
**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): August 20, 2018

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE
(State or other jurisdiction
of incorporation)

000-51476
(Commission
File Number)

20-2903526
(IRS Employer
Identification No.)

248 Route 25A, No. 2
East Setauket, New York 11733
(Address of principal executive offices)

(631) 942 7959
(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))
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Item 1.01. Entry into a Material Agreement.

Effective August 20, 2018, the Company and H. Lee Moffitt Cancer Center and Research Institute Hospital Inc. (“Moffitt”) entered into a Clinical Trial Research Agreement (the “Clinical Trial Agreement”) and an Exclusive License Agreement (the “License Agreement”). Pursuant to the Clinical Trial Agreement, Moffitt is to conduct a Phase 1b/2 study of the safety and therapeutic benefit of the Company’s lead clinical compound, LB-100, in patients with myelodysplastic syndrome (“MDS”). Pursuant to the License Agreement, Moffitt is granting to the Company an exclusive license under certain patents of Moffitt (the “Licensed Patents”) relating to treating MDS and a non-exclusive license under inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the Licensed Patents) necessary or useful for the practice of any claim of a Licensed Patent or the use, development, manufacture or sale of any product for the treatment of MDS which would otherwise infringe a valid claim under a Licensed Patent.

The foregoing description of the terms of the Clinical Trial Agreement and License Agreement does not purport to be complete and is subject to and qualified in its entirety by reference to the Clinical Research Agreement and License Agreement, copies of which are filed with this Form 8-K and incorporated by reference. Portions of the Clinical Trial Agreement will be subject to a FOIA confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Item 8.01. Other Events.

On August 21, 2018, the Company issued a press release regarding the agreements with Moffitt Cancer Center.

Item 9.01. Financial Statements and Exhibits.

(d) There is filed as part of this report the exhibit listed on the accompanying Index to Exhibits which exhibit is incorporated herein by reference

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: August 23, 2018

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: /s/ JOHN S. KOVACH

John S. Kovach, Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Clinical Trial Research Agreement ¹
10.2	Exclusive License Agreement
99.1	Press Release regarding the agreements with Moffitt Cancer Center

¹ Certain portions of the Exhibit have been omitted based upon a pending request for confidential treatment filed by the Company with the Securities and Exchange Commission.

EXECUTION VERSION

CLINICAL TRIAL RESEARCH AGREEMENT

This CLINICAL TRIAL RESEARCH AGREEMENT (this “AGREEMENT”) is entered into on August 20, 2018 (the “Effective Date”), by and between H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc., with a primary location at 12902 Magnolia Drive, Tampa, FL 33612-9497, hereinafter called “INSTITUTION,” and Lixte Biotechnology Holdings, Inc., with its office and place of business at 248 Route 25A, No. 2, East Setauket, NY, hereinafter called “LIXTE.” (“INSTITUTION” and “LIXTE”, each referred to as a “Party” and together, “Parties”)

WHEREAS, INSTITUTION is dedicated to undertaking research for the purpose of discovering and making available to the public new and improved disease treatments;

WHEREAS, INSTITUTION desires to conduct a clinical research protocol which it has conceived and designed, with input from Lixte;

WHEREAS, the STUDY (defined below) contemplated by this Agreement is of mutual interest and benefit to INSTITUTION and LIXTE, and will further INSTITUTION’s instructional, basic science, clinical science and fundamental research objectives in a manner consistent with its status as a nonprofit educational and health care institution; and

WHEREAS, LIXTE, consistent with its commitment to clinical research, wishes to provide certain support to INSTITUTION on the terms and conditions described in this AGREEMENT.

PRINCIPAL INVESTIGATOR (named in Article 2 below) and INSTITUTION desire to study the safety and/or efficacy of LB-100 For Injection (the “STUDY DRUG”) for certain clinical trial research to be conducted during the term of and pursuant to the terms and conditions set forth in this Agreement, as further described herein (the “STUDY”). The Parties agree as follows:

1. Scope of Work

The STUDY to be performed under this AGREEMENT shall be performed in accordance with the terms of the final protocol, as developed by PRINCIPAL INVESTIGATOR, with input from Lixte, including as it may be amended in accordance with the terms of this AGREEMENT, entitled “A Ph1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy,” (the “PROTOCOL”) set forth in Exhibit A and incorporated into this AGREEMENT by reference. INSTITUTION certifies that, to its best knowledge, its facilities, resources and population are adequate to perform the STUDY contemplated by this AGREEMENT and the PROTOCOL . INSTITUTION and PRINCIPAL INVESTIGATOR (named in Article 2 below) agree that all aspects of the STUDY will be conducted in conformity with all applicable federal, state, local laws, regulations including CFR Title 21, Part 312, and the principles of good clinical practice as laid down by the ICH topic E6, Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 (hereinafter referred to as “GCP”). INSTITUTION further agrees not to conduct any research activities with the STUDY DRUG which are contrary to the provisions of the PROTOCOL or outside the scope of the PROTOCOL. INSTITUTION shall be the legal sponsor of the PROTOCOL and the STUDY. PRINCIPAL INVESTIGATOR and INSTITUTION will undertake the STUDY and will fulfill the requisite sponsor duties and obligations in conducting the STUDY as defined in the Federal Regulations and Guidance Documents.

It is anticipated that (i) the STUDY shall commence promptly following the Effective Date, but in no event more than six (6) months from the Effective Date, and (ii) INSTITUTION and PRINCIPAL INVESTIGATOR shall use reasonable efforts to complete the STUDY within twenty-four (24) months of the Effective Date, but in no event more than thirty six (36) months after the Effective Date. The STUDY shall be deemed to have commenced when INSTITUTION enters the first patient on the clinical trial contemplated under the STUDY (the “STUDY COMMENCEMENT”; “COMMENCE THE STUDY” has the correlative meaning).

2. PRINCIPAL INVESTIGATOR

INSTITUTION’S principal investigator is Rami Komrokji, MD, (“PRINCIPAL INVESTIGATOR”). PRINCIPAL INVESTIGATOR will be responsible for the direction and supervision of all STUDY efforts in accordance with this AGREEMENT, including the organization and overall responsibility of any subsites, in accordance with applicable INSTITUTION policies, the PROTOCOL and this AGREEMENT and Federal Regulations. In the event that the PRINCIPAL INVESTIGATOR who signs either the Protocol and/or this AGREEMENT leaves or is removed from the INSTITUTION, then INSTITUTION shall, within thirty (30) days of such departure by PRINCIPAL INVESTIGATOR, provide written notice of such event to LIXTE. Any successor to PRINCIPAL INVESTIGATOR must be approved, in writing, by LIXTE and such successor shall be required to agree to all the terms and conditions of the PROTOCOL and this AGREEMENT and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this AGREEMENT).

INSTITUTION represents and certifies that it will not knowingly use in any capacity, in connection with any services to be performed under this AGREEMENT, any individual who has been debarred pursuant to the Federal Food, Drug and Cosmetic Act, or excluded from a federal healthcare program.

INSTITUTION and/or PRINCIPAL INVESTIGATOR agrees to immediately inform LIXTE in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of INSTITUTION’S knowledge, is threatened, relating to the debarment of INSTITUTION or any person performing services hereunder. INSTITUTION acknowledges that no action, suit, claim, investigation or legal or administrative proceeding is pending or threatened relating to PRINCIPAL INVESTIGATOR’S debarment and PRINCIPAL INVESTIGATOR will inform LIXTE in writing promptly, but in no event within more than two (2) days, if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for PRINCIPAL INVESTIGATOR’S debarment.

3. Inspection Rights

It is agreed that LIXTE or others designated by LIXTE may, at mutually agreeable times and with prior written notice, during normal business hours prior to the STUDY COMMENCEMENT, during the STUDY and for a reasonable time after completion or early termination of the STUDY (not to exceed three (3) years), arrange with PRINCIPAL INVESTIGATOR or his/her designee:

- (i) to examine and inspect qualifications of the staff and INSTITUTION facilities required for performance of the STUDY according to GCP requirements (to the extent the GCP requirements are adopted by the United States Food and Drug Administration (“FDA”));
- (ii) to inspect and make copies of all data and supporting study documentation as defined in E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)(FDA Guidance for Industry March 2018) necessary for LIXTE to confirm that the STUDY is being conducted in conformance with the PROTOCOL and this AGREEMENT, and in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA; and if at any time (whether or not in connection with an inspection) LIXTE identifies any deficiencies with respect to the foregoing, the INSTITUTION will address these deficiencies with appropriate corrective action and development and implementation of a prevention plan.
- (iii) LIXTE agrees to not use any monitor or auditor to inspect or audit INSTITUTION if such person is, to the best of its knowledge, a former employee of INSTITUTION. All monitoring and audits will be conducted in accordance with INSTITUTION’s policies and procedures regarding access to its facilities and information systems. LIXTE will not, for the period of this AGREEMENT and for two (2) years thereafter, directly or indirectly solicit for employment any person who participated in the STUDY and at the time of such solicitation is employed or retained by INSTITUTION without the prior written consent of INSTITUTION.

4. Clinical Trial Approvals

A. LIXTE shall be responsible for the following:

- (i) IND Lixte will hold the IND and file the protocol with sample informed consent to the FDA including the signed FDA Form 1572.

B. INSTITUTION shall be responsible for obtaining the following:

- (i) approval of the Protocol, any informed consent relating to the STUDY and advertisement, if any, pertaining to the enrollment of subjects in the STUDY by the appropriate Institutional Review Board (“IRB”) prior to beginning the STUDY on human subjects;
- (ii) an informed consent which complies with all applicable federal, state, and local laws and regulations signed by each human subject prior to the subject’s participating in the STUDY; and PRINCIPAL INVESTIGATOR will not represent in the informed consent or elsewhere that LIXTE is the STUDY sponsor; and
- (iii) informed consent shall provide subject consent to allow PRINCIPAL INVESTIGATOR to disclose personal health information to LIXTE and its representatives who will use such information to evaluate the STUDY DRUG. Subject’s information may also be shared with the FDA and with health authorities in other countries.
- (iii) All other essential documents and recordkeeping requirements as defined under GCPs.

B. In the event the IRB requires changes in the Protocol or informed consent, LIXTE shall be advised in advance of and shall have the right to approve all modifications to the Protocol and informed consent. INSTITUTION and PRINCIPAL INVESTIGATOR shall not modify the STUDY described in the PROTOCOL once finalized and after approval by the IRB without the prior written approval of LIXTE; provided, however, that PRINCIPAL INVESTIGATOR shall be permitted to deviate from the Protocol if necessary to address concerns for the safety, health or welfare of the Study subjects, provided that PRINCIPAL INVESTIGATOR shall provide prompt notice of same to LIXTE.

C. The PRINCIPAL INVESTIGATOR and INSTITUTION shall ensure that IRB approval shall be maintained current at all times and in the event that the STUDY continues beyond the period of the initial IRB approval, shall ensure that appropriate periodic IRB re-approval is obtained without lapse in approval status.

D. In the event that IRB approval lapses, becomes suspended, or is withdrawn, PRINCIPAL INVESTIGATOR or INSTITUTION shall notify LIXTE within 24 hours of that event and IRB’s reasons for approval lapse, suspension or withdrawal.

5. Term of Agreement

The term of this AGREEMENT shall be five (5) years from the execution of this AGREEMENT, unless early terminated pursuant to Section 6 below. The obligations set forth in Sections 9, 10 and 12, to the extent applicable, shall extend for a period of five (5) years after termination of this AGREEMENT.

6. Termination

A. LIXTE may terminate this AGREEMENT by giving thirty (30) days written notice to the other party. In the event thirty (30) days is determined by either party to be insufficient notice based upon evaluation of risks to enrolled research subject(s) then receiving the STUDY DRUG, the parties will cooperate to safely withdraw subjects from drug treatment over a mutually agreeable period of time but in no event shall LIXTE's obligation to supply STUDY DRUG hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event LIXTE or INSTITUTION (1) believes that immediate termination is necessary due to an evaluation of risks to enrolled research subject(s), or (2) is informed that approval to conduct the Study has been withdrawn by the FDA, IRB or other applicable regulatory authority, LIXTE or INSTITUTION, as applicable, may terminate this AGREEMENT immediately.

B. Notwithstanding any other provision hereof, either party shall be entitled to terminate this AGREEMENT for any Material Breach. A Material Breach by INSTITUTION shall be defined as:

- (i) INSTITUTION fails to COMMENCE THE STUDY within six (6) months after the Effective Date or fails to complete the STUDY within thirty six (36) months after the Effective Date.
- (ii) INSTITUTION'S failure to comply with its obligations, responsibilities and the terms and conditions of this AGREEMENT and the Protocol;
- (iii) INSTITUTION'S failure to comply with: (a) its obligations for keeping LIXTE informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the STUDY; or (c) the Protocol regarding the work to be performed under this AGREEMENT.

C. In the event of any termination:

- (i) INSTITUTION shall return to LIXTE, at LIXTE's expense, all unused materials, including but not limited to, STUDY DRUG and clinical supplies (unless written authorization to retain or destroy them is given by LIXTE in which case INSTITUTION shall comply with the applicable provisions of Article 11 hereof);

- (ii) the parties agree that (a) LIXTE will make all payments due hereunder to INSTITUTION for work actually performed in accordance with the Protocol as of the date of notice of termination, and (b) LIXTE will pay for any non-cancelable costs (as defined in Exhibit B) incurred, except where the termination is for INSTITUTION's material breach, in which case INSTITUTION shall waive any payment for non-cancelable costs and shall pay for all costs associated with the breach, and;
- (iii) PRINCIPAL INVESTIGATOR shall return to LIXTE, at LIXTE's expense, all CONFIDENTIAL INFORMATION (as defined in Article 9 hereof) owned or controlled by LIXTE and in the possession of INSTITUTION.

D. The termination of this AGREEMENT shall not relieve either party of its obligation to the other in respect of:

- (i) retaining in confidence all CONFIDENTIAL INFORMATION (as defined in Article 9 hereof) ;
- (ii) complying with record keeping and reporting obligations (under Article 7 hereof);
- (iii) complying with any publication obligations (under Article 10 hereof) and obtaining any written approval and consents for any publicity and promotional purposes (under Article 18 hereof);
- (iv) complying with obligations relating to clinical supplies (under Article 11 hereof);
- (v) indemnification and insurance obligations (under Article 12 hereof); and
- (vi) inspection rights (under Article 3 hereof);

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this AGREEMENT.

E. INSTITUTION shall not disclose to LIXTE or induce LIXTE to use any secret or confidential information or material belonging to others, or without prior notice to LIXTE, use in the STUDY any proprietary compounds or materials of any third party, including other sponsors of other clinical trials.

