

***] Indicates redacted information subject to a request for confidential treatment.

**STANDARD EXCLUSIVE LICENSE AGREEMENT
WITH SUBLICENSING TERMS**

TABLE OF CONTENTS

Section 1	Definitions
Section 2	Grant
Section 3	Due Diligence
Section 4	Payments
Section 5	Certain Warranties and Disclaimers of FSURF
Section 6	Record Keeping
Section 7	Patent Prosecution
Section 8	Infringement and Invalidity
Section 9	Term and Termination
Section 10	Assignability
Section 11	Dispute Resolution Procedures
Section 12	Product Liability; Conduct of Business
Section 13	Use of Names
Section 14	Miscellaneous
Section 15	Notices
Section 16	Contract Formation and Authority
Section 17	United States Government Interests
Section 18	Confidentiality
Section 19	University Rules and Regulations
Appendix A –	Inter-institutional Agreement
Appendix B –	Development Plan
Appendix C –	Development Report
Appendix D –	FSURF Royalty Report
Appendix E –	Due Diligence

This Agreement is made effective the ____ day of _____, 2016, (the "Effective Date") by and between the Florida State University Research Foundation, Inc. (hereinafter called "FSURF"), a nonstock, nonprofit Florida corporation, having its principal place of business at 2000 Levy Avenue, Suite 351, Tallahassee, Florida 32310, and Spotlight Innovation Inc. (hereinafter called "Licensee"), a corporation organized and existing under the laws of Nevada, having its principle place of business at 6750 Westown Pkwy, Ste. 200-226, Des Moines, Iowa 50266;

WHEREAS, U.S. Department of Health and Human Services, as represented by National Center for Advancing Translational Sciences (HHS), and Johns Hopkins University (JHU) are co-owners with Florida State University Research Foundation of certain inventions that are described in the "Licensed Patents" (defined below) and has granted FSURF the right to license its undivided rights pursuant to that certain Inter-institutional Agreement effective [***] and attached as Appendix A;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

Section 1 Definitions

1.1 The term "Affiliate" shall mean: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the Licensee or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the Licensee or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of Licensee or (d) any entity in which any officer or employee is also an officer or employee of Licensee or any person who is an officer or employee of Licensee.

1.2 "Development Plan" shall mean a written report summarizing the development activities that are to be undertaken by the Licensee to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix B.

1.3 "Development Report" shall mean a written account of Licensee's progress under the Development Plan having at least the information specified on Appendix C to this Agreement, and shall be sent to the address specified on Appendix C.

1.4 "Licensed Field" shall include treatment of viral infection(s).

1.5 "Licensed Patents" shall refer to and mean all of the following FSURF intellectual property:

1.5.1 the United States patent(s)/patent application(s) U.S. Provisional patent applications [***], and all U.S. patents and foreign patents and patent applications based on these U.S. applications.

1.5.2 United States and foreign patents issued from the applications listed in 1.5.1 above and from divisionals and continuations of these applications, to the extent the claims are directed to subject matter specifically described in the applications listed in 1.5.1 above and

are dominated by the claims of those patent applications and patents issuing thereon or reissues thereof, and any and all foreign patents and patent applications corresponding thereto, all to the extent owned or controlled by Florida State University.

1.6 “Licensed Product” and “Licensed Process” shall mean:

1.6.1 In the case of a Licensed Product, any product or part thereof developed by or on behalf of Licensee that:

- (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any product is made, used or sold;
- (b) is manufactured by using a process which is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any such process is used or in which any such product is used or sold.

1.6.2 In the case of a Licensed Process, any process which:

- (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents in any country in which such process is practiced.

1.7 “Licensed Territory” shall be worldwide.

