Definitions

For purposes of this Agreement only, the definitions included in the attached Exhibit I are added.

2. Expanded Study

2.1 Collaboration. As recited hereinabove, the Parties agree that, as between the Parties, the Collaboration shall consist of: (a) LIXTE's contribution of LB-100 to the Institution to conduct the Expanded Study, (b) the Institution's contribution of its personnel, expertise and resources to perform the Expanded Study (including clinic trials of 21 patients) and complete the deliverables under the GSK Agreement.

2.2 Term and Termination. The term of the Collaboration shall commence on the Effective Date and continue until the later of the completion of the Expanded Study and the termination or expiration of the GSK Agreement. This Agreement may not be

terminated by the Parties (whether prior to, on or after the date of such completion and termination or expiration) without the written consent or agreement of the Parties. LIXTE's payment obligations hereunder shall survive the termination or expiration of this Agreement.

3. Financial Arrangement

3.1 Milestone Payments. In consideration of Institution conducting the Expanded Study at its cost for patients 22-41, LIXTE shall pay Institution the following one-time, nonrefundable payments (each, a "**Milestone Payment**"), for the following respective events with respect to the Expanded Study (each, a "**Milestone Event**") regardless of whether the relevant Milestone Event is achieved by LIXTE, an Affiliate, its licensee:

(i) $500,000 upon Initiation of the first Pivotal Clinical Trial.

(ii) $500,000 upon achievement of Breakthrough Therapy designation or upon achievement of Accelerated Approval designation.

(iii) $500,000 upon U.S. Food and Drug Administration ("**FDA**") approval in clear cell ovarian cancer.

LIXTE shall immediately notify Institution of the achievement of any of the Milestone Events set forth above. Each of the Milestone Payments shall (i) be made by LIXTE to Institution within thirty (30) days of LIXTE submission of the notice that notified Institution of the achievement of the Milestone Event and (ii) not reduce the amount of any other payment provided for in this Agreement.

3.2 Royalties. In addition to the above Milestone Payments, and in consideration of Institution conducting the Expanded Study at its cost for patients 22-41, LIXTE shall pay Institution the following royalties:

A 3.75% royalty, on a Product-by-Product and country-by-country basis, based on annual Net Profit of each Product. Royalties shall begin to accrue upon FDA Approval for LB-100 or any Product in clear cell ovarian cancer. The term for royalty payments under this Agreement shall be from the Effective Date of this Agreement until the later of the expiration of PCT/US2017/065270 or December 8 2037.

3.3 Payments. Milestone and royalty payments shall be payable in US dollars (including amounts in local currencies and converted to US dollars) and royalties shall be paid annually within sixty (60) days after December 31 of the applicable Calendar Year. No stacking or offsets will be applied. The above Milestones Payments and royalties are due to Institution regardless of the LIXTE party (LIXTE, an Affiliate, its licensee, or a Sublicensee) achieving the Milestone Event or generating the revenue. Any fees and/or taxes associated with a payment due to Institution hereunder shall be borne by LIXTE so that Institution receives the full amounts due as described in the Agreement.

With each such payment, LIXTE will furnish to Institution a reasonably detailed report ("**Payment Report**") showing the following information, on a country-by-country and Product-by-Product basis: (a) with respect to royalty payments, (i) the gross invoiced amount for each Product during the reporting period Sold by LIXTE or its Sublicensees; (ii) the deductions taken in calculating Net Profit for each Product during such reporting period and the Net Profit for each such Product; and (iii) the royalties payable with respect to such Net Profit.

During the term of this Agreement and for so long as Product is being offered and/or Sold, LIXTE agrees to keep complete and accurate records of its, and its Sublicensees', Sales and Net Profit in sufficient detail to enable the royalties and other payments due under this Article 3 to be determined. LIXTE agrees to permit an independent auditor selected by Institution, at Institution's expense, no more than once per Calendar Year,

to periodically examine LIXTE's books, ledgers, and records during regular business hours for the purpose of and to the extent necessary to verify any report required under this Agreement. If any amounts due Institution are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then LIXTE will pay the cost of the examination. LIXTE shall pay accrued interest at the highest rate allowed by applicable law on any and all late payments under this Agreement (regardless of whether the deficiency is identified by audit or otherwise), with such interest commencing on the date after the due date.