7. Records and Reports

A. PRINCIPAL INVESTIGATOR and INSTITUTION shall have the following record keeping and reporting obligations:

- (i) preparation and maintenance of complete, accurately written records, accounts, notes, reports, STUDY files and data (Case Report Forms/Electronic Data Capture) relating to the STUDY under this AGREEMENT; and

- (ii) conduct of the STUDY and maintenance of records and data during and after the term or early termination of this AGREEMENT in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA.
- (iii) Preparation and submission of periodic progress reports as requested by LIXTE which will include the following (but is not limited to):
 - (a) Enrollment summaries,
 - (b) Enrollment forecasting for drug supply management,
 - (c) Final study report or acceptable equivalent according to specified content within a reasonable time after completion of the STUDY but in no event longer than three (3) months after completion of the STUDY.
 - (d) Electronic copy of the final data set used in support of the final study report in SAS or other usable data format (non-PDF) suitable for inclusion in future regulatory submissions.
- (iv) PRINCIPAL INVESTIGATOR and/or INSTITUTION shall be the responsible party as defined in Section §801 of the Food and Drug Administration Amendments Act of 2007. PRINCIPAL INVESTIGATOR and/or INSTITUTION, as the responsible party, shall submit the required clinical trial information to the Director of the National Institutes of Health (NIH) for inclusion in the registry and results database via *Clinicaltrials.gov* within twenty-one (21) days after the first patient is enrolled in this clinical investigation.

B. INSTITUTION and PRINCIPAL INVESTIGATOR further agree to report adverse events, including Expedited Alert Reports to LIXTE and to relevant regulatory agencies, in compliance with all applicable legal and regulatory requirements and in fulfillment of the requisite duties and obligations in conducting the STUDY.

C. PRINCIPAL INVESTIGATOR shall notify INSTITUTION, and LIXTE within one (1) working day after learning of any defect or possible defect associated with the STUDY DRUG provided by LIXTE.

8. **FUNDING**

The IND will be filed in the name of, and be owned by, LIXTE. LIXTE will provide funding for up to forty-seven (47) patients at the rate specified in the Budget which is attached as Exhibit B and which is incorporated into this AGREEMENT by reference. The Parties acknowledge that the actual costs of the STUDY may exceed the amounts specified in the Budget and that LIXTE shall have no obligation to pay any amount in excess of those specified in the Exhibit B as payable by LIXTE.

9. CONFIDENTIAL INFORMATION

A. During and for a period of five (5) years after the term or early termination of this AGREEMENT, INSTITUTION and PRINCIPAL INVESTIGATOR shall retain in confidence all test articles and proprietary data and/or information obtained from LIXTE, including, but not limited to, the investigator's brochure and any other information or material disclosed under secrecy agreements previously entered into between the parties ("CONFIDENTIAL INFORMATION"). This restriction shall not apply to CONFIDENTIAL INFORMATION:

- (i) which is or becomes public knowledge (through no fault of INSTITUTION or PRINCIPAL INVESTIGATOR); or
- (ii) which is lawfully made available to INSTITUTION or PRINCIPAL INVESTIGATOR by an independent third party owing no obligation of confidentiality to LIXTE with regard thereto (and such lawful right can be properly demonstrated by INSTITUTION or PRINCIPAL INVESTIGATOR); or
- (iii) which is already in INSTITUTION'S or PRINCIPAL INVESTIGATOR'S possession at the time of receipt from LIXTE (and such prior possession can be properly demonstrated by INSTITUTION or PRINCIPAL INVESTIGATOR); or
- (v) which is independently developed by INSTITUTION or PRINCIPAL INVESTIGATOR (and such independent development can be properly demonstrated by INSTITUTION or PRINCIPAL INVESTIGATOR);
- (vi) which is approved for release through prior written authorization of LIXTE;
- (vii) which is published in accordance with the express terms of Section 10(B) this AGREEMENT; or
- (v) which is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by INSTITUTION.

B. To permit LIXTE an opportunity to intervene by seeking a protective order or other similar order, in order to limit or prevent disclosures of CONFIDENTIAL INFORMATION, INSTITUTION or PRINCIPAL INVESTIGATOR shall promptly notify LIXTE, in writing, if it is requested by a court order, a governmental agency, or any other entity to disclose CONFIDENTIAL INFORMATION in INSTITUTION'S or PRINCIPAL INVESTIGATOR'S possession and thereafter INSTITUTION or PRINCIPAL INVESTIGATOR shall disclose only the minimum CONFIDENTIAL INFORMATION required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by LIXTE.

C. Subject to applicable federal, state or local legal and regulatory requirements, INSTITUTION and PRINCIPAL INVESTIGATOR agree to promptly return to LIXTE, upon its request and at its expense, and only if legally permissible, all CONFIDENTIAL INFORMATION obtained from LIXTE or belonging to LIXTE pursuant to this AGREEMENT; provided, however, that INSTITUTION may retain one copy of CONFIDENTIAL INFORMATION in a secure location for purposes of identifying INSTITUTION'S obligations under these confidentiality provisions.

D. INSTITUTION and PRINCIPAL INVESTIGATOR shall limit disclosure of CONFIDENTIAL INFORMATION received hereunder to only those of its representatives, agents, officers and employees (collectively, "AGENTS") who are directly involved with the STUDY and only on a need to know basis. INSTITUTION shall advise its AGENTS upon disclosure to them of any CONFIDENTIAL INFORMATION of the proprietary nature thereof and the terms and conditions of this AGREEMENT and shall use all reasonable safeguards to prevent unauthorized disclosure by such AGENTS. INSTITUTION shall be responsible for any breach of these confidentiality provisions by its AGENTS.

E. INSTITUTION acknowledges and expressly agrees that any disclosure of CONFIDENTIAL INFORMATION in violation of this AGREEMENT may be detrimental to LIXTE's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, LIXTE shall be entitled to seek equitable relief by way of injunction or otherwise.

F. Information regarding INSTITUTION's business practices (i.e., health care delivery practices, utilization data, membership or other health plan information) ("INSTITUTION CONFIDENTIAL INFORMATION"), the PROTOCOL, data and patient medical records unrelated to the STUDY (originating at the INSTITUTION) from which the data for the STUDY is collected shall be deemed INSTITUTION Confidential Information and shall continue to be the sole and exclusive property of INSTITUTION. LIXTE agrees to treat INSTITUTION Confidential Information in the same confidential manner and subject to the same use and disclosure limitations to which INSTITUTION and PRINCIPAL INVESTIGATOR are subject with respect to LIXTE's Confidential Information.

10. Data, Publications and Other Rights

a. Without limiting LIXTE's rights in LIXTE CONFIDENTIAL INFORMATION provided by LIXTE to INSTITUTION hereunder (which shall at all times remain the exclusive property of LIXTE), LIXTE agrees that all new research data and results generated solely by INSTITUTION during the course of the STUDY (the "RESULTS") shall be the sole and exclusive property of INSTITUTION; provided, however, that LIXTE (i) shall be provided access to all RESULTS, and is hereby granted a non-exclusive, irrevocable, perpetual, transferable and sublicensable license to use the RESULTS for any lawful purpose, and (ii) shall have the right to access and use SAMPLES (as defined in Article 15 herein) for any purpose permitted by the informed consent and/or this Agreement. For the avoidance of doubt, the term "RESULTS" does not include any CONFIDENTIAL INFORMATION or intellectual property rights of LIXTE.

b. In recognition of the importance of disseminating information relating to any novel or important observations or results arising from the STUDY and understanding that such need must be balanced with LIXTE's obligations to maintain control over CONFIDENTIAL INFORMATION as well as to comply with appropriate rules and regulations of the FDA, and for LIXTE'S to exercise its rights in intellectual property and to file patent applications, as set forth herein and in the Exclusive License Agreement (defined below), the parties hereby agree to the following:

- i. Subject to the terms and conditions of this AGREEMENT, including without limitation LIXTE's prior right of review pursuant to Section 10(B)(ii), (a) INSTITUTION has the right and is encouraged to publicly present and/or publish RESULTS in a peer-reviewed journal and (b) if RESULTS do not merit publication in a peer-reviewed journal or if INSTITUTION does not intend to publish RESULTS in a peer-reviewed journal then INSTITUTION may make the RESULTS available by an alternative means such as ClinicalStudyResults.org, which is consistent with PhRMA Principles on the Conduct of Clinical Trials Communication and Clinical Trial Results. INSTITUTION shall acknowledge LIXTE as a supporter of the Study in any such presentation, publication or distribution.
- ii. PRINCIPAL INVESTIGATOR and INSTITUTION agree not to publish, publicly present, or distribute by alternative means (as set forth in Section 10(B)(i)) any interim or final RESULTS of the STUDY, or any other information related to the STUDY or the Protocol, without the prior written review of LIXTE, as provided below. PRINCIPAL INVESTIGATOR and INSTITUTION further agree to provide thirty (30) days written notice to LIXTE prior to submission for publication, presentation or distribution to permit LIXTE to review drafts of abstracts and manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, e.g. any computer access system such as the Internet, World Wide Web etc., or patent application filing, collectively or individually a "PUBLIC PRESENTATION") which report any RESULTS arising out of the STUDY. LIXTE shall have the right to review and comment, with respect to a PUBLIC PRESENTATION, including but not limited to, the data analysis and presentation and to ensure that CONFIDENTIAL INFORMATION is not disclosed in violation of this AGREEMENT and to exercise LIXTE'S rights in intellectual property and to file patent applications, as set forth herein and in the Exclusive License Agreement.

- iii. If the parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of LIXTE's CONFIDENTIAL INFORMATION, INSTITUTION agrees to meet with LIXTE's representatives at the clinical STUDY site or as otherwise agreed, prior to submission of a PUBLIC PRESENTATION, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

D. No PUBLIC PRESENTATION shall contain any CONFIDENTIAL INFORMATION of LIXTE and shall be confined to new discoveries and interpretations of scientific fact.

E. If LIXTE believes there is patentable subject matter contained in any PUBLIC PRESENTATION submitted for review, LIXTE shall promptly identify such subject matter to INSTITUTION. If LIXTE requests and at LIXTE's expense, INSTITUTION shall delay such PUBLIC PRESENTATION for a reasonable period of time, up to ninety (90) days, until such patent application covering the subject matter is properly filed and shall use reasonable efforts to assist LIXTE, at LIXTE's expense, to file such patent application.

11. **STUDY DRUG**

LIXTE shall make available sufficient quantities of LB-100 for Injection free of charge as reasonably necessary to carry out the STUDY, it being understood that INSTITUTION and PRINCIPAL INVESTIGATOR shall take responsibility to maintain appropriate records and assure appropriate supply, handling, storage, distribution and usage of these materials in accordance with the Protocol and any applicable laws and regulations relating thereto and that it shall not be transferred to any other person without the knowledge of LIXTE. STUDY DRUG shall be provided at no cost to STUDY subjects and may not be used for any other purpose than that stated in the Protocol. All unused materials will be returned, at LIXTE's expense, to LIXTE or its agent by INSTITUTION at the conclusion of the STUDY or upon earlier termination of this AGREEMENT, unless written authorization to destroy or retain them is given by LIXTE. If authorization to destroy unused material is given, INSTITUTION is responsible for drug accountability and destruction according to ICH/GCP guidelines and all applicable local laws. In addition to the other requirements under this AGREEMENT and the Protocol, in the event a re-supply of STUDY DRUG is required in order to continue to conduct the STUDY in accordance with this AGREEMENT and the Protocol, it will be done conditional on LIXTE's receipt of current IRB approval documentation.

Any use of LIXTE's STUDY DRUG, or methods of making and using the same, which are beyond the scope of the rights set forth in this AGREEMENT shall constitute a material breach of this AGREEMENT.

12. Indemnification and Insurance

A. LIXTE shall indemnify, defend and hold harmless INSTITUTION, its trustees, officers, agents, faculty, directors, employees and PRINCIPAL INVESTIGATOR, (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, or damage to property, arising out of or connected with the failure of the STUDY DRUG to meet product specifications or from its use or misuse of RESULTS (excluding any claim alleging that LIXTE is not permitted to use the RESULTS or claim regarding the accuracy or completeness of the RESULTS). As a precondition for such indemnity, INSTITUTION agrees: (i) to promptly notify LIXTE of any such claim, proceeding, investigation or suit; (ii) to cooperate fully with LIXTE, at LIXTE's expense, in defending against such claim, proceeding, investigation or suit, and to tender to LIXTE the right to control the defense of the foregoing; and (iii) in the event of a proceeding or suit, to attend hearings and trials and assist in securing and giving evidence, and to use reasonable efforts to obtain the attendance of necessary and proper witnesses, the reasonable cost of which shall be reimbursed by LIXTE.

B. Notwithstanding the foregoing or anything in the Agreement to the contrary, LIXTE shall have no indemnification obligation or liability for loss or damage resulting from:

- (i) failure of INSTITUTION or PRINCIPAL INVESTIGATOR to adhere to the terms and provisions of the PROTOCOL (including agreed amendments thereto), this AGREEMENT, or LIXTE's written recommendations and instructions relative to the administration and use of any drug substances involved in the STUDY, including, but not limited to, the STUDY DRUG, any comparative drug and any placebo;
- (ii) failure of INSTITUTION or PRINCIPAL INVESTIGATOR to comply with any INSTITUTION policies and procedures, applicable FDA or other governmental or state law, rules or regulations applicable to the performance of its obligations under this AGREEMENT;
- (iii) failure of INSTITUTION or PRINCIPAL INVESTIGATOR to conduct the STUDY in a normal, prudent manner; or
- (iv) negligent act or omission or willful misconduct by PRINCIPAL INVESTIGATOR, INSTITUTION, its trustees, officers, agents or employees related to the performance of services under this AGREEMENT.

C. A condition of LIXTE's indemnity obligation is that, whenever PRINCIPAL INVESTIGATOR and/or INSTITUTION has information from which it may reasonably conclude an incident of bodily injury, death or property damage has occurred, INSTITUTION shall promptly give notice to LIXTE of all pertinent data surrounding such incident. In addition, PRINCIPAL INVESTIGATOR and INSTITUTION shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this AGREEMENT and the Protocol and any appendix or attachment thereto. In the event claim is made or suit is brought, INSTITUTION and PRINCIPAL INVESTIGATOR shall assist LIXTE, at LIXTE's expense, and cooperate in the gathering of information with respect to the time, place, and circumstances and in obtaining the names and addresses of the injured parties and available witnesses. PRINCIPAL INVESTIGATOR and INSTITUTION agree to cooperate with and to authorize LIXTE to carry out sole management and defense of such claim or action. Neither PRINCIPAL INVESTIGATOR nor INSTITUTION, its trustees, officers, agents or employees shall compromise or settle any claim or action without the prior written approval of LIXTE, and LIXTE shall not compromise or settle any claim or action against INSTITUTION or PRINCIPAL INVESTIGATOR without the prior written approval of INSTITUTION.