1.8 “Liquidation Event” means (a) a merger, share exchange or other reorganization, (b) the sale by one or more stockholders of a majority of the voting power of Licensee, (c) the sale of all or substantially all of the assets of Licensee, or (d) an asset sale of a Licensed Product(s) and or Licensed Process(es), in which, with respect to (a), (b), and (c), the stockholders of Licensee prior to such transaction do not own, directly or indirectly, a majority of the voting power of the acquiring, surviving or successor entity, as the case may be. For the avoidance of doubt, a Liquidation Event shall not include the issuance and sale of Licensee’s equity securities, or securities convertible into Licensee’s equity securities, in a private placement transaction or other transaction that is not an Initial Public Offering or the issuance of Licensee’s equity securities to a bona fide creditor of Licensee in exchange for the cancellation of indebtedness owed by Licensee, in each case, even if such sale or issuance transaction results in the stockholders of Licensee immediately prior to such transaction not owning, directly or indirectly, a majority of the voting power of Licensee after such transaction.

1.9 “Net Sales” shall mean the gross invoice price charged by, and the value of non-cash consideration owed to, Licensee, an Affiliate or a Sublicensee for sales of Licensed Products and Licensed Processes, less (a) sales taxes or other taxes (other than income taxes), (b) shipping and insurance charges, (c) actual allowances, rebates, credits, or refunds for returned or defective goods, chargeback payments (or the equivalent thereof), (d) trade, quantity, and other discounts, retroactive price reductions, or other allowances actually allowed or granted from the billed amount and taken (provided that such discounts shall be limited to discounts in amounts customary in the trade), and (e) any import or export duties, tariffs,

or similar charges incurred with respect to the import or export of Licensed Products or Licensed Processes into or out of any country in the Licensed Territory. Licensed Products and Licensed Processes will be considered sold when it is shipped, delivered, or invoiced, whichever is earlier, by Licensee, an Affiliate or a Sublicensee, as the case may be. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to (a) the distribution of reasonable quantities of promotional samples of Licensed Products and (b) Licensed Products and Licensed Processes provided for clinical trials and research purposes. For purposes of calculating Net Sales, a sale to a Sublicensee for end use by the Sublicensee will be treated as a sale at Licensee's list price. For clarity, the term "Net Sales" does not include consideration received by Licensee for the grant of rights under a Sublicense (for which payment shall be governed solely by Section 2.2.2 hereof) or for royalties under a Sublicense (for which payment shall be governed solely by Section 2.2.2 hereof).

1.10 The term "Sublicensee" shall mean any third party to whom Licensee confers the right to make, use or sell Licensed Product and/or Licensed Processes and/or any of the intellectual property rights embodied in Licensed Patents.

Section 2 Grant

2.1 License.

2.1.1 License Under Licensed Patents

FSURF hereby grants to Licensee an exclusive license, limited to the Licensed Field and the Licensed Territory, under the Licensed Patents to make, use and sell Licensed Products and/or Licensed Processes. FSURF reserves to itself, Florida State University, HHS, and JHU the right to make and use the Licensed Patents, Licensed Products and/or Licensed Processes solely for their internal research, clinical (including, but not limited to patient care), and educational purposes. In addition, FSURF reserves to itself, as well as to Florida State University, HHS, JHU and to all non-profit research institutions, the right to use materials that might be covered under Licensed Patents solely for their internal research, educational, and clinical purposes and to meet all applicable governmental requirements governing the ability to transfer materials. This license grant is subject to the government license rights in Section 17 herein.

2.2 Sublicense.

2.2.1 Licensee may grant written, Sublicenses to third parties. Any agreement granting a Sublicense shall state that the Sublicense is subject to the termination of this Agreement. Licensee shall have the same responsibility for the activities of any Sublicensee or Affiliate as if the activities were directly those of Licensee. This right is subject to the requirement that any sublicense is subject to the HHS Inter-Institutional Agreement attached as Appendix A.