All payments required to be made to Institution under this Agreement will be made in US Dollars, without deductions for taxes, assessments, fees, or charges of any kind, by bank wire transfer in immediately available funds to the applicable account listed below (or such other account as Institution will from time to time advise LIXTE in writing):

JPMorgan Chase Bank, N.A.
707 Travis
Houston, Texas 77002
SWIFT: CHASUS33
ABA ROUTING NO: 021000021 (wire)
ABA ROUTING NO: 111000614 (ACH)
ACCOUNT NAME:Univ. of Texas MD Anderson Cancer Center-Office of Grants and Contracts
ACCOUNT NO: 680858060

Each payment shall include appropriate references, including title and Effective Date of Agreement and type of payment (e.g., milestone payment, royalty payment) and for any payments for patent expenses, please reference the Institution invoice number, invoice number).

4. Ownership and Licenses

4.1 Ownership. With the exception of original laboratory notebooks and medical records ("**MDACC Data**"), which shall be solely owned by Institution, all other de-identified data and results generated in the conduct of the Expanded Study, ("**Expanded Study Data**") shall be promptly disclosed by Institution to LIXTE and will be jointly owned by LIXTE and Institution.

Each Party shall own all right, title and interest in and to its Background Technology.

Inventions that are invented solely by one Party without use of or based upon the other party's Confidential Information (as defined in the GSK Agreement) shall be solely owned by the inventing Party ("**Sole Inventions**").

Inventions that are invented jointly by the Parties, or that are invented solely by one Party, but are based upon or use the other Party's Confidential Information, shall be jointly and equally owned by the Parties ("**Joint Inventions**").

The costs associated with joint patent applications shall be shared by both Parties.

4.2 Licenses.

Institution hereby grants to LIXTE the option to obtain: an exclusive license to any Joint Inventions, and an exclusive or non-exclusive license to any Sole Inventions of Institution, subject to a written license agreement or agreements negotiated in good faith by the Parties.

To the extent there is any conflict or inconsistency between the GSK Agreement and this Article 4, the GSK Agreement shall control.

5. Effect of Agreement

5.1 This Agreement is effective as of the Effective Date described above and shall expire on the date of the last payment due hereunder to Institution has been paid by LIXTE.

5.2 The provisions of Article 18 (Miscellaneous) of the GSK Agreement shall, as between the Parties, apply to this Agreement and the Parties hereunder, *mutatis mutandis*.

5.3 Except as modified herein, all other terms, provisions, conditions, and covenants of the Agreement, as amended, continue in full force and effect.

5.4 In the event of a conflict between or among this Agreement and the GSK Agreement, the documents shall govern in this order: (1) this Agreement (except as otherwise stated herein), and (2) the GSK Agreement.

6. Counterparts and Signatures

6.1 This Agreement may be signed (including electronic signatures, including PDF signatures) in counterparts, each executed by at least one (1) or more of the Parties. Each counterpart will be an original of this Agreement and all counterparts taken together will constitute one (1) instrument.

[Signatures on following page]

This Agreement has been entered into for and on behalf of:

LIXTE Biotechnology Holdings, Inc.