D. Without limiting INSTITUTION'S and PRINCIPAL INVESTIGATOR'S obligations to comply with the terms of this Agreement, INSTITUTION agrees to be responsible for any acts or omissions caused by gross negligence or willful misconduct by INSTITUTION or PRINCIPAL INVESTIGATOR in connection with this Agreement to the extent permitted by applicable Florida law, and shall be financially and legally responsible for such liabilities, costs, damages, and expenses resulting therefrom or attributable thereto. Without limiting the foregoing or any requirements under applicable law, INSTITUTION shall have no obligation hereunder to indemnify Sponsor and/or its agents, employees and representatives. Notwithstanding, INSTITUTION'S liability is limited in accordance with Florida Statute 768.28.

E. INSTITUTION is an instrumentality of the State of Florida pursuant to Section 1004.3, Florida Statutes, and its liability is limited as set forth in Section 768.28, Florida Statutes. In addition, and without waiving its sovereign immunity, INSTITUTION shall maintain commercial insurance for no less than \$1,000,000 per claim and \$3,000,000 in the aggregate to insure against covered losses and damages. Upon request of LIXTE, copies of certificates evidencing such insurance coverage will be made available to LIXTE and INSTITUTION shall provide thirty (30) days' prior written notice to LIXTE in the event of cancellation or any material change in such insurance.

F. LIXTE is responsible, at its own expense, for insurance to cover its liability exposures.

G. LIXTE shall promptly reimburse INSTITUTION for reasonable and necessary medical expenses incurred by STUDY subjects for medical care, including hospitalization, in the diagnosis and treatment of complications, injuries or illness caused by the STUDY DRUG following its administration in compliance with the PROTOCOL, which are not attributable to the negligence or misconduct of any person in the employment of INSTITUTION and that would not be expected from the standard treatment using currently approved therapies. The term "complications, injuries or illness" does not mean the natural progression of an underlying or pre-existing condition or events that would have been expected from the standard treatment using currently approved therapies for the STUDY subject's condition. This section shall survive termination of this Agreement.

13. Inventions and Patents

A. Other than as expressly provided herein, nothing contained in this AGREEMENT shall be deemed to grant either directly or by implication, estoppel or otherwise, any license under any patents, patent applications or other proprietary interests or discoveries of either party.

B. Title to any and all inventions, discoveries or innovations, whether patentable or not, arising directly or indirectly in connection with the conduct of the STUDY under this AGREEMENT (“INVENTIONS”) that use or incorporate the STUDY DRUG or LIXTE’s CONFIDENTIAL INFORMATION (“LIXTE INVENTIONS”), shall be the sole and exclusive property of LIXTE. INSTITUTION shall notify LIXTE in writing with respect to any such LIXTE INVENTION within fifteen (15) business days of the date that the department that handles patent matters at INSTITUTION or PRINCIPAL INVESTIGATOR becomes aware of such LIXTE INVENTION. INSTITUTION and PRINCIPAL INVESTIGATOR hereby assign to LIXTE all rights, title and interests in and to such LIXTE INVENTIONS. LIXTE shall have the sole and exclusive right to obtain, at its option, patent protection in the United States and foreign countries on any LIXTE INVENTION. LIXTE hereby grants to INSTITUTION a limited, non-exclusive, non-transferable and non-sublicensable license under such LIXTE INVENTION, solely for internal non-commercial, academic, research and patient care purposes. All INVENTIONS other than LIXTE INVENTIONS shall be owned by INSTITUTION if invented solely by INSTITUTION and jointly owned by both Parties if jointly invented by LIXTE and INSTITUTION; provided, however, that INSTITUTION hereby grants to LIXTE a limited, non-exclusive, non-transferable and non-sublicensable license to use any such INVENTIONS. Without limiting the foregoing and upon notice to the INSTITUTION, LIXTE may elect to receive an exclusive license under such INVENTIONS on the terms set forth in the Exclusive License Agreement between INSTITUTION and LIXTE, dated as of the Effective Date (the “Exclusive License Agreement”). Upon such election, such INVENTION is deemed to be LICENSED PATENT or LICENSED INFORMATION, as the case may be, under the Exclusive License Agreement. Patent Application 62/287,858 entitled “Clinical Regimen for Treating Myelodysplastic Syndrome with Phosphatase Inhibitor”, filed by the parties with the United States Patent and Trademark Office prior to the date of this AGREEMENT, is a LICENSED PATENT under the Exclusive License Agreement and rights to such patent shall be governed by the provisions set forth in the Exclusive License Agreement and not by the terms of this AGREEMENT.

14. **Notice**

Whenever any notice is to be given hereunder, it shall be in writing and mailed postage prepaid by certified or registered mail, return receipt requested, or personally delivered to the appropriate party at the address indicated below, or via electronic delivery or reputable overnight service with written verification of receipt at such other place or places as either party may designate in a written notice to the other:

To INSTITUTION:

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.
Attn: Brian Springer, Vice President Research
12902 Magnolia Drive
Tampa, Florida 33612

with courtesy copy to:

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.
Attn: Office of General Counsel
Mailstop: SRB-OGC
12902 Magnolia Drive
Tampa, Florida 33612-9497

and

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.
Attn: Director, Clinical Trial Business Office
Mailstop: MBC OCTBC
12902 Magnolia Drive
Tampa, FL 33612-9497

To PRINCIPAL INVESTIGATOR:

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.
12902 Magnolia Drive
FOB 3rd 5.3117
Tampa, FL 33612-9497
Attn.: Rami Komrokji, MD

To LIXTE:

Lixte Biotechnology Holdings Inc.
248 Route 25A No. 2
East Setauket, NY 11733
Attn.: John S Kovach, MD

Notice shall be deemed to have been received at the earlier of receipt or five (5) days from the date of mailing (in the case of a letter).

15. **Transfer and Use of SAMPLES**

A. "SAMPLES" shall mean, without limitation, blood, serum, fluid and tissue biopsy samples collected from subjects enrolled in the STUDY. SAMPLES further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, DNA, and/or RNA. As between the Parties, INSTITUTION shall be the owner of SAMPLES provided by INSTITUTION to LIXTE in accordance with this Section 15.

B. LIXTE may receive pre-determined quantities of SAMPLES from INSTITUTION, as set forth in the Protocol, for use in research as described in the Protocol or research as otherwise approved by an IRB, provided that such research complies with all applicable laws and regulations, including, but not limited to those of HIPAA, NIH, FDA, and/or DHHS Federal Code of Regulations for the protection of human subjects (45 CFR § 46.102).

C. LIXTE shall in no way attempt to identify or contact the patients associated with the specimen(s) that make up the SAMPLES. Furthermore, LIXTE shall not attempt to obtain or otherwise acquire any additional patient identifiable information associated with the SAMPLES without the prior written consent of the INSTITUTION.

D. LIXTE acknowledges and accepts that LIXTE shall be responsible for all reasonable costs and expenses associated with the transportation of SAMPLES supplied by INSTITUTION to LIXTE, and LIXTE shall comply with all laws, regulations and requirements that apply to shipping SAMPLES.

E. Upon termination or expiration of the STUDY, whichever occurs first, the rights granted to LIXTE to receive and use the SAMPLES shall terminate immediately unless (i) the Protocol or other IRB-approved research has provision for continued analysis or re-analysis of the SAMPLES extending beyond the term of the STUDY up to a period of ten (10) years, or (ii) a separate agreement is in place between INSTITUTION and LIXTE, which agreement shall be at least as restrictive as this AGREEMENT with respect to SAMPLES.

F. The SAMPLES are provided AS IS without WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, AS TO ANY MATTER INCLUDING, BUT NOT LIMITED TO, ACCURACY, RELIABILITY, COMPLETENESS, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, EXCLUSIVITY, RESULTS OBTAINED FROM USE, OR FREEDOM FROM PATENT, TRADEMARK, OR COPYRIGHT INFRINGEMENT.

G. LIXTE acknowledges that the SAMPLES being supplied may have unknown characteristics and may carry infectious agents. All personnel handling the SAMPLES shall be properly trained. LIXTE warrants that it has the knowledge and ability to safely handle any SAMPLES supplied to it and agrees to use prudence and care in the handling, storage, transportation and containment of the SAMPLES. All costs and expenses associated with such protective measures shall be borne by LIXTE. LIXTE shall be permitted to use an outside laboratory for carrying out studies with the SAMPLES described herein provided LIXTE has an agreement in place between LIXTE and outside laboratory at least as restrictive as this AGREEMENT with respect to the SAMPLES.

H. The obligations of the parties under this Section 15 shall survive the termination or expiration of this AGREEMENT.

16. Assignment

This AGREEMENT is not assignable by INSTITUTION and any attempted assignment or delegation in violation hereof shall be void. Notwithstanding the foregoing, INSTITUTION shall have the right to assign or delegate this AGREEMENT to one of its affiliates, subject to LIXTE's written consent, such consent not to be unreasonably withheld or delayed. This Agreement, including the indemnification provisions, shall be binding upon and inure to the benefit of the parties hereto, their respective permitted successors, assigns, legal representatives and heirs.

17. Dispute Resolution

In the event of any bona fide disagreement or disputed claim of any kind or nature between the Parties arising out of or relating to this AGREEMENT or the breach, termination, enforcement, interpretation or validity thereof, the rights or obligations of the parties hereunder, or any payments due hereunder (each, a "DISPUTE"), the parties shall attempt in good faith to resolve any DISPUTE promptly by negotiation between executives who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for administration of this AGREEMENT. Upon the occurrence of a DISPUTE, a disputing Party shall notify the other Party in writing of such DISPUTE (a "DISPUTE NOTICE"). The DISPUTE NOTICE shall include a statement of the Party's position and a summary of arguments supporting that position, together with information reasonably necessary for the other Party to assess and respond to the subject of the DISPUTE, including copies of available supporting documents. Promptly following such DISPUTE NOTICE, the executives of both parties shall meet at a mutually acceptable time and place in good faith to attempt to resolve such DISPUTE by mutual agreement. If the DISPUTE has not been so resolved within thirty (30) days of the DISPUTE NOTICE, either Party may seek equitable and legal remedies under the court system.

18. Publicity

Neither party shall use the name of the other party (or the name of any of LIXTE's divisions or affiliated companies) for promotional purposes without the prior written consent of the party whose name is proposed to be used; provided that, each Party acknowledges that its name, the title of the Protocol and the total funded amount may be disclosed by the other Party to comply with reporting obligations and applicable law. No news release, publicity or other public announcement, either written or oral, regarding this AGREEMENT or performance hereunder or regarding results arising from the STUDY, shall be made by INSTITUTION without the prior written approval of LIXTE.

19. AGREEMENT Modifications

This AGREEMENT may not be altered, amended or modified except by written document signed by both parties.

20. Severability

If any term or condition of this AGREEMENT, the deletion of which would not adversely affect the receipt of any material benefit by either party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this AGREEMENT shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

21. **No Waiver**

Failure on the part of LIXTE or INSTITUTION to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

22. **Force Majeure**

Noncompliance by either party with the obligations of this AGREEMENT due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers), or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this AGREEMENT and such party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it first notifies the other party in writing of such prevention and that it uses reasonable efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

23. **Entire Understanding**

This AGREEMENT, including the Protocol, constitutes the entire agreement and sets forth the understanding between the parties herein, and cannot be changed or amended except by written agreement executed by the parties. In the event of any inconsistency in this AGREEMENT, the inconsistency shall be resolved by giving precedence first, to the Articles of this AGREEMENT, and then, to the Protocol. The Parties agree that this AGREEMENT may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

[REMAINDER OF PAGE BLANK; SIGNATURE PAGE IMMEDIATELY FOLLOWS]

IN WITNESS WHEREOF, the parties have caused this AGREEMENT to be executed, by duly authorized representatives, as of the last date written below.

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc.

Lixte Biotechnology Holdings, Inc.

BY: _____

BY: _____

NAME: John Musser _____

NAME: John S. Kovach, MD _____

TITLE: Director, Clinical Trial Business Office _____

TITLE: President & CEO _____

DATE: _____

DATE: _____

AGREED AND ACCEPTED:

BY: _____

NAME: Rami Komrokji _____

TITLE: PRINCIPAL INVESTIGATOR _____

DATE: _____

EXHIBIT A

A Ph1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy.

The PROTOCOL is to be attached hereto and made a part hereof.

TITLE: A Phase 1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy

Sponsor: H. Lee Moffitt Cancer Center & Research Institute

Funding: Lixte Biotechnology

Principal Investigator: Rami Komrokji, MD
H. Lee Moffitt Cancer Center & Research Institute
12902 Magnolia Drive
Tampa, FL 33612
Telephone: 813-745-4291
e-mail address: rami.komrokji@moffitt.org

Co-Investigators: Eric Padron, MD
Jeffrey E Lancet, MD
Kendra Sweet, MD
Ling Zhang, MD
Kathy McGraw, Ph.D

Physician Scientists: Alan List, MD
David Sallman, MD

Statistician: Dung-Tsa Chen, PhD

Version: Initial

Date: 04/18/2018

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Protocol Synopsis

Title: A Phase 1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy

<p>Study Objectives</p>	<p><u>Primary Objective (Phase 1b):</u></p> <ol style="list-style-type: none"> To determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of LB-100 as determined by dose-limiting toxicities (DLTs) <p><u>Primary Objective (Phase 2):</u></p> <ol style="list-style-type: none"> To estimate overall best response rates of LB-100 using standard international working group (IWG) 2006 response criteria <p><u>Secondary Objectives (Phase 1b and 2) :</u></p> <ol style="list-style-type: none"> To characterize the plasma pharmacokinetics (PK) of LB-100 (Phase 1b only) To evaluate the effect of LB-100 on the hematologic and cytogenetic response in patients with deletion 5q (del(5q)) MDS To estimate the duration of response To estimate the time to AML transformation of subjects on LB-100 To characterize <i>in vivo</i> LB-100 target inhibition To characterize the effect of LB-100 treatment on erythropoietin signaling To determine whether recurrent genetic mutations are predictive of LB-100 response
<p>Study Endpoints</p>	<p><u>Primary</u></p> <ol style="list-style-type: none"> Phase 1b: In the first 2 cycles, the occurrence of DLTs, as defined below, graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5. Phase 2: Achievement of hematological improvement (HI) and/or cytogenetic response by the IWG 2006 criteria (see appendix B). Patients who achieve such a response will be categorized as “responders” and the rest of the patients will be categorized as non-responders. <p><u>Secondary</u></p> <ol style="list-style-type: none"> Plasma concentrations within Phase 1b patient cohort only The response of MDS patients with del(5q) who achieve HI and/or cytogenetic response. Duration of response defined as the time from achievement of HI, PR, CR, mCR until progression of disease or death due to disease. Acute myeloid leukemia (AML) transformation according to World Health Organization (WHO) criteria (see Appendix B). PP2A activity measured via Active PP2A assay kit in peripheral blood before and after LB-100 administration and assess downstream target inhibition in phosphorylation of PP2A substrates (e.g. CDC25C, MDM2, AKT) and p53 expression by immunohistochemistry (IHC) in bone marrow (BM) samples. Erythropoietin-induced STAT5 activation in erythroid progenitors as measured by flow cytometry. Determine recurrent gene mutations in <i>ABL1</i> , <i>ASXL1</i> , <i>CBL</i> , <i>CEBPA</i> , <i>CSF3R</i> , <i>CUX1</i> , <i>DNMT3A</i> , <i>ETV6</i> , <i>EZH2</i> , <i>FLT3</i> , <i>IDH1</i> , <i>IDH2</i> , <i>IKZF1</i> , <i>JAK2</i> , <i>KIT</i> , <i>KRAS</i> , <i>MLL</i> , <i>MPL</i> , <i>MYD88</i> , <i>NPM1</i> , <i>NRAS</i> , <i>PHF6</i> , <i>RUNX1</i> , <i>SETBP1</i> , <i>SF3B1</i> , <i>SH2B3</i> , <i>SRSF2</i> , <i>TET2</i> , <i>TP53</i> , <i>U2AF1</i> , <i>WT1</i> , and <i>ZRSR2</i> at study entry and end of treatment.