2.2.2 In respect to Sublicenses granted by Licensee under 2.2.1 above, Licensee shall pay to FSURF an amount equal to what Licensee would have been required to pay to FSURF had Licensee sold the amount of Licensed Products or Licensed Processes sold by such Sublicensee. In addition, if Licensee receives any fees, minimum royalties, or other payments in consideration for any rights granted under a Sublicense, and such payments are not based directly upon the amount or value of Licensed Products or Licensed Processes sold by the Sublicensee, then Licensee shall pay FSURF an amount equal to [***] of such payments for any Sublicense entered into during the first two years following the Effective Date, and an amount equal to [***] of such payments for a Sublicense entered into thereafter, of such payments in the manner specified in Section 4. Licensee shall not receive from Sublicensees anything of value in lieu of cash payments in consideration for any Sublicense under this Agreement without the express prior written permission of FSURF.

2.2.3 Licensee shall provide FSURF with an unredacted copy of each sublicense agreement and any agreement which transfers intellectual property rights granted hereunder, at least thirty (30) days prior to the execution of the sublicense agreement and a fully executed version within thirty (30) days of execution.

2.2.4 In the event that FSURF notifies Licensee in writing of a third party's interest in a field of use which Licensee is not addressing at the time of receipt of the notice, Licensee shall respond to FSURF in writing within thirty (30) days of receipt of such notice to inform FSURF whether Licensee intends to pursue the Field of Use. If in such response, Licensee elects to forego the Field of Use, FSURF may terminate the Licensee's license in said field and negotiate and execute said license directly.

Section 3 Due Diligence

3.1 Development.

3.1.1 Licensee agrees to and warrants that:

- (a) it has, or will obtain, the expertise necessary to independently evaluate the inventions of the Licensed Patents;
- (b) it will establish and actively and diligently pursue the Development Plan (see Appendix B) to the end that the inventions of the Licensed Patents will be utilized to provide Licensed Products and/or Licensed Processes for sale in the retail market within the Licensed Field;
- (c) it will diligently develop markets for Licensed Products and Licensed Processes; and
- (d) until the date of first commercial sale of Licensed Products or Licensed Processes, it will supply FSURF with a written Development Report annually fifteen (15) days after the end of the calendar year (see Appendix C).

3.1.2 Licensee agrees that the first commercial sale of products to the retail customer shall occur on or before January 1, 2023 or FSURF shall have the right to terminate the Agreement pursuant to Section 9.3 hereto. In addition, Licensee agrees to pay the product development milestone payments listed in Section 4.3.3 and to complete the due diligence activities listed in Appendix E or FSURF shall have the right to terminate the Agreement pursuant to Section 9.3. Licensee will notify FSURF in writing as each milestone or due diligence activity is met.

3.1.3 Licensee may issue a written request to negotiate extensions of individual milestones listed in Section 4.3.3 or due dates for individual due diligence activities listed in Appendix E. Provided that such requests are received by FSURF no less than ninety (90) days prior to the original due date in the case of milestone payments, or no less than forty five (45) days prior to the original due date in the case of due diligence activities, and that each request describes fully Licensee's diligent efforts to achieve the milestones or complete the due diligence activities, FSURF shall consider in good faith such requests. Upon granting each such request, FSURF and Licensee shall negotiate in good faith the length of the extension. FSURF shall not unreasonably withhold requests to negotiate extensions.

3.1.4 Florida State University policies may require approval of clinical trials involving technology invented at the University. Accordingly, Licensee will notify FSURF prior to commencing any clinical trials at Florida State University or its affiliated medical facilities.

Section 4 Payments

4.1 Obligation in Lieu of License Issue Fee (Alternative Fee).

In lieu of a license issue fee, in the case of a Liquidation Event after the Effective Date, Licensee agrees to pay to FSURF an amount equal to [***] of the transaction value ascribed to those assets, products, and properties related to or stemming from the licensed technology defined in the Agreement (the "Alternative Fee"). Payment of the Alternative Fee shall be due thirty (30) days following the closing of such Liquidation Event.

4.2 Royalty.

Licensee agrees to pay to FSURF as earned royalties a royalty calculated as a percentage of Net Sales from the sale of Licensed Product and/or Licensed Process. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by Licensee or its Sublicensee(s), or the date a Licensed Product and/or Licensed Process is transferred to a third party for any promotional reasons. The royalty shall remain fixed while this Agreement is in effect at a rate of [***] of Net Sales.