By: Geordan Pursglove :
Name: Geordan Pursglove
Title CEO
Email: gpursglove@lixte.com

THE UNIVERSITY OF TEXAS
M. D. ANDERSON CANCER CENTER

DocuSigned by:
By: Omer F. Sultan
3077F1FEB118480...
Name: Omer F. Sultan
Title: Sr. Vice President and Chief Financial Officer
Email: ofsultan@mdanderson.org

Read and Acknowledged by:

MD ANDERSON USE ONLY:
Reviewed and Approved as to Form by MD Anderson Legal Services:
DocuSigned by:
Sana Shaikh 12/17/2025

INVESTIGATOR

DocuSigned by:
998CFD7843E14D9...
Name: Amir Jazaeri, MD

Approved as to Content by SIVOTC:

DocuSigned by:
2B3BEB029380480...
Name: Emily Barnhill
Title: VP, Strategic Indstry Ventures, Strategic Industry Ventures

Exhibit I

DEFINITIONS

"Accelerated Approval" means the FDA process that allows drugs for serious or life-threatening conditions to be approved based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit, rather than requiring the full set of extensive clinical trial data.

"Affiliate" means any entity which, directly or indirectly through one (1) or more intermediaries, controls, is controlled by or is under common control with a Party to this Agreement, for so long as such control exists, regardless of whether such Affiliate is or becomes an Affiliate on or after the Effective Date. An entity shall be deemed to "control" another entity if it: (a) owns, directly or indirectly, beneficially or legally, more than fifty percent (50%) of the outstanding voting securities or capital stock of such other entity, or has equal or greater ownership interest with respect to any entity other than a corporation; or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the entity.

"Background Technology" shall mean a Party's owned and/or controlled Technology existing prior to execution of the GSK Agreement or developed outside of the GSK Agreement and this Agreement.

"Break Through Therapy" means a legal designation granted by the FDA under Section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA), defining a drug intended to treat a serious or life-threatening disease and for which preliminary clinical evidence indicates a substantial improvement over existing therapies.

"Calendar Year" means a period of twelve (12) consecutive months beginning on January 1 and ending on December 31 provided, however, that (a) the first Calendar Year of the Term will begin on the Execution Date and end on December 31 of the calendar year within which the Execution Date falls, and (b) the last Calendar Year of the Term will end on the effective date of the expiration or termination of this Agreement.

"Combination Product" means a combination or bundled product that contains (a) Product and (b) one or more components and/or services that are any test, service, or ingredients/components other than the Product, whether packaged together or in the same package or administered or having an approved use together.

"Control", "Controls" or "Controlled" means, with respect to any Technology, Patent, and/or other intellectual property, the legal authority or right of such party (whether through ownership or license, other than pursuant to a license under this Agreement) to grant another party with access, a license or sublicense in and to such Technology, Patent, and/or other intellectual property without (i) violating the terms of any agreement or arrangement with a third party or (ii) misappropriating the Technology of a third party.

"Cover" means, with respect to a Technology and the applicable Patent, that, in the absence of ownership of or a license granted under such Patent, the practice or other Exploitation of such Technology (when practiced by one or more Persons acting either alone, independently with others or in concert with others) would infringe at least one (1) Valid Claim of such Patent (or, in the case of a Patent that has not yet issued, would infringe at least one (1) Valid Claim of such Patent if it were to issue). "Covering" and "Covered" shall have the correlative meaning.

"Dollars" or "$" means the legal tender of the United States of America.

"FDA Approval" means the approval by the FDA of an NDA or BLA (including accelerated or conditional approval) permitting commercial sale of a Product in the United States.

"Indication" means any human disease or condition, or sign or symptom of a human disease or condition.

"Inventions" shall mean Technology first conceived by a Party and arising out of the Expanded Study.

"Net Profit" means the gross amounts received by LIXTE, its Affiliates, licensees or its Sublicensees from Sales of Compound Product less (a) all trade, quantity, and cash discounts actually allowed, (b) all credits and allowances actually granted due to rejections, returns, billing errors, and retroactive price reductions, (c) export duties, (d) excise, sale and use taxes, and equivalent taxes, and (e) reasonable allowances for non-collectable receivables after reasonable collection efforts, provided that any such amounts that are collected in a subsequent period shall be included in Net Profit for such subsequent period.