EXHIBIT B

BUDGET AND PAYMENT TERMS

Sponsor: Lixte Biotechnology Holdings, Inc.
Protocol TITLE: A Ph1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy

[***]

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT is made and entered into on August 20, 2018 (hereinafter "EFFECTIVE DATE") by and between H. Lee Moffitt Cancer Center and Research Institute, Inc. a non-profit Florida corporation organized pursuant to Section 1004.43, Florida Statutes, whose address is 12902 Magnolia Drive Tampa, Florida 33612-9497 (hereinafter "MOFFITT") and Lixte Biotechnology Holdings, Inc. a Delaware corporation, whose address is 248 Route 25A, No. 2, East Setauket, NY 11733 (hereinafter "LICENSEE"). MOFFITT and LICENSEE are referred herein collectively as the "Parties" and each individually, as a "Party".

WHEREAS, the Internal Revenue Service has determined that MOFFITT is exempt from Federal income tax under Internal Revenue Code Section 501(a) as an organization described in Code Section 501(c)(3) and classified it as a public charity under Code Section 509(a)(1) as a publicly supported organization described in Code Section 170(b)(1)(A)(vi);

WHEREAS, LICENSEE owns certain compounds designated LB-100 and LB-151 (the "Compounds"), which Compounds, and various uses thereof and processes related thereto, are covered by various patents and patent applications owned by LICENSEE;

WHEREAS, pursuant to a certain Material Transfer Agreement between LICENSEE and MOFFITT dated September 27, 2013 ("MTA"), LICENSEE supplied certain Material (as defined in the MTA) including the Compounds, for use by MOFFITT in certain Research (as defined in the MTA) and, pursuant to the MTA, LICENSEE was granted an option for an exclusive license to any rights of MOFFITT in any inventions developed in the course of the Research and, in the course of the Research, certain inventions were developed, including the inventions listed on Appendix A;

WHEREAS, MOFFITT wishes to have the inventions claimed in the LICENSED TECHNOLOGIES, and any resulting patents, commercialized to benefit the public good; and

WHEREAS, MOFFITT is willing to grant an exclusive license to its rights in the LICENSED TECHNOLOGIES to LICENSEE and LICENSEE desires to receive an exclusive license to the LICENSED TECHNOLOGIES, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, MOFFITT and LICENSEE agree as follows:

ARTICLE 1
DEFINITIONS AND RULES OF CONSTRUCTION

1.1 The following terms when capitalized, whether used in the singular or plural, shall have the respective meanings set forth below.

(a) "AFFILIATE" shall mean, with respect to a Party, any entity or person that directly or indirectly controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" means the direct or indirect: (i) ownership or control of greater than fifty percent (50%) of the voting equity of such Person; or (ii) right to direct or cause the direction of the policies and management of such Person, whether by the ownership of voting securities, by contract or otherwise. In any jurisdiction where ownership or control of greater than fifty percent (50%) is not permitted under applicable law, the "greater than 50%" threshold shall be deemed satisfied by the possession of substantially maximum percentage of ownership or control allowable in such jurisdiction.

(b) "CLASS A CLAIM" shall mean any VALID CLAIM that is not a CLASS B CLAIM.

(c) "CLASS B CLAIM" shall mean any VALID CLAIM that (i) is directed to a composition comprising monosodium glutamate or a method of use thereof, or (ii) otherwise contains a claim limitation of monosodium glutamate.

(d) "COMMENCEMENT DATE" means the date on which MOFFITT has entered the first patient on the clinical trial contemplated in the CTA.

(e) "COMMERCIALY REASONABLE EFFORTS" shall mean, with respect to either Party in relation to this Agreement, such efforts that are consistent with the efforts and resources used by a biopharmaceutical company of similar size and market capitalization or a research institute of similar size and financial capability, as the case may be, as such Party in the exercise of its commercially reasonable business practices relating to an exercise of a right or performance of an obligation under this Agreement, including the research, development, manufacture and commercialization of a pharmaceutical or biologic compound or product, as applicable, at a similar stage in its research, development or commercial life as the relevant ROYALTY-BEARING PRODUCT, and that has commercial and market potential similar to the relevant ROYALTY-BEARING PRODUCT, taking into account issues of intellectual property coverage, safety and efficacy, stage of development, product profile, competitiveness of the marketplace, proprietary position, regulatory exclusivity, anticipated or approved labeling, present and future market and commercial potential, the likelihood of receipt of regulatory approval, profitability (including pricing and reimbursement status achieved or likely to be achieved), amounts payable to licensors of patent or other intellectual property rights, alternative products, and legal issues.

(f) "CONFIDENTIAL INFORMATION" of a Party shall mean all non-public or proprietary information disclosed by such PARTY to the other during the negotiation of or under this Agreement in any manner, whether orally, visually or in tangible form, that relates to LICENSED TECHNOLOGIES or the ROYALTY-BEARING PRODUCTS, or the business of such PARTY or the terms of this Agreement. CONFIDENTIAL INFORMATION includes the following, whether or not patentable: materials, know-how and data (whether technical or non-technical), trade secrets, inventions, methods and processes. Notwithstanding anything to the contrary herein, CONFIDENTIAL INFORMATION of LICENSEE includes all information that LICENSEE supplies pursuant to LICENSEE's obligations under ARTICLE 6 and ARTICLE 8 of this Agreement. MOFFITT CONFIDENTIAL INFORMATION may include certain CONFIDENTIAL INFORMATION of the University of South Florida ("USF") or other third-parties that is obtained by MOFFITT in accordance with one or more agreements between MOFFITT and USF or the applicable third party.

(g) “CTA” means the Clinical Trial Research Agreement between MOFFITT and LICENSEE, dated as of July 2, 2018.

(h) “EARNED ROYALTY” is defined in [Article 5.2](#).

(i) “EFFECTIVE DATE” is defined in the introductory paragraph of this Agreement.

(j) “FIELD” shall mean oncology diagnostics and therapeutics.

(k) “FIRST SALE” shall mean the first SALE of a ROYALTY-BEARING PRODUCT that results in NET SALES in any country.

(l) “IND” shall mean an investigational new drug application (including any amendment or supplement thereto) submitted to the FDA pursuant to U.S. 21 C.F.R. Part 312, including any amendments or successor provisions thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. for the investigation of any product in any other country or group of countries (such as a Clinical Trial Application filed in the European Union).

(m) “INSOLVENT” shall mean that LICENSEE (i) has ceased to pay its debts in the ordinary course of business, (ii) is insolvent as defined by the United States Federal Bankruptcy Law, as amended from time to time, or (iii) has commenced bankruptcy, reorganization, receivership or insolvency proceedings, or any other proceeding under any Federal, state or other law for the relief of debtors.

(n) “INTELLECTUAL PROPERTY RIGHTS” shall mean any intellectual or industrial property rights, in any jurisdiction worldwide, whether registered or unregistered, including such rights in and to patents, trademarks, copyrights, data or databases, trade secrets or know-how, and any application for registration of any of the foregoing.

(o) “LICENSE” refers to the license granted under [Section 2.1](#).

(p) “LICENSED INFORMATION” shall mean all inventions, concepts, processes, information, data, know-how, research results, clinical data, and the like (other than the LICENSED PATENTS) that are owned or controlled by MOFFITT OR ITS AFFILIATES as of the EFFECTIVE DATE, and necessary or useful for (i) the practice of any claim of a LICENSED PATENT or (ii) the use, development, manufacture or sale of any ROYALTY-BEARING PRODUCT.

(q) “LICENSED PATENTS” shall mean MOFFITT’s and its AFFILIATES’ rights in and to: (i) the patents and patent applications listed on [Appendix A](#); (ii) any other patent or patent application covering an invention made, in whole or part, in the course of the Research or which was derived from use of the Material, or which discloses or claims any LICENSED INFORMATION; (iii) any additional patents or patent applications that LICENSEE elects to be included in LICENSED PATENTS pursuant to Section 13B of the CTA; (iv) any continuations, continuations-in-part (to the extent that they do not include new subject matter), divisionals, reissues, re-examinations, extensions or substitutions of any of the foregoing; (v) foreign equivalents or counterparts to any of the foregoing; and (vi) any patents that issue from any of the foregoing. Nothing in this Agreement is intended to establish or stipulate the owner(s) or ownership of the LICENSED PATENTS.

(r) "LICENSED TECHNOLOGIES" shall mean the LICENSED PATENTS and the LICENSED INFORMATION.

(s) "LICENSED TERRITORY" shall mean the entire world.

(t) "NDA" shall mean a new drug application filed with the United States Food and Drug Administration to obtain marketing approval for a ROYALTY-BEARING PRODUCT in the United States or any comparable application filed with a regulatory authority in or for a country or group of countries other than the United States.

(u) "NET SALES" shall mean:

(i) the total gross revenues invoiced by LICENSEE or any of its AFFILIATES from the SALE of ROYALTY-BEARING PRODUCTS to a Third Party during the ROYALTY TERM, less the following deductions ("DEDUCTIONS"), provided they actually pertain to the disposition of ROYALTY-BEARING PRODUCTS as demonstrated by reasonable business records:

a) all reasonable and customary discounts, retroactive price reductions, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers;

b) all reasonable returns (including wholesaler and cash discounts customary in the trade to the extent that they are actually granted), credits and allowances on account of returns, bad debt deductions actually written off during the QUARTER in which sales occurred;

c) reasonable and customary packing charges, outbound transportation and freight charges; and

d) reasonable and customary duties, taxes (but not income taxes) and other governmental charges levied on the sale, transportation or delivery of ROYALTY-BEARING PRODUCTS, but not including income taxes of the LICENSEE.

e) wholesaler and cash discounts customary in the trade to the extent that they are actually granted.

(ii) No DEDUCTION shall be made for any other costs or expenses, including commissions to any person or entity on LICENSEE's or an AFFILIATE's payroll for the cost of collection.

(iii) Notwithstanding any provision in this Agreement to the contrary, NET SALES shall not include: (a) the gross invoice price for ROYALTY-BEARING PRODUCTS used by, sold to, or leased to, any AFFILIATE unless such AFFILIATE is an end-user of such ROYALTY-BEARING PRODUCTS, in which case such NET SALES shall be calculated using the average gross invoice price charged to Third Parties who are not AFFILIATES during the same quarter or (b) the supply of ROYALTY-BEARING PRODUCTS for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, any non-clinical development use or compassionate use, or as commercial samples. In the event that ROYALTY-BEARING PRODUCTS are leased or exchanged for consideration other than money, the gross invoice price shall be the average gross invoice price charged to Third Parties during the same Quarter.

(iv) NET SALES shall not include sublicensee sales.

(v) If a ROYALTY-BEARING PRODUCT is SOLD as part of a COMBINATION PRODUCT (as defined below), the amount to be used to determine the EARNED ROYALTIES (“X”) for such NET SALES of the COMBINATION PRODUCT will be determined by the following formula (determined on a country by country basis):

$$(X) = \frac{\text{NET SALES for COMBINATION PRODUCT}}{\text{(calculated after DEDUCTIONS as set forth above)}} \times \frac{A}{A+B}$$

Where: “A” is the gross invoice price in such country of the applicable ROYALTY-BEARING PRODUCT that is SOLD as the sole active ingredient and not in a combination with other drug products or other bundled products; and

“B” is the gross invoice price in such country of the other therapeutically active product(s) comprised in the combination other than the applicable ROYALTY-BEARING PRODUCT (or in the case of bundled products, the other product(s) sold in the bundle other than the applicable ROYALTY-BEARING PRODUCT), when such other products are not sold as part of a combination with the applicable ROYALTY-BEARING PRODUCT.

If “A” or “B” cannot be determined by reference to non-COMBINATION PRODUCT SALES as described above, then NET SALES will be calculated as above, but the gross selling price in the above equation will be determined by mutual agreement reached in good faith by the PARTIES prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variations in dosage units and the relative fair market value of each component in the COMBINATION PRODUCT.

As used in this definition, “COMBINATION PRODUCT” shall mean, in the case of a finished co-formulated pharmaceutical product, a product that comprises the therapeutically active ingredient(s) of the ROYALTY-BEARING PRODUCT co-formulated within such finished product with one or more additional active pharmaceutical ingredients that are not included in the ROYALTY-BEARING PRODUCT; and, in the case of one or more bundled products, a ROYALTY-BEARING PRODUCT that is SOLD in a bundle together with one or more separate product(s) each of which is not a ROYALTY-BEARING PRODUCT.

(v) “OUT OF POCKET COSTS” means reasonable fees and costs actually incurred and paid or payable to a Third Party, as demonstrated by the incurring Party upon reasonable and contemporaneous documentation. The term “ OUT OF POCKET COSTS ” does not include any costs or expenses: (i) that have been reimbursed by LICENSEE, have been reimbursed or are reimbursable by any THIRD PARTY, or (ii) that are for core facilities charges, employee salaries, utilities and other overhead or indirect costs for MOFFITT.

(w) “PERSON” shall mean any natural person, firm, partnership, limited liability company, joint venture, business trust, trust, association, corporation, company, unincorporated entity or other entity.

(x) “PHASE 1B/2 CLINICAL TRIAL” shall mean the Clinical Protocol of LB-100 in the treatment of MDS set forth in Appendix B, including the clinical trial that is the subject of the CTA.

(y) “PHASE 2 CLINICAL TRIAL” shall mean a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by the relevant regulatory authorities in a country other than the United States.