4.3 Other Payments.

4.3.1 Licensee agrees to pay FSURF maintenance fees according to the schedule below upon each anniversary of the Effective Date.

Payment	[***]
\$ [***]	[***]
\$ [***]	[***]
\$ [***]	[***]
\$ [***]	[***]
\$ [***]	[***] and every [***] thereafter on the same date, for the life of this Agreement.

4.3.2 Upon the first quarter that sales are made, the maintenance fee shall no longer be required, and minimum royalty payments shall be made according to the schedule below and shall be creditable against royalties.

Payment	[***]
---------	-------

\$ [***] [***]
\$ [***] [***]
\$ [***] [***]
\$ [***] [***] and every [***] thereafter on the same date, for the life of this Agreement

Upon the first quarter following the quarter in which commercial sales of the applicable Licensed Product and/or Licensed Process begin, the above minimum royalties shall be paid on a quarterly basis, with such amounts due within thirty (30) days of the end of the calendar quarter, such calendar quarters ending on March 31, June 30, September 30, and December 31. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. Any earned royalties paid in a calendar year will be credited against the minimum royalties due for said calendar year. It is understood that earned royalties will be applied against minimum royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due FSURF for other than the same calendar year in which the royalties were earned.

4.3.3 In addition to all other payments required under this Agreement, Licensee agrees to pay FSURF milestone payments, as follows:

Milestone payments for the first product:

[***]– upon the earlier of (a) the [***], or (b) [***]anniversary of the date of this license.
[***]– upon the earlier of (a) [***], or (b) [***]anniversary of the Effective Date.
[***]– upon the [***].
[***]– upon filing of the [***].
[***]– within [***]after the [***].

Milestones payments for each additional product:

[***]– upon [***].

***]- upon ***]
***]- within ***]after the ***].

4.4 Accounting for Payments.

4.4.1 Amounts owing to FSURF under Sections 4.1 and 4.2 shall be paid on a quarterly basis after the amount of minimum royalties paid is exceeded, with such amounts due and received by FSURF on or before the thirtieth day following the end of the calendar quarter ending on March 31, June 30, September 30 or December 31 in which such amounts were earned. Any amounts which remain unpaid after the date they are due to FSURF shall accrue interest from the due date at the rate of ***]. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. Licensee shall also be responsible for repayment to FSURF of any attorney, collection agency, or other out-of-pocket FSURF expenses required to collect overdue payments due from this Section, or any other applicable section of this Agreement.

4.4.2 Except as otherwise directed, all amounts owing to FSURF under this Agreement shall be paid in U.S. dollars to FSURF at the following address:

President
Florida State University Research Foundation, Inc.
Attn: Gary K. Ostrander
2000 Levy Avenue, Suite 351
Tallahassee, FL 32310

All royalties owing with respect to Net Sales stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation - Value of Foreign Currencies on the day preceding the payment due date.

4.4.3 A certified full accounting statement showing how any amounts payable to FSURF under Section 4.3 have been calculated shall be submitted to FSURF on the date of each such payment. In addition to being certified, such accounting statements shall contain a written representation signed by an executive officer of Licensee that states that the statements are true, accurate, and fairly represent all amounts payable to FSURF pursuant to this Agreement. Such accounting shall be on a per-country and product line, model or trade name basis and shall be summarized on the form shown in Appendix D – FSURF Royalty Report of this Agreement.

4.4.4 FSURF is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on FSURF by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to FSURF pursuant to this Agreement. All such taxes, assessments, or other charges shall be assumed by Licensee.