In the event a Product is sold as a component of a Combination Product, the Net Profit of the Combination Product, for the purpose of determining royalty payments, shall be:

a. if the Product and the other components of such Combination Product are each sold separately in finished form in a country, then Net Profit for such Combination Product in such country shall be calculated by multiplying actual Net Profit of such Combination Product in such country by the fraction A/(A+B), where A is the average Net Profit price of the Product as sold separately in finished form by LIXTE or any of its Affiliates, licensees or Sublicensees in such country, and B is the average net sales (calculated in a manner analogous to the manner in which Net Profit are calculated as set forth above) of the other components in the Combination Product as sold separately in finished form in such country;

b. if the Product of such Combination Product is sold separately in finished form by LIXTE or any of its Affiliates, licensees or Sublicensees in such country but the other components of the Combination Product are not sold separately in finished form in such country, then Net Profit for such Combination Product in such country shall be calculated by multiplying actual Net Profit of such Combination Product in such country by the fraction A/D, where A is the average Net Profit of the Product as sold separately in finished form by LIXTE or any of its Affiliates, licensees or Sublicensees in such country, and D is the average Net Profit of the Combination Product as sold separately in finished form by LIXTE or any of its Affiliates, licensees or Sublicensees in such country; and

c. if neither subsection (i) nor (ii) above is applicable, the Parties shall determine Net Profit for such Combination Product in such country by mutual agreement based on the relative contribution of the Product portion and the other components of the Combination Product.

"Initiation" means the first administration of the investigational product to a human subject in such Pivotal Clinical Trial, as documented in the clinical trial protocol or regulatory submission accepted by the FDA.

"Patent(s)" means (a) any national, regional and international issued patents and pending patent applications, including provisional patent applications, (b) any patent applications filed either from the foregoing or from an application claiming priority to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, continuations-in-part, divisionals, renewals and continued prosecution applications, and all patents granted thereon, (c) patents of addition, revalidations, reissues, reexamination and extensions or restorations by existing or future extensions or restoration mechanisms, including patent term adjustments and any patent term extension under 35 U.S.C. §156 or any non-U.S. counterpart or equivalent of the foregoing, including supplemental protection certificates and any other extensions that are now available or become available in the future, (d) inventor's certificates, utility models, petty patents, innovation patents and design patents, (e) other forms of government-issued rights comparable in scope to any of the foregoing, including so-called pipeline protection or any importation, revalidation,

confirmation or introduction patent or registration patent or patent of additions to any of such foregoing, and (f) U.S. and foreign counterparts of any of the foregoing.

"Patent Expenses" means out-of-pocket expenses incurred by Institution during Prosecution of a Patent.

"Person(s)" means any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

"Phase 2 Study" means: (a) that portion of the FDA submission and approval process which provides for early controlled clinical studies conducted to obtain preliminary data on the effectiveness of a product for a particular indication, as more specifically defined by the rules and regulations of the FDA, including 21 C.F.R. § 312.21(b) or any future revisions or substitutes therefor; or (b) a similar clinical trial in any national jurisdiction other than the United States. For the avoidance of doubt, although not expressly included in 21 C.F.R. § 312.21(b), for purposes of this Agreement, Phase 2 Study shall include any study which provides for Phase Ib, cohort expansions, or any other study where one or two doses have already been fixed and/or any study that aims at looking for an efficacy signal and/or for which the safety has already been established.

"Pivotal Clinical Trial" means a human clinical trial of a Product which is designed to provide the substantial evidence of safety and efficacy required by the FDA to support the approval of a New Drug Application ("NDA"), Biologics License Application ("BLA"), or any equivalent application for marketing authorization, whether such approval is regular or conditional. For clarity, a Phase 2 trial may constitute a Pivotal Clinical Trial if it is intended in writing by the sponsor and accepted by the FDA as a registration-enabling study.