(z) “PHASE 3 CLINICAL TRIAL” shall mean a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to (i) establish that the product is safe and efficacious for its intended use, (ii) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (iii) support regulatory approval for such product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

(aa) “PLAN” is defined in Section 6.1.

(bb) “ROYALTY-BEARING PRODUCT” shall mean any product approved for use and used in connection with the treatment of MDS whose manufacture, use, sale, offer for sale or import would, but for the LICENSE granted hereunder, infringe a VALID CLAIM in the country in which such product is manufactured or sold.

(cc) ROYALTY TERM is defined in Section 5.1.

(dd) “SALE” shall mean, with respect to a ROYALTY-BEARING PRODUCT, the invoicing of sale, lease, transfer or disposition of such ROYALTY-BEARING PRODUCT from a LICENSEE or its AFFILIATE to a THIRD PARTY, provided that each of the following shall not constitute a SALE: (i) a transfer among LICENSEE, any of its AFFILIATES and/or any SUBLICENSEE, and (ii) any transfer, use or disposition for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes, any non-clinical development use or compassionate use, or as commercial samples. “SOLD” and “SELL” have the correlative meanings.

(ee) "SUBLICENSE" shall mean a sublicense or other similar right, license, privilege or immunity granted by LICENSEE or an AFFILIATE to a THIRD PARTY under the LICENSED PATENTS to make, have made, use, sell, have sold, distribute, import or export ROYALTY-BEARING PRODUCTS.

(ff) "SUBLICENSE INCOME" shall mean consideration in any form received by LICENSEE or an AFFILIATE specifically in consideration of the grant to any Third Party of a SUBLICENSE. SUBLICENSE INCOME shall include any license signing fee, license maintenance fee, milestone payments, unearned portion of any minimum royalty payment received by LICENSEE or its AFFILIATE, in each case which is directly and specifically related to the grant of a SUBLICENSE and not for the grant of other rights, including other Intellectual Property Rights. SUBLICENSE INCOME shall not include funding specifically designated and used for research and development.

(gg) "SUBLICENSEE" shall mean a THIRD PARTY that is the recipient of a SUBLICENSE.

(hh) "SUBLICENSEE ROYALTY RATE" shall mean an amount equal to twenty percent (20%) of the SUBLICENSE INCOME actually received by LICENSEE from any SUBLICENSEE.

(ii) "TERM" is defined in [Section 12.1](#).

(jj) "THIRD PARTY" shall mean, with respect to LICENSEE, any PERSON other than LICENSEE or any of its AFFILIATES, and with respect to MOFFITT, any PERSON other than MOFFITT or any of its AFFILIATES.

(kk) "VALID CLAIM" means either: (i) a claim of an issued and unexpired LICENSED PATENT that has not been permanently revoked or declared unenforceable or invalid by an unreversed and unappealable decision of a court or other appropriate body of competent jurisdiction and which has not been abandoned, disclaimed, denied, or admitted to be invalid or unenforceable or surrendered through reissue, re-examination, disclaimer, or otherwise; or (ii) a claim of a pending patent application for a LICENSED PATENT that was filed in good faith and has not been cancelled, withdrawn, abandoned, or finally disallowed without the possibility of appeal or refiling of such application and has not been pending for more than ten (10) years.

1.2 [Additional Definitions](#). Each of the following definitions is set forth in the Section of this Agreement indicated below:

<u>Definition:</u>	<u>Section:</u>
CHALLENGE	12.3(c)
CLAIM	13.1
COMPOUNDS	Preamble
DELAYING EVENT	6.5
DISPUTE	16.1
DISPUTE NOTICE	16.2
DISPUTE RESOLUTION PROCESS	16.1
FEDERAL PATENT POLICY	2.2
MRP	5.4
NON-PROSECUTING PARTY	9.3
PROSECUTING PARTY	9.3
QUARTER	5.3
ROYALTY TERM	5.1
THIRD PARTY IPR	5.7

1.3 Rules of Interpretation and Construction. In this Agreement, except to the extent expressly provided otherwise:

(a) As used herein, the singular shall be deemed to include the plural, and the plural shall be deemed to include the singular, and all pronouns shall include the masculine, feminine and neuter, whenever the context and facts require such construction. The headings, captions, titles and subtitles herein are inserted for convenience of reference only and are to be ignored in any construction of the provisions hereof. Except as otherwise indicated herein, all references to Articles, Sections and Appendixes herein shall be deemed to refer to the Articles, Sections and Appendixes of and to this Agreement, and the terms “herein”, “hereof”, “hereto”, “hereunder” and similar terms refer to this Agreement generally rather than to the particular provision in which such term is used. Whenever the words “including”, “include” or “includes” are used in this Agreement, they shall be interpreted in a non-exclusive manner as though the words “but not limited to” immediately followed the same. The word “will” shall be construed to have the same meaning and effect as the word “shall.” The word “any” shall mean “any and all” unless otherwise clearly indicated by context. “\$” as used in this Agreement means the lawful currency of the United States of America. Derivative forms of any capitalized term defined herein shall have meanings correlative to the meaning specified herein.

(b) Except as otherwise expressly provided herein, references in this Agreement to any agreement, instrument or other document are to such agreement, instrument or other document as amended, modified or supplemented from time to time. It is the intention of the Parties hereto that every provision of this Agreement shall be construed simply according to its fair meaning and without any presumption, inference or rule requiring construction or interpretation of any such provision against the interests of any Party that drafted such provision (notwithstanding any rule of law requiring a provision to be strictly construed against the drafting party), it being understood that the parties to this Agreement are sophisticated and have had adequate opportunity and means to retain counsel to represent their interests and to otherwise negotiate the provisions of this Agreement.

ARTICLE 2
LICENSE GRANT AND TERM

2.1 Subject to all the terms and conditions of this Agreement, MOFFITT hereby grants to LICENSEE (a) an exclusive license to its rights under the LICENSED PATENTS, with the right to grant sublicenses, to make, have made, use, sell, have sold, import or export products within the FIELD in the LICENSED TERRITORY, and to practice processes and methods covered by the LICENSED PATENTS in connection with the foregoing, and (b) a non-exclusive license under the LICENSED INFORMATION to make, have made, use, sell, have sold, import or export products within the FIELD in the LICENSED TERRITORY and to practice processes and methods covered by the LICENSED INFORMATION in connection with the foregoing (collectively, the "LICENSE").

2.2 To the extent that any invention included within the LICENSED TECHNOLOGIES has been funded in whole or in part by the United States government, the United States government retains certain rights in such invention including but not limited to 35 U.S.C. §200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations (collectively the "FEDERAL PATENT POLICY"). As a condition of the LICENSE granted hereby, LICENSEE acknowledges and shall comply with all aspects of the FEDERAL PATENT POLICY applicable to the LICENSED TECHNOLOGIES, including the obligation that LICENSED TECHNOLOGIES used or sold in the United States be manufactured substantially in the United States. Nothing contained in this Agreement obligates or shall obligate MOFFITT to take any action that would conflict in any respect with its past, current or future obligations to the United States Government under the FEDERAL PATENT POLICY with respect to the LICENSED TECHNOLOGIES.

2.3 Except as expressly provided in this Agreement, under no circumstances shall LICENSEE, as a result of this Agreement, obtain any interest in or any other right to any technology, know-how, patents, patent applications, materials or other intellectual or proprietary property of MOFFITT or its AFFILIATES, nor shall MOFFITT, as a result of this Agreement, acquire any interest in or any other right to any technology, know-how, patents, patent applications, materials or other intellectual or proprietary property of LICENSEE, its AFFILIATES or SUBLICENSEES.

2.4 MOFFITT shall disclose the LICENSED INFORMATION to LICENSEE, which LICENSEE shall be entitled to use as provided in this ARTICLE 2.

2.5 MOFFITT represents and warrants that to the best of its knowledge after due inquiry: (a) it has obtained from all relevant persons appropriate agreements vesting in MOFFITT and/or USF all rights to LICENSED PATENTS necessary to grant to LICENSEE the rights granted hereunder, and, upon the request of LICENSEE, MOFFITT shall provide to LICENSEE copies of such agreements and (b) MOFFITT and its AFFILIATES have not licensed, sublicensed, transferred or assigned any rights to a Third Party in any LICENSED PATENTS licensed under this Agreement.

2.6 Other than the obligations expressly provided in this Agreement, LICENSEE assumes no obligation (financial or otherwise) to any other PERSON not a party to this Agreement under any oral or written agreement between MOFFITT and such other PERSON (including any inter-institutional agreement between MOFFITT and USF). For the avoidance of doubt, LIXTE has no obligations under this Agreement to make any payments to USF, and any payment or other obligations to USF that may arise under the agreement between MOFFITT and USF are solely the obligation of MOFFITT.

ARTICLE 3
SUBLICENSES

3.1 LICENSEE shall have the right to grant SUBLICENSES under the LICENSEE to SUBLICENSEES:

(a) Any SUBLICENSE granted by LICENSEE shall be set forth in a written agreement that complies with and is consistent with all applicable terms and conditions of this Agreement. A SUBLICENSE agreement between the LICENSEE and any SUBLICENSEE shall be subject to and subordinate to this Agreement.

(b) LICENSEE shall provide MOFFITT with a final copy of each executed SUBLICENSE agreement within thirty (30) days after execution thereof, and LICENSEE may reasonably redact the economic and business terms of such SUBLICENSE agreement, provided that such SUBLICENSE agreement must be sufficiently unredacted so that MOFFITT can confirm that the terms of such SUBLICENSE agreement are consistent with the terms of this Agreement. During the term of a SUBLICENSE agreement, LICENSEE shall be responsible to MOFFITT for each SUBLICENSEE'S material compliance with all terms and conditions of this Agreement applicable to a SUBLICENSEE, and LICENSEE shall use COMMERCIALY REASONABLE EFFORTS to cause its SUBLICENSEE to comply in all material respects with all provisions of this Agreement applicable to SUBLICENSEE.

3.2 LICENSEE shall pay to MOFFITT a portion of all SUBLICENSE INCOME received by LICENSEE at the SUBLICENSEE ROYALTY RATE, provided that, if as of the date on which a payment obligation under this Section 3.2 accrues, there is at least one CLASS B CLAIM and there is no CLASS A CLAIM, then the SUBLICENSEE ROYALTY RATE shall be reduced to twelve percent (12%) of the SUBLICENSE INCOME actually received by LICENSEE from any SUBLICENSEE. Commencing on the date on which there are no VALID CLAIMS in the LICENSED PATENTS, LICENSEE'S payment obligation under this Section 3.2 shall cease.

3.3 LICENSEE agrees that it has sole responsibility to promptly provide MOFFITT with a copy of any amendments to any SUBLICENSE agreement granted by LICENSEE under this Agreement (subject to reasonable redaction consistent with Section 3.1 and notify MOFFITT of termination of any SUBLICENSE agreement.

3.4 Upon termination of this Agreement for any reason, any SUBLICENSEE not then in default under its SUBLICENSE agreement shall have the right to receive a direct license from MOFFITT on substantially the same terms and conditions as its SUBLICENSE agreement with LICENSEE. LICENSOR agrees to negotiate such licenses in good faith under reasonable terms and conditions, and the SUBLICENSE shall remain in force during such good faith negotiations.

ARTICLE 4
LICENSE ISSUE FEE; LICENSE MAINTENANCE FEE; MILESTONE PAYMENTS

4.1 LICENSEE shall pay to MOFFITT a non-refundable license issue fee of twenty five thousand (\$25,000) within ten (10) days of the COMMENCEMENT DATE.

4.2 During the ROYALTY TERM of this Agreement, LICENSEE agrees to pay to MOFFITT an annual license maintenance fee (“LMF”) of twenty five thousand (\$25,000), commencing on the first anniversary of the EFFECTIVE DATE and every anniversary thereafter until LICENSEE starts to pay Minimum Royalty Payments under ARTICLE 5. The LMF payable in years in which milestone payments as described in Article 4.4 are paid shall be fully creditable against such milestone payments.

4.3 Subject to Section 4.5, LICENSEE shall pay the following milestone payments to MOFFITT:

(a) a non-refundable milestone payment of twenty thousand dollars (\$20,000) when LICENSEE initiates its first PHASE 2 CLINICAL TRIAL of a ROYALTY-BEARING PRODUCT for MDS, other than the second portion of the Phase 1b/2 Clinical Trial set forth in Appendix B;

(b) a non-refundable milestone payment of ninety thousand dollars (\$90,000) when LICENSEE initiates its first PHASE 3 CLINICAL TRIAL of a ROYALTY-BEARING PRODUCT for MDS;

(c) a non-refundable milestone payment of one hundred and fifty thousand (\$150,000) upon the acceptance for review by the FDA of the first NDA for a ROYALTY-BEARING PRODUCT for MDS;

(d) a non-refundable milestone payment of three hundred and thirty seven thousand dollars (\$337,000) upon the approval in favor of LICENSEE by the FDA of an NDA for the first indication of a ROYALTY-BEARING PRODUCT for MDS;

(e) a non-refundable milestone payment of one hundred and fifty thousand dollars (\$150,000) upon approval in favor of LICENSEE of a European equivalent of an NDA for a first indication of a ROYALTY-BEARING PRODUCT for MDS;

(f) a non-refundable milestone payment of one hundred and fifty thousand dollars (\$150,000) upon approval in favor of LICENSEE of a Japanese equivalent of an NDA for a first indication of a ROYALTY-BEARING PRODUCT for MDS;

(g) a non-refundable milestone payment of one million dollars (\$1,000,000) when LICENSEE reaches a total of one billion dollars (\$1,000,000,000) in cumulative NET SALES for SALES of ROYALTY-BEARING PRODUCTS.

4.4 For avoidance of doubt, initiation of clinical trials in Section 4.1 occurs upon the dosing of the first patient in the applicable clinical trial. The milestone fees set forth in Section 4.1 shall not be credited against EARNED ROYALTIES payable by LICENSEE under ARTICLE 5. For the avoidance of doubt, each of the milestone payments listed in Section 4.1 shall be payable no more than one time, and, without limiting Section 4.5, in no event shall LICENSEE be obligated to pay aggregate milestone payments in an amount greater than one million, eight hundred ninety seven thousand U.S. dollars (\$1,897,000).

4.5 Notwithstanding anything to the contrary herein, LICENSEE shall be obligated to pay the amounts specified in Sections 4.2, 4.3 and 12.5 only if, on the date on which the applicable payment obligation accrues, there is at least one VALID CLAIM, provided that if on such date, there is at least one CLASS B CLAIM but there is no CLASS A CLAIM, then the payment obligations otherwise applicable under Sections 4.2, 4.3 and 12.5, as the case may be, shall be reduced to sixty percent (60%) of the amounts specified above. Commencing on the date on which there are no VALID CLAIMS in the LICENSED PATENTS, all of LICENSEE's payment obligations under Sections 4.2, 4.3 and 12.5 shall cease.

ARTICLE 5
EARNED ROYALTIES; MINIMUM ROYALTY PAYMENTS

5.1 Unless terminated earlier as provided in ARTICLE 12, the obligation hereunder to pay EARNED ROYALTIES shall commence on the date of the FIRST SALE of a ROYALTY-BEARING PRODUCT, and shall automatically expire on a country-by-country basis, on the date on which the last VALID CLAIM of the LICENSED PATENTS expires, lapses or is declared invalid, and the obligation to pay any EARNED ROYALTIES under this Agreement shall terminate on the date on which the last VALID CLAIM of the LICENSED PATENTS expires, lapses or is declared to be invalid in all countries (the "ROYALTY TERM").

5.2 During the ROYALTY TERM, as partial consideration for the LICENSE, subject to Section 5.7, LICENSEE shall pay to MOFFITT an earned royalty of four percent (4%) on worldwide cumulative NET SALES of ROYALTY-BEARING PRODUCTS by LICENSEE or its AFFILIATES ("EARNED ROYALTIES"), provided that, if as of the date on which a payment obligation under this Section 5.2 accrues, there is at least one CLASS B CLAIM and there is no CLASS A CLAIM, then the royalty rate payable under this Section 5.2 shall be reduced to two percent (2%) and each applicable MRP payable under Section 5.4 shall be reduced to sixty percent (60%) of the amount specified in Section 5.4.

5.3 LICENSEE shall pay all EARNED ROYALTIES accruing to MOFFITT within sixty (60) days from the end of each quarter ("QUARTER") (i.e., by March 31, June 30, September 30 and December 31), beginning in the QUARTER in which NET SALES occur.

5.4 During the ROYALTY TERM, LICENSEE agrees to pay MOFFITT annual Minimum Royalty Payments ("MRP"), commencing on the first anniversary of the EFFECTIVE DATE to occur at least twelve (12) month after the First Sale, each anniversary of the EFFECTIVE DATE thereafter during the ROYALTY TERM. LICENSEE shall continue to pay the MRP until the end of the ROYALTY TERM. MOFFITT shall fully credit each MRP made against any EARNED ROYALTIES payable by LICENSEE in the same year. Subject to Section 5.7, the MRP shall be in the following amounts:

Years after FIRST SALE	MRP
1 through 4	\$ 50,000
Beginning upon the first anniversary of year 5 and each year thereafter	\$ 100,000

5.5 All EARNED ROYALTIES and other payments due under this Agreement shall be paid to MOFFITT in United States Dollars. In the event that conversion from foreign currency is required in calculating a payment under this Agreement, the exchange rate used shall be the Interbank rate quoted by Citibank (or successor) at the end of the last business day of the quarter in which the royalty was earned. If overdue, the royalties and any other payments due under this Agreement shall bear interest until payment at a per annum rate two percent (2%) above the prime rate in effect at Citibank (or successor) as of the payment due date. If the interest rate required in this subsection exceeds the legal rate in a jurisdiction where a claim for such interest is being asserted, the required interest rate shall be reduced, for such claim only, to the maximum interest rate allowable in the jurisdiction. The payment of such interest shall not foreclose MOFFITT from exercising any other right it may have as a consequence of the failure of LICENSEE to make any payment when due.

5.6 No multiple royalties shall be payable because any ROYALTY-BEARING PRODUCT, its manufacture, use, lease or sale are or shall be covered by more than one of the LICENSED PATENTS licensed under this Agreement.

5.7 If LICENSEE or its AFFILIATES obtain a license under any INTELLECTUAL PROPERTY RIGHTS of a THIRD PARTY ("THIRD PARTY IPR") to make, use, sell, offer for sale or import or export a ROYALTY-BEARING PRODUCT in consideration of a payment payable to a THIRD PARTY, then the EARNED ROYALTIES and MRP payable hereunder in respect of each ROYALTY-BEARING PRODUCT covered by or incorporating such THIRD PARTY IPR shall be reduced by an amount equal to twenty five percent (25%) of the amount of the payment to such THIRD PARTY, provided that the EARNED ROYALTIES or MRP payable to MOFFITT shall in no event be reduced more than seventy five percent (75%) of the applicable amount specified in Section 5.2 or 5.4, as the case may be.

5.8 LICENSEE is responsible for any and all wire/bank fees associated with all payments due to MOFFITT pursuant to this Agreement.

ARTICLE 6 DUE DILIGENCE

6.1 LICENSEE shall develop, commercialize, and market the ROYALTY-BEARING PRODUCTS and has designed a plan for such purpose that includes a description of research and development, testing, government approval, manufacturing, marketing and sale or lease of ROYALTY-BEARING PRODUCTS ("PLAN"). A copy of the PLAN is attached to this Agreement as Appendix C and incorporated herein by reference.

6.2 LICENSEE shall use COMMERCIALY REASONABLE EFFORTS to implement the PLAN and to obtain regulatory approval for the ROYALTY-BEARING PRODUCTS.

6.3 Within sixty (60) days of each anniversary of the EFFECTIVE DATE, LICENSEE shall provide a written report to MOFFITT, indicating LICENSEE's progress and problems to date in performance under the PLAN. Such report shall include a detailed description of each research study performed with respect to ROYALTY-BEARING PRODUCTS. From time to time while this Agreement is in effect, LICENSEE shall furnish MOFFITT with reasonable requested information pertaining to the development, marketing, and commercialization of the ROYALTY-BEARING PRODUCTS, provided that MOFFITT shall not make such request more than once every QUARTER. All information provided to MOFFITT under this Section 6.3 shall be CONFIDENTIAL INFORMATION of LICENSEE hereunder.

6.4 If at any time LICENSEE abandons or suspends its research, development, or marketing of the ROYALTY-BEARING PRODUCTS or its intent to research, develop and market such products, or otherwise fails to materially comply with its due diligence obligations under this Article for a period exceeding ninety (90) days, LICENSEE shall immediately notify MOFFITT giving reasons and a statement of its intended actions.

6.5 LICENSEE agrees that MOFFITT shall be entitled to terminate this Agreement pursuant to Section 12.3(b) upon the occurrence of any of the following:

(a) LICENSEE has failed to achieve one of the following undertakings:

(i) Execution of a strategic alliance/SUBLICENSE agreement with a commercial partner within twenty four (24) months after completion by LICENSEE or its designee of a PHASE 2 CLINICAL TRIAL for an indication of a ROYALTY BEARING PRODUCT for MDS, and submission of final trial report to LICENSEE for such trial; or

(ii) If a satisfactory strategic alliance and/or SUBLICENSE cannot be arranged as set forth in Section 6.5(a)(i), LICENSEE reserves the right to market the ROYALTY-BEARING PRODUCT, provided that LICENSEE or its SUBLICENSEE shall initiate a PHASE 3 CLINICAL TRIAL for an indication of a ROYALTY BEARING PRODUCT for MDS within four (4) years after completion of the PHASE 2 CLINICAL TRIAL referenced in subsection (i) above.

The termination provisions of Section 6.5 shall not apply if LICENSEE demonstrates COMMERCIALY REASONABLE EFFORTS to achieve either one of (i) or (ii) above. For the avoidance of doubt and notwithstanding anything to the contrary herein, LICENSEE will not be deemed to have failed to have exercised COMMERCIALY REASONABLE EFFORTS if the failure to achieve such undertaking results from one or more of the following events or circumstances has occurred (each, a "DELAYING EVENT"): (1) the occurrence of serious adverse events or safety or toxicity issues such that LICENSEE, its AFFILIATE and/or SUBLICENSEE (as the case may be) determines to hold or delay a study, (2) any regulatory hold, constraint or restriction imposed or raised by a regulatory authority that is not consequent on regulatory filing deficiencies of LICENSEE, (3) process development, manufacture or supply delays or failures arising from events not under LICENSEE's (or its AFFILIATE'S and/or SUBLICENSEE'S, as the case may be) control, (4) any force majeure event, (5) delay attributable to any act or omission by MOFFITT or its AFFILIATES or (6) a third party alleges that the development, manufacture, use or sale of the ROYALTY-BEARING PRODUCT infringes its INTELLECTUAL PROPERTY RIGHTS.

ARTICLE 7
CONFIDENTIALITY AND PUBLICITY

7.1 Subject to the Parties' rights and obligations pursuant to this Agreement, MOFFITT and LICENSEE agree that during the TERM of this Agreement and for five (5) years after termination of the Agreement, each Party:

(a) will keep confidential and will cause their Affiliates and, in the case of LICENSEE, its SUBLICENSEES, to keep confidential, CONFIDENTIAL INFORMATION disclosed to it by the other Party, by taking whatever action the Party receiving the CONFIDENTIAL INFORMATION would take to preserve the confidentiality of its own CONFIDENTIAL INFORMATION, which in no event shall be less than reasonable care; and

(b) will only disclose that part of the other's CONFIDENTIAL INFORMATION to its officers, employees or agents that is necessary for those officers, employees or agents who need to know to carry out its responsibilities under this Agreement; and

(c) will not use the other Party's CONFIDENTIAL INFORMATION other than as expressly set forth in this Agreement or disclose such CONFIDENTIAL INFORMATION to any Third Parties under any circumstance without advance written permission from the other Party; and

(d) will within sixty (60) days of termination of this Agreement, return or destroy all the CONFIDENTIAL INFORMATION disclosed to it by the other Party pursuant to this Agreement except for one copy which may be retained by the recipient for monitoring compliance with this ARTICLE 7 and/or for use in complying with any regulatory requirements.

7.2 The obligations of confidentiality described in Section 7.1 above shall not pertain to that part of the CONFIDENTIAL INFORMATION that as established by written records:

(a) is already in the recipient's possession prior to receipt from the disclosing party; or

(b) is in the public domain by use and/or publication at the time of receipt from the disclosing party, or enters into the public domain through no improper act of the receiving party; or

(c) is developed independently by the receiving party without reference to the information of the disclosing party; or

(d) is properly obtained by receiving party from a Third Party with a valid legal right to disclose such information and such Third Party is not under a confidentiality obligation to such information to the disclosing party; or

(e) is required to be disclosed pursuant to the securities laws; or

(f) is required to be disclosed by law, as confirmed by an opinion of recipient's outside counsel, but only after the disclosing party is given prompt written notice and an opportunity to seek a protective order.

7.3 Except as required by law, neither Party may disclose the financial terms of this Agreement without the prior written consent of the other Party, except that (a) MOFFITT may share such terms with USF, subject to USF entering into an appropriate confidentiality with LICENSEE and/or its SUBLICENSEE (as the case may be) and (b) LICENSEE may share such terms, and potential acquirers, investors or SUBLICENSEES, under confidentiality terms no less stringent than the terms provided in this ARTICLE 7, and with its accountants and tax advisors.

ARTICLE 8 ROYALTY REPORTS, RECORDS AND INSPECTIONS

8.1 LICENSEE shall, within sixty (60) days after the QUARTER in which NET SALES first occur, and within sixty (60) days after each QUARTER (March 31, June 30, September 30 and December 31) thereafter, provide MOFFITT with a written royalty report, substantially similar to the Moffitt Cancer Center Royalty Report format in Appendix D (a "ROYALTY REPORT"), detailing the NET SALES made by LICENSEE and its AFFILIATES, and SUBLICENSEE INCOME received from SUBLICENSEES for the SALE of ROYALTY-BEARING PRODUCTS during the preceding QUARTER, and calculating the payments due pursuant to ARTICLE 5. NET SALES of a ROYALTY-BEARING PRODUCT shall be deemed to have occurred on the date of collection of invoices for such ROYALTY-BEARING PRODUCT. Each such ROYALTY REPORT shall be signed by an officer of LICENSEE (or the officer's designee), and must include:

(a) the number of ROYALTY-BEARING PRODUCTS manufactured, sold, leased or otherwise transferred or disposed of by LICENSEE or its AFFILIATES;

(b) a calculation of NET SALES for the applicable reporting period in each country, including the gross invoice prices charged for the ROYALTY-BEARING PRODUCTS and any permitted DEDUCTIONS;

(c) a calculation of total EARNED ROYALTIES due, including any exchange rates used for conversion; and

(d) names and addresses of all SUBLICENSEES and the amount of any SUBLICENSEE INCOME received from each SUBLICENSEE.

8.2 LICENSEE shall keep and maintain accurate books and records reflecting the underlying data for NET SALES and SUBLICENSEE INCOME, containing an accurate accounting of all data in sufficient detail to enable verification of EARNED ROYALTIES and other payments under this Agreement. Such books and records shall be open to inspection by MOFFITT and/or an independent accounting firm designated by MOFFITT and reasonably acceptable to LICENSEE, at MOFFITT'S expense, during normal business hours upon at least fifteen (15) days' written notice and at a time that is mutually convenient for the parties, for purposes of confirming the accuracy of LICENSEE'S ROYALTY REPORTS, provided that such auditor has entered into a reasonable confidentiality agreement with LICENSEE, and provided further that such inspection shall not occur more than once every calendar year. Such auditor may disclose to MOFFITT its conclusions with respect to the accuracy of the ROYALTY REPORTS, but it may not disclose to MOFFITT the underlying data or work papers. LICENSEE shall preserve such books and records for three (3) years after the calendar year to which they pertain. In the event that such audit determines that LICENSEE had underpaid the amounts due to MOFFITT with respect to the audited period by more than ten percent (10%) and such conclusion is not disputed by LICENSEE, LICENSEE shall pay the reasonable cost of such examination, together with the deficiency not previously paid, and accrued interest on the underpayment at the lesser of the maximum rate allowed by law or 1.5% per month, all within thirty (30) days of receiving notice thereof from MOFFITT. In the event that following such audit the Parties cannot agree on the discrepancies in any EARNED ROYALTIES or payments due, the Parties shall resolve such disagreement pursuant to the procedures set forth in ARTICLE 16.

ARTICLE 9
PATENT PROTECTION

9.1 LICENSEE shall be responsible for all OUT OF POCKET COSTS of preparing, filing, prosecuting and maintaining of all patent applications and patents contained in the LICENSED PATENTS (a) incurred by MOFFITT prior to the EFFECTIVE DATE and (b) incurred by LICENSEE during the TERM. For the avoidance of doubt, prosecution shall include re-examinations, reissues, interferences, inter-parties review, post-grant review, oppositions and the like. MOFFITT agrees that the amount payable under subsection (a) of this Section 9.1 shall not exceed \$ 27,000. Such amount shall be paid to MOFFITT within ten (10) days of the COMMENCEMENT DATE.