"Product" means any

(a) product, component, test, assay, method or service that is generated, studied, validated, improved, researched, developed or discovered by either Party under the Agreement (including, but not limited to Dostarlimab and/or LB-100); and/or

(b) any product or component that,

(i) comprises, uses or is made using Technology Covered by one or more Valid Claims, or

(ii) enables a Person, acting either alone, independently with other Person or in concert with other Person, to perform or practice one more Valid Claims, or

(iii) incorporates, uses or is made using an Invention; and/or

(c) any method or process that, when performed by one or more Persons acting either alone, independently with other Persons or in concert with other Persons,

(i) practices one or more Valid Claims, or

(ii) incorporates or uses Invention, and/or;

(d) any product, component, test, assay, method, or service made or developed, at least in part, as a result of an Indication or target that was generated, studied, validated, improved, researched, developed or discovered through or as part of a Research Study.

"Prosecution" means, with respect to a Patent, the preparation, filing, prosecution and maintenance thereof (including conducting all correspondence and interactions with the USPTO and foreign patent offices, seeking, conducting and defending any interferences, reissue proceedings, reexaminations, oppositions, post-grant proceedings, post-issuance proceedings and similar proceedings, obtaining patent term extensions, or their equivalents with respect thereto). When used as a verb, "Prosecute" means to engage in Prosecution.

"Regulatory Approval" means all activities relating to the approval, license or authorization of the applicable Regulatory Authority necessary for the marketing and sale of a product for a particular Indication in a country in the Territory, excluding separate pricing or reimbursement approvals that may be required, and including the approval by the applicable Regulatory Authority of any expansion or modification of the label for such Indication.

"Regulatory Authority" means the Food and Drug Administration (FDA) in the U.S. or any health regulatory authority in another country in the Territory that is a counterpart to the FDA and holds responsibility for granting Regulatory Approval for a product in such country, and any successor(s) thereto.

"Reseller" means a third party wholesaler or distributor that (a) has no significant responsibility for marketing and promotion of a Product within its distribution territory or field and (b) does not pay any consideration to LIXTE or its Sublicensees for wholesale or distribution rights.

"Sale" means the transfer or other disposition of a Product, as applicable, for value; provided, however, a transfer or other disposition of a Product, as applicable, for value shall not be included in this definition of Sale if (a) the transfer is to LIXTE Affiliate or a Sublicensee that does not acquire such or Product, as applicable, for end use or (b) the transfer or disposition is for use either in clinical trials or for compassionate use (or patient assistance programs) at no charge, or (c) the transfer is to a Royalty-Free Practitioner. "Royalty-Free Practitioner" means Institution and any individual: (x) listed as an inventor of a Patent that (i) Covers a Invention and (ii) Covers the Product, as applicable, and (x) that, at the time of such Sale(s), is a physician, nurse practitioner, physician assistant, advanced practice provider or other prescriber. "Sales" and "Sold" shall have the correlative meanings.

"Sublicensee" means any entity, including an Affiliate, to whom an express license agreement or Sublicense agreement has been granted under any Invention. For the avoidance of doubt, "Sublicensee" does not include a Reseller, which merely purchases and resells Products.

"Technology" means (i) information, inventions, discoveries, compounds, machines, devices, compositions, assays, materials, formulations, formulas, procedures, processes, methods, know-how, trade secrets, techniques, designs, drawings, computer programs, documents, specifications, apparatus, results, strategies, regulatory documentation, (ii) data, including pharmacological, toxicological, non-clinical and clinical data, analytical and quality control data, manufacturing data and data, and (iii) software, including computer programs, operating systems, applications, firmware, and other code, such as source code, object code, application programming interfaces, data files, databases, protocols, algorithms and other documentation thereof, and in each case (i), (ii), and (iii) and the like, in written, electronic, oral or other tangible or intangible form, now known or hereafter developed, whether or not patentable.

"Territory" means worldwide.