9.2 During the ROYALTY TERM, LICENSEE shall pay for OUT OF POCKET COSTS for filing, prosecuting and maintaining the patent applications and patents contained in the LICENSED PATENTS. If LICENSEE does not agree to pay such OUT OF POCKET COSTS of filing, prosecuting or maintaining a patent application or patent in any country, then it shall so inform MOFFITT, and thereafter MOFFITT may file, prosecute and maintain such patent application or patent in such country at its own expense, and LICENSEE's rights under this Agreement shall terminate automatically with respect to such patent application or issued patent.

9.3 LICENSEE shall have the right to file, prosecute and maintain the patent applications and patents contained in the LICENSED PATENTS using its own counsel at its own cost during the TERM of this AGREEMENT.

9.4 With respect to any patent applications and patents contained in the LICENSED PATENTS, the Party responsible for directing prosecution (the "Prosecuting Party") and its patent counsel shall (a) consult with the other Party (the "Non-prosecuting Party") and keep the Non-prosecuting Party reasonably informed of the progress of the preparation, filing, prosecution and maintenance of such patent applications and patents, (b) consult with the Non-prosecuting Party and keep the Non-prosecuting Party reasonably informed about patent strategy with respect to such patent applications and patents, (c) provide to the Non-prosecuting Party advance copies of documents relevant to preparation, filing, prosecution and maintenance of such patent applications and patents sufficiently in advance of filing to allow the Non-prosecuting Party a reasonable opportunity to review and comment on such documents, (d) consider and implement the Non-prosecuting Party's reasonable comments on such patent filings, and (e) provide the Non-prosecuting Party with final copies of such documents. Without limiting the foregoing, LICENSEE agrees to use COMMERCIALY REASONABLE EFFORTS to pursue a strategy to obtain broad and strong patent protection in the best interest of MOFFITT and LICENSEE. The Prosecuting Party will not finally abandon any patent application without the Non-prosecuting Party's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. For the avoidance of doubt, any patent application that is abandoned as set forth in this Section 9.4, or any issued patent or patent application for which LICENSEE's rights have been terminated as set forth in Section 9.2, shall cease to be a LICENSED PATENT hereunder as of such abandonment or termination, as the case may be. LICENSEE shall be the Prosecuting Party and MOFFITT shall be the Non-prosecuting Party for all LICENSED PATENTS unless otherwise agreed to in writing.

9.5 LICENSEE shall apply, and shall require SUBLICENSEES to apply the patent marking notices required by the law of any country where such ROYALTY-BEARING PRODUCTS are made, sold, used or shipped, including the applicable patent laws of that country.

9.6 With respect to the prosecution of International Patent Application No. PCT/US2015/041709 (the “’709 Application”) and International Patent Application No. PCT/US2015/041714 (the “’714 Application”):

(a) The Parties agree that the ’709 Application (including the national stage applications thereof) will be abandoned, and

(b) LICENSEE (as the Prosecuting Party) agrees to take COMMERCIALY REASONABLE EFFORTS in the prosecution of the ’714 Application (including the national stage applications thereof).

ARTICLE 10 INFRINGEMENT AND LITIGATION

10.1 Each Party shall promptly notify the other in writing in the event that (a) it obtains knowledge of activity by THIRD PARTIES infringing or otherwise violating the INTELLECTUAL PROPERTY RIGHTS in the LICENSED PATENTS, or (b) it is sued or threatened with an infringement suit, in any country in the LICENSED TERRITORY as a result of activities relating to the ROYALTY-BEARING PRODUCTS.

10.2 During the TERM:

(a) LICENSEE shall have the first right, but not the obligation, to assert and defend LICENSED PATENTS respecting infringement or other violation of INTELLECTUAL PROPERTY RIGHTS relating to the ROYALTY-BEARING PRODUCTS by THIRD PARTIES in the LICENSED TERRITORY using counsel of its own selection. This right includes bringing any legal action for infringement and defending any counter claim of a THIRD PARTY respecting the LICENSED PATENTS such as a counter claim or declaratory judgment for invalidity, non-infringement, or unenforceability. If, in the reasonable opinion of LICENSEE’s and MOFFITT’s respective counsel, MOFFITT is required to be a named party to any such suit for standing purposes, LICENSEE may join MOFFITT as a party and MOFFITT shall consensually appear in such action; provided, however, that (i) MOFFITT shall not be the first named party in any such action, (ii) the pleadings and any public statements about the action shall state that the action is being pursued by LICENSEE and that LICENSEE has joined MOFFITT as a party; and (iii) LICENSEE shall keep MOFFITT reasonably apprised of all developments in any such action. No settlement, consent judgment, or other voluntary final disposition of any action by LICENSEE that admits the invalidity, unenforceability, or scope of the LICENSED PATENTS may be entered into without the prior written consent of MOFFITT, such consent not to be unreasonably withheld, delayed or conditioned. MOFFITT shall bear their own legal expenses with respect to any such litigation. Except for providing reasonable assistance, at the request and expense of LICENSEE, MOFFITT shall have no obligation regarding the legal actions described in Section 10.2 unless required to participate by law. However, MOFFITT shall have the right to participate in any such action through its own counsel and at its own expense. Any recovery shall first be applied to LICENSEE’s OUT OF POCKET COSTS and second shall be applied to MOFFITT’s OUT OF POCKET COSTS, including legal fees. MOFFITT shall recover twenty percent (20%) of any excess recovery over those expenses.

(b) In the event LICENSEE fails to initiate and pursue or participate in the actions described in the preceding paragraph (a) within sixty (60) days of LICENSEE first becoming aware of an infringement of LICENSED PATENTS or other violation of intellectual property rights relating to the ROYALTY-BEARING PRODUCTS or (b) upon notice by LICENSEE to MOFFITT that it does not intend to initiate, pursue or participate in such action(s), whichever is earlier, MOFFITT shall have the right to initiate or take over such legal action at its own expense and MOFFITT may use the name of LICENSEE as a party in such action if, in the reasonable opinion of LICENSEE's and MOFFITT's respective counsel, LICENSEE is required to be a named party to any such suit for standing purposes. In such case, LICENSEE shall provide reasonable assistance to MOFFITT if requested to do so. No settlement, consent judgment, or other voluntary final disposition of any action by MOFFITT that admits the invalidity, unenforceability, or scope of the LICENSED PATENTS may be entered into without the prior written consent of LICENSEE, such consent not to be unreasonably withheld, delayed or conditioned. Any recovery shall first be applied to MOFFITT's OUT OF POCKET COSTS and second shall be applied to LICENSEE's OUT OF POCKET COSTS, including legal fees. Any excess recovery over those fees shall be split between MOFFITT and LICENSEE on a pro rata basis as determined by the relative total OUT OF POCKET COSTS incurred by each party in pursuing the legal action.

10.3 In the event LICENSEE is permanently enjoined from exercising its LICENSE under this Agreement pursuant to an infringement action brought by a THIRD PARTY, or if both LICENSEE and MOFFITT elect not to undertake the defense or settlement of a suit alleging infringement for a period of six (6) months from notice of such suit, then either Party shall have the right to terminate this Agreement in the country where the suit was filed with respect to the LICENSED PATENT following thirty (30) days' written notice to the other party in accordance with the terms of ARTICLE 14.

**ARTICLE 11
USE OF NAMES**

Neither Party shall use the names of the other Party or its AFFILIATES, or any of their employees, or any adaptation thereof, in any advertising, promotional or sales literature without prior written consent obtained from the other Party or the applicable AFFILIATE in each case, except that LICENSEE and/or MOFFITT may state that LICENSEE has licensed from MOFFITT one or more of the patents and/or applications within the LICENSED PATENTS. Nothing herein shall prevent MOFFITT from complying with public information requests as required under Florida law or from including general information about the Agreement in reports, or LICENSEE from complying with any disclosure requirements under applicable law.

**ARTICLE 12
TERM AND TERMINATION**

12.1 The term of this Agreement shall commence on the EFFECTIVE DATE and continue until terminated pursuant to this ARTICLE 12 (the “TERM”).

12.2 After the expiration of the ROYALTY TERM in all countries, all of LICENSEE’s and its AFFILIATE’S obligations worldwide under Sections 3.1(b), 3.2, 3.3, ARTICLE 4 (Milestone Payments), ARTICLE 5 (Earned Royalties; Minimum Royalty Payments) (in each of the foregoing, other than payment obligations that accrued prior to such expiration); ARTICLE 6 (Due Diligence) and ARTICLE 8 (Reports, Records and Inspections) (other than Section 8.2) will terminate, but the LICENSE to the LICENSED INFORMATION granted under Section 2.1 shall continue in all respects, provided that it shall be fully-paid, royalty-free, irrevocable and non-terminable.

12.3 MOFFITT shall have the right, at its option, upon written notice to LICENSEE to terminate this Agreement in the event that LICENSEE:

(a) fails to make any payment whatsoever due and payable pursuant to this Agreement and which is not the subject of a bona fide dispute, unless LICENSEE shall make all such payments (and all interest due on such payments under Article 5.5) within the thirty (30) day period after receipt of written notice from MOFFITT; or

(b) commits a material breach of any other provision of this Agreement which is not cured (if capable of being cured) within the sixty (60) day period after receipt of written notice thereof from MOFFITT, or upon receipt of such notice if such breach is not capable of being cured; or

(c) challenges, or directly or indirectly urges a Third Party on behalf of the LICENSEE to challenge, whether as a claim, a cross-claim, counterclaim the validity or enforceability of any of the LICENSED PATENT before any court, arbitrator, or other tribunal or administrative agency in any jurisdiction a (“CHALLENGE”), provided that (i) pursuit of or participation in any proceeding to determine whether John Kovach is an inventor or ownership of the LICENSED PATENTS set forth on Schedule A shall not be deemed a CHALLENGE hereunder and will not be a basis for termination under this Section 12.3(c), and (ii) it shall not be deemed a CHALLENGE and will not be a basis for termination under this Section 12.3(c) if LICENSEE challenges the validity or enforceability of any LICENSED PATENT in response to or defend a prior assertion by MOFFITT or any successor to the ownership interest of a LICENSED PATENT that LICENSEE, its AFFILIATE, SUBLICENSEE or any agent or customer of the foregoing is infringing a LICENSED PATENT.

12.4 Notwithstanding any provision herein to the contrary, this Agreement shall terminate automatically without any notice to LICENSEE in the event LICENSEE shall cease to carry on its business or becomes insolvent, or a petition in bankruptcy is filed against LICENSEE and is consented to, acquiesced in or remains undismissed for sixty (60) days, or LICENSEE makes a general assignment for the benefit of creditors, or a receiver is appointed for LICENSEE.

12.5 LICENSEE shall have the right to terminate this Agreement upon written notice to MOFFITT:

(a) in the event that MOFFITT commits a material breach of any of the provisions of this Agreement and such breach is not cured (if capable of being cured) within the sixty (60) day period after receipt of written notice thereof from LICENSEE, or upon receipt of such notice if such breach is not capable of being cured;

(b) for convenience upon sixty (60) days prior notice, with the payment of a termination fee in this Section 12.5(b). If as of the date of such termination LICENSEE has discontinued or cancelled development of all ROYALTY-BEARING PRODUCTS, then there shall be no termination fee. If as of the date of such termination LICENSEE has not discontinued or cancelled development of all ROYALTY-BEARING PRODUCTS, the termination fee shall be two million five hundred thousand dollars (\$2,500,000). For the avoidance of doubt, (i) the term “discontinued or cancelled development of all ROYALTY-BEARING PRODUCTS” as used herein does not include delaying or temporarily suspending development of a ROYALTY-BEARING PRODUCT, (ii) LICENSEE shall be deemed to have discontinued or cancelled development of all ROYALTY-BEARING PRODUCTS for purposes of this Section 12.5(b) if it has publicly announced the discontinuance or cancellation of its development program(s) for all ROYALTY-BEARING PRODUCTS, but is in the process of winding down development and/or completing existing clinical trials as required by applicable legal or regulatory requirements and (iii) there is no termination fee for any termination hereunder other than a termination by LICENSEE under this Section 12.5(b).

12.6 Upon termination of this Agreement for the reasons set forth in Section 12.3 above, all rights and licenses granted to LICENSEE under the terms of this Agreement are terminated and MOFFITT has the option, in its discretion, to terminate any sublicense granted by LICENSEE, provided that any SUBLICENSEES not then in default shall have the right to obtain a license under the LICENSED PATENTS directly from MOFFITT on terms and conditions substantially the same as the terms and conditions of its SUBLICENSE agreement. MOFFITT agrees to negotiate such licenses in good faith under reasonable terms and conditions, and the sublicenses shall remain in force during such good faith negotiations. Upon such termination, LICENSEE’s LICENSE under the LICENSED TECHNOLOGIES shall terminate. Within sixty (60) days of the effective date of termination LICENSEE shall return to MOFFITT:

(a) All materials relating to or containing the LICENSED INFORMATION, and all CONFIDENTIAL INFORMATION disclosed by MOFFITT, subject to Section 7.1(d);

(b) the last report required under ARTICLE 6 or ARTICLE 8; and

(c) all payments incurred up to the effective date of termination.

12.7 Termination of this Agreement shall not affect any rights or obligations accrued prior to the effective date of such termination and specifically LICENSEE's obligation to pay all EARNED ROYALTIES and other payments specified by ARTICLE 4 and ARTICLE 5 accrued prior to termination. The following provisions shall survive any termination: ARTICLE 1 (Definitions), ARTICLE 7 (Confidentiality and Publicity), Section 8.2, ARTICLE 11(Use of Names), Sections 12.6 -12.9, ARTICLE 13 (Indemnification; Insurance; No Warranties), ARTICLE 14 (Notices, Payments), ARTICLE 16 (Dispute Resolution) and ARTICLE 17 (Miscellaneous).

12.8 The rights provided in this ARTICLE 12 shall be in addition and without prejudice to any other rights and remedies under the law which the parties may have with respect to any breach of the provisions of this Agreement.

12.9 Waiver by either Party of one or more defaults or breaches shall not deprive such party of the right to terminate because of any subsequent default or breach.

ARTICLE 13 INDEMNIFICATION; INSURANCE; NO WARRANTIES

13.1 LICENSEE shall defend, indemnify and hold harmless MOFFITT and its AFFILIATES, and both of their trustees, directors, officers, employees, and agents and their respective successors, heirs and assigns against any and all liabilities, claims, demands, damages, judgments, losses and expenses of any nature, including without limitation legal expenses and reasonable attorneys' fees (a "CLAIM"), arising out of any theory of liability (including tort, warranty, or strict liability) or the death, personal injury, or illness of any person or out of damage to any property related in any way to the rights granted under this Agreement; or resulting from the production, manufacture, sale, use, lease, or other disposition or consumption or advertisement of the ROYALTY-BEARING PRODUCTS by LICENSEE, its AFFILIATE, SUBLICENSEES or any other transferees; or in connection with any statement, representation or warranty of LICENSEE, its AFFILIATES, SUBLICENSEES or any other transferees with respect to the ROYALTY-BEARING PRODUCTS or arising from this Agreement or from the relationship of the parties; provided, however, that the LICENSEE shall not be responsible to indemnify MOFFITT pursuant to this Section 13.1 to the extent any Claim arises out of MOFFITT's material omissions, negligence or willful misconduct or material breach of this Agreement.

13.2 LICENSEE shall purchase and maintain in effect and shall require its SUBLICENSEES to purchase and maintain in effect a policy of commercial, general liability insurance sufficient to protect MOFFITT with respect to events described in Section 13.1. Such insurance shall:

- (a) list “MOFFITT their trustees, directors, officers, employees and agents” as additional insureds under the policy;
- (b) provide that such policy is primary and not excess or contributory with regard to other insurance MOFFITT may have;

(c) be endorsed to include product liability coverage in amounts no less than Three Million Dollars (\$3,000,000) per incident and Five Million Dollars (\$5,000,000) annual aggregate during the conducting of clinical trials; and upon commercialization of the ROYALTY-BEARING PRODUCTS to maintain a liability insurance program consistent with sound business practices and at least Three Million Dollars (\$3,000,000) per incident and Five Million Dollars (\$5,000,000) annual aggregate;

- (d) be endorsed to include contractual liability coverage for LICENSEE’s indemnification under Section 13.1; and

(e) by virtue of the minimum amount of insurance coverage required under Section 13.2 (c) not be construed to create a limit of LICENSEE’s liability with respect to its indemnification under Section 13.1;

provided that, if LICENSEE grants a SUBLICENSE and no longer commercializes any ROYALTY-BEARING PRODUCT by itself, it shall no longer be required to purchase and maintain such commercial, general liability insurance provided in this Section 13.2.

13.3 By signing this Agreement, LICENSEE certifies that the requirements of Section 13.2 will be met on or before the earlier of (a) the date of FIRST SALE of any ROYALTY-BEARING PRODUCT or (b) the date any ROYALTY-BEARING PRODUCT is tested or used on humans, and will continue to be met thereafter. Upon MOFFITT’S request, LICENSEE shall furnish a Certificate of Insurance and a copy of the current Insurance Policy to MOFFITT. Such policy shall require thirty (30) days’ written notice to MOFFITT prior to any cancellation of or material change to the policy.

(a) MOFFITT MAKES NO REPRESENTATIONS OR WARRANTIES THAT ANY CLAIMS OF THE LICENSED PATENTS , ISSUED OR PENDING, ARE VALID, OR THAT THE MANUFACTURE, USE, SALE OR OTHER DISPOSAL OF THE ROYALTY-BEARING PRODUCTS OR USE OF THE LICENSED INFORMATION DOES NOT OR WILL NOT INFRINGE ANY PATENT OR OTHER RIGHTS NOT VESTED IN MOFFITT OR ITS AFFILIATES.

(b) MOFFITT DISCLAIMS ALL WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. LICENSEE SHALL MAKE NO STATEMENTS, REPRESENTATION OR WARRANTIES WHATSOEVER TO ANY THIRD PARTIES WHICH ARE INCONSISTENT WITH SUCH DISCLAIMER.

ARTICLE 14 NOTICES, PAYMENTS

14.1 Any payment, notice or other communication required by this Agreement (a) shall be in writing, (b) may be delivered personally, sent via electronic mail, or sent by reputable overnight courier with written verification of receipt or by registered or certified first class United States Mail, postage prepaid, return receipt requested, (c) shall be sent to the following addresses or to such other address as such party shall designate by written notice to the other party, and (d) shall be effective upon receipt:

FOR MOFFITT:

Sr. Director
Office of Innovation and Industry
Alliances

12902 Magnolia Drive, MRC INNOV
Tampa, Florida 33612

With Copies to:

H. Lee Moffitt Cancer Center and Research Institute, Inc.
Attention: Office of General Counsel
12902 Magnolia Drive, SRB-OGC
Tampa, Florida 33612-9497

FOR LICENSEE:

Lixte Biotechnology Holdings, Inc.
248 Route 25A, No. 2

East Setauket, NY 11733
jkovach@lixte.com

ARTICLE 15 LAWS, FORUM AND REGULATIONS

15.1 LICENSEE shall comply, and shall cause its SUBLICENSEES to comply, with all foreign and United States federal, state, and local laws, regulations, rules and orders applicable to the testing, production, transportation, packaging, labeling, export, sale and use of the ROYALTY-BEARING PRODUCTS. In particular, LICENSEE shall be responsible for assuring compliance with all United States export laws and regulations applicable to this LICENSE and LICENSEE's and its SUBLICENSEE'S activities under this Agreement.

ARTICLE 16 DISPUTE RESOLUTION

16.1 In the event of any bona fide disagreement or disputed claim of any kind or nature between the Parties arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof, the rights or obligations of the Parties hereunder, or any payments due hereunder (each, a "DISPUTE"), such DISPUTE shall be fully and finally resolved in accordance with the process (the "DISPUTE RESOLUTION PROCESS") set forth in this ARTICLE 16.

16.2 The Parties shall attempt in good faith to resolve any DISPUTE promptly by negotiation between executives who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for administration of this Agreement. Upon the occurrence of a DISPUTE, a disputing Party shall notify the other Party in writing of such DISPUTE (a "DISPUTE NOTICE"). The DISPUTE NOTICE shall include a statement of the Party's position and a summary of arguments supporting that position, together with information reasonably necessary for the other Party to assess and respond to the subject of the DISPUTE, including copies of available supporting documents. Promptly following such DISPUTE NOTICE, the executives of both parties shall meet at a mutually acceptable time and place in good faith to attempt to resolve such DISPUTE by mutual agreement. If the DISPUTE has not been so resolved within ten (10) days of the DISPUTE NOTICE, either Party may seek equitable and legal remedies under the court system. MOFFITT may not terminate this Agreement if there is a bona fide DISPUTE regarding the purported grounds for termination, until such DISPUTE is fully and finally resolved in accordance with this ARTICLE 16.

ARTICLE 17 MISCELLANEOUS

17.1 This Agreement shall be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

17.2 This Agreement constitutes the entire agreement of the Parties relating to the LICENSED TECHNOLOGIES, and all prior representations, agreements and understandings, written or oral, are merged into it and are superseded by this Agreement.

17.3 The provisions of this Agreement shall be deemed separable. If any part of this Agreement is rendered void, invalid, or unenforceable, such determination shall not affect the validity or enforceability of the remainder of this Agreement unless the part or parts which are void, invalid or unenforceable shall substantially impair the value of the entire Agreement as to either party

17.4 Article headings are inserted for convenience of reference only and do not form a part of this Agreement.

17.5 No Person not a party to this Agreement, including any employee of either Party to this Agreement, shall have or acquire any rights by reason of this Agreement. Nothing contained in this Agreement shall be deemed to constitute the Parties' partner with each other or any Third Party.

17.6 This Agreement may not be amended or modified except by written agreement executed by each of the Parties. This Agreement shall not be assigned by a Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned provided that a Party shall not be required to seek the consent of the other Party for any assignment or transfer that occurs in connection with the sale of all or substantially all of such Party's equity or assets, or the merger of such Party whether or not such Party is the surviving Party of such merger. Any attempted assignment in contravention of this Section 17.6 shall be null and void ab initio and shall constitute a material breach of this Agreement.

17.7 The failure of any party hereto to enforce at any time, or for any period of time, any provision of this Agreement shall not be construed as a waiver of either such provision or of the right of such party thereafter to enforce each and every provision of this Agreement.

17.8 LICENSEE acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by LICENSEE that it shall not export such items to certain foreign countries without prior approval of such agency.

17.9 This Agreement may be executed by the Parties in counterparts, all of which together shall constitute the same instrument.

17.10 The Parties agree that this Agreement may be executed and delivered by facsimile, electronic mail, internet, or any other suitable electronic means, and the Parties agree that signatures delivered by any of the aforementioned means shall be deemed to be original, valid, and binding upon the Parties.

IN WITNESS to their Agreement, the parties have caused this Agreement to be executed by their duly authorized representatives.

**H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE,
INC.**

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: _____
Name: Dr. James J. Mulé
Title: Associate Center Director
Translational Science

By: _____
Name: JOHN S. KOVACH, MD
Title: PRESIDENT AND CEO

Appendix A

- U.S. Patent Application No. 62/028,729 entitled “Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes” filed July 24, 2014, (14MA063PR0).
- U.S. Patent Application No. 62/029,327 entitled “Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes” filed July 25, 2014, (14MA063PR).
- International Patent Application No. PCT/US2015/041709 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on July 23, 2015 (14MA063PRW01)
- International Patent Application No. PCT/US2015/041714 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on July 23, 2015 (14MA063PRW02)
- Chinese Patent Application No. 201580041767.1 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on July 23, 2015
- European Patent Application No. 15825076.1 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on July 23, 2015
- Japanese Patent Application No. 2017-504104 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on July 23, 2015
- U.S. Patent Application No. 15/328,838 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on January 24, 2017 (14MA063PRW0US1)
- U.S. Patent Application No. 15/328,235 entitled Protein Phosphatase 2A Inhibitors for Treating Myelodysplastic Syndromes filed on January 23, 2017 (14MA063PRW0US2)
- U.S. Patent Application No. 62/287,858 entitled “Clinical Regimen for Treating Myelodysplastic Syndrome with Phosphatase Inhibitor” filed on January 27, 2016. (17MB046PR)
- International Patent Application No. PCT/US2017/015237 entitled Clinical Regimen for Treating Myelodysplastic Syndrome with Phosphatase Inhibitor filed on January 27, 2017 (17MB046PRW0)

Appendix B

Protocol

A Ph1b/2 Study Evaluating the Safety and Efficacy of Intravenous LB-100 in Patients with Low or Intermediate-1 Risk Myelodysplastic Syndromes (MDS) who had Disease Progression or are Intolerant to Prior Therapy

Appendix C

Commercialization Plan

The plan for commercial development of LB-100 alone and /or in combination with other established and investigational anti-cancer drugs for the treatment of Myelodysplastic Syndrome is to partner with a pharmaceutical company skilled in this area. Lixte will seek such a partner when characterization of the treatments claimed in the patent applications has been brought to a state needed to attract such a partner. These steps are characterization of the toxicity of the LB-100 therapies and demonstration of anti-tumor activity in human beings with Myelodysplastic Syndrome.

When therapeutic benefit of LB-100 alone or in combination with other established and investigational anti-cancer drugs is demonstrated, Lixte will engage in discussions with one or more pharmaceutical companies with anti-cancer drug development programs. Members of the scientific advisory board of Lixte have identified senior contacts in the drug development sections of such companies. It should be noted that Myelodysplastic Syndrome is a disease which falls in the “orphan drug category”, a circumstance expected to enhance the interest of the drug industry.

Appendix D

MOFFITT CANCER CENTER ROYALTY REPORT

LICENSEE: _____

Agreement Number: _____

Period Covered: From: / / Through: / /

Prepared By: _____

Approved By: _____

Report Currency: _____

Country	Volume of Sales	Total Gross Sales*	Less Deductions**	NET SALES	Royalty Rate	Royalty Amount	Conversion Rate	Total Royalty in US \$
TOTAL:								

If license covers several major product lines, please prepare a separate report for each product line. Then combine all product lines into a summary report.

* Gross sales represent amount invoiced or billed to a third party.

** On a separate page, please itemize all deductions and indicate the reasons for such deductions. Permitted deductions are listed in the LICENSE Agreement.



Lixte Biotechnology Announces a Clinical Trial Agreement with Moffitt Cancer Center to Initiate a Phase 1b/2 Trial Evaluating the Safety and Efficacy of LB-100 in Treatment of Patients with Low or Intermediate-1 Risk Myelodysplastic Syndrome

EAST SETAUKET, NY — (August 21, 2018) - [Lixte Biotechnology Holdings, Inc.](#) (OTCQB: LIXT) announced that it has entered into a Clinical Trial Agreement and Exclusive License Agreement with [Moffitt Cancer Center](#) to conduct a Phase 1b/2 study of the safety and therapeutic benefit of Lixte's lead clinical compound, LB-100, in patients with myelodysplastic syndrome (MDS). The trial will enter low and intermediate-1 risk MDS patients, including those with del(5q) MDS who have failed or are intolerant of standard treatment.

Dr. John S. Kovach, founder and CEO of Lixte, said, "Certain cancers possessing unique genetic changes are vulnerable to inhibition of an enzyme, protein phosphatase 2A (PP2A), by LB-100. Among these is myelodysplastic syndrome (MDS), an increasingly common family of neoplastic diseases, especially in persons aged 65 and older. MDS is characterized by failure of the bone marrow often causing significant anemia and requiring frequent blood transfusions. In preclinical models of MDS, treatment with LB-100 inhibits the growth and/or induces the death of the abnormal blood cells. Cells of one variant of MDS, termed del(5q) MDS, are missing 50% of their PP2A activity rendering them sensitive to PP2A inhibition."

Currently there is only one drug, lenalidomide, approved for the treatment of del(5q) MDS, and virtually all patients become resistant to this therapy.

"We are excited to embark on the clinical investigation of LB-100 in lower-risk MDS patients. If LB-100 proves to be effective in the clinic, it could be an important addition to the limited treatment options for patients failing standard treatment," said [David Sallman](#), M.D., assistant member of Moffitt's Malignant Hematology Department.

About Lixte Biotechnology Holdings, Inc.

[Lixte](#) is a biotech company that identifies enzyme targets associated with serious common diseases and then designs novel compounds to attack those targets. Lixte's product pipeline is primarily focused on inhibitors of protein phosphatases, used alone and in combination with cytotoxic agents and immune checkpoint blockers.

About Moffitt Cancer Center

[Moffitt](#) is dedicated to one lifesaving mission: to contribute to the prevention and cure of cancer. The Tampa-based facility is one of only 49 [National Cancer Institute-designated Comprehensive Cancer Centers](#), a distinction that recognizes Moffitt's scientific excellence, multidisciplinary research, and robust training and education. Moffitt is a Top 10 cancer hospital and has been nationally ranked by [U.S. News & World Report](#) since 1999. Moffitt devotes more than 2 million square feet to research and patient care. Moffitt's expert nursing staff is recognized by the American Nurses Credentialing Center with Magnet[®] status, its highest distinction. With more than 6,000 team members, Moffitt has an economic impact in the state of \$2.1 billion. For more information, call 1-888-MOFFITT (1-888-663-3488), visit [MOFFITT.org](#), and follow the momentum on [Facebook](#), [Twitter](#) and [YouTube](#).

Forward-Looking Statements

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 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. 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, research results, competition from other similar businesses, and market and general economic factors. This discussion should be read in conjunction with the Company's filings with the United States Securities and Exchange Commission at <http://www.sec.gov/edgar.shtml>.

Additional information on the Company is available at www.lixte.com.

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