"Valid Claim" means a claim of: (a) an issued patent, that is within the definition of patents Covering Invention, that has not expired, lapsed, been cancelled or abandoned, or been dedicated to the public, disclaimed, or held unenforceable, invalid, or cancelled by a court or administrative agency of competent jurisdiction in an order or decision from which no appeal has been or can be taken, including through opposition, reexamination, reissue or disclaimer; or (b) a pending patent application that has not been finally abandoned or finally rejected and which has been pending for no more than seven (7) years from the filing date of such patent application, to the extent that such claim continues to be prosecuted in good faith. For clarity, a claim of an issued patent that ceased to be a Valid Claim before the applicable patent application issued because the patent application had been pending for longer than the period prescribed under clause (b), but the patent application subsequently issued and is otherwise

described by clause (a) of the foregoing sentence shall again be considered to be a Valid Claim once the patent application issues. The same principle shall apply in similar circumstances such as if, for example (but without limitation), a final rejection of a claim is overcome.

Exhibit 99.1

LIXTE and its Collaborators Expand Clear Cell Ovarian Cancer Trial

—Plans to double the Number of Patients in Study—
—Company Expects Initial Findings to be presented in 2026—

BOCA RATON, Fla., December 23, 2025 — LIXTE Biotechnology Holdings, Inc. ("LIXTE" or the "Company") (Nasdaq: LIXT), a biotech company focused on advancing cancer treatments, today announced it is expanding its collaboration with The University of Texas MD Anderson Cancer Center and pharmaceutical manufacturer GSK on an ongoing clinical trial with LIXTE's proprietary compound, LB-100, to treat ovarian clear cell cancer.

The trial, which combines LB-100 with GSK's Dostarlimab to enhance the effectiveness of immunotherapy, was initiated in January 2024. It is directed by lead clinical investigator Amir Jazaeri, MD, Professor of Gynecologic Oncology, at MD Anderson.

A second trial site was added earlier this year at the Robert H. Lurie Comprehensive Cancer Center (Lurie Cancer Center) of Northwestern University, led by Emily M. Hinchcliff, MD, MPH.

MD Anderson and Northwestern Medical Center plan to double the number of enrollments in the trial to 42 patients, after successfully attaining its initial target of 21 patients earlier this year. The Company also announced that it expects data to be presented from the trial on the initial 21 patients in the first half of 2026.

"We are gratified to be expanding the patient population of this important clinical trial," said Bas van der Baan, LIXTE's Chief Scientific Officer, who leads the Company's LB-100 program. "There is a tremendous unmet need in the treatment of ovarian clear cell cancer. Based on extensive published preclinical data, we believe LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve patient outcomes."

Geordan Pursglove, LIXTE's Chief Executive Officer, added: "Expansion of this important trial is in keeping with LIXTE's mission of treating cancer with exceptional, innovative therapies and cutting-edge technologies. With each step forward, we are hopeful of attaining our goal."

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company focused on new targets for cancer drug development and developing and commercializing cancer therapies. LIXTE has demonstrated that its first-in-class lead clinical PP2A inhibitor, LB-100, is well-tolerated in cancer patients at doses associated with anti-cancer activity. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly enhance chemotherapies and immunotherapies and improve outcomes for patients with cancer.

LIXTE's lead compound, 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. LIXTE's new approach is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are currently in progress for Ovarian Clear Cell Carcinoma and Metastatic Colon Cancer. Additional information about LIXTE can be found at www.lixte.com.

Forward-Looking Statement Disclaimer

This announcement contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. For example, statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future activities, including the continuing development of proprietary compounds, the planning, funding, coordination and potential results of clinical trials, the patent and legal costs to protect and maintain the Company's intellectual property worldwide, and the Company's ability to maintain compliance with Nasdaq's continued listing requirements, are all forward-looking statements. These statements, also including, but not limited to, expectation of presenting initial findings in the first half of 2026, 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.

The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company 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, available cash resources, research results, competition from other similar businesses, and market and general economic factors.

Readers are urged to read the risk factors set forth in the Company's filings with the United States Securities and Exchange Commission at https://www.sec.gov. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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