Section 5 Certain Warranties and Disclaimers of FSURF

5.1 FSURF warrants that, except as otherwise provided under Section 17.1 of this Agreement and the Inter-Institutional Agreement attached as Appendix A, with respect to U.S. Government interests, it is the co-owner of the Licensed Patents or otherwise has the right to grant the licenses granted to Licensee in this Agreement. However, nothing in this Agreement shall be construed as:

5.1.1 a warranty or representation by FSURF as to the validity or scope of any right included in the Licensed Patents;

5.1.2 a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of third parties;

5.1.3 an obligation to bring or prosecute actions or suits against third parties for infringement of Licensed Patents;

5.1.4 an obligation to furnish any know-how not provided in Licensed Patents or any services other than those specified in this

Agreement; or

5.1.5 a warranty or representation by FSURF that it will not grant licenses to others to make, use or sell products not covered by the claims of the Licensed Patents which may be similar and/or compete with products made or sold by Licensee.

5.2 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, FSURF MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF LICENSED PATENTS CLAIMS, ISSUED OR PENDING. FSURF ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION BY LICENSEE, ITS SUBLICENSEE(S), OR THEIR VENDEES OR OTHER TRANSFEREES OF PRODUCT INCORPORATING OR MADE BY

Section 6 Record Keeping

6.1 Licensee and its Sublicensee(s) shall keep books and records sufficient to verify the accuracy and completeness of Licensee's and its Sublicensee(s)'s accounting referred to above, including without limitation, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products and/or Licensed Processes. Such books and records shall be preserved for a period not less than six years after they are created or as required by federal law, both during and after the term of this Agreement.

6.2 Licensee and its Sublicensee(s) shall take all steps necessary so that FSURF may, within thirty (30) days of its written request, audit, review and/or copy all of the books and records at a single U.S. location to verify the accuracy of Licensee's and its Sublicensee(s)'s accounting. Such review may be performed by any authorized employees of FSURF as well as by any attorneys and/or accountants designated by FSURF, upon reasonable notice and during regular business hours. If a deficiency with regard to any payment hereunder is determined, Licensee and its Sublicensee(s) shall pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4.4.1. If a royalty payment deficiency for a calendar year exceeds [***] of the royalties paid for that year, then Licensee and its Sublicensee(s) shall be responsible for paying FSURF's out-of-pocket expenses incurred with respect to such review.

6.3 At any time during the term of this agreement, FSURF may request in writing that Licensee verify the calculation of any past payments owed to FSURF through the means of a self-audit. Within ninety (90) days of the request, Licensee shall complete a self-audit of its books and records to verify the accuracy and completeness of the payments owed. Within thirty (30) days of the completion of the self-audit, Licensee shall submit to FSURF a report detailing the findings of the self-audit and the manner in which it was conducted in order to verify the accuracy and completeness of the payments owed. If Licensee has determined through its self-audit that there is any payment deficiency, Licensee shall pay FSURF the deficiency along with applicable interest under Section 4.4.1 with the submission of the self-audit report to FSURF.

Section 7 Patent Prosecution

7.1 FSURF shall diligently prosecute and maintain the Licensed Patents using counsel of its choice. FSURF shall provide Licensee with copies of all patent applications amendments, and other filings with the United States Patent and Trademark Office and foreign patent offices. FSURF will also provide Licensee with copies of office actions and other communications received by FSURF from the United States Patent and Trademark Office and foreign patent offices relating to Licensed Patents. Licensee agrees to keep such information confidential.

7.2 Licensee shall pay to FSURF the sum of [***], within thirty (30) days of the Effective Date to reimburse any and all expenses associated with preparation, filing, prosecution, issuance, maintenance, defense, and reporting of the Licensed Patents incurred prior to the Effective Date. (NOTE: the above referenced dollar amount in this Section 7.2 is subject to change, as all related patent prosecution expense invoices may not have been received from the law firm at the time of license terms negotiation. In addition, the amounts in this article are separate from other amounts due for payment listed elsewhere.)

7.3 Licensee shall be responsible for and pay all costs and expenses incurred by FSURF related to the preparation, filing, prosecution, issuance, maintenance, defense and reporting of the Licensed Patents subsequent to and separate of those expenses cited in Section 7.2 within thirty (30) days of receipt of an invoice from FSURF. It shall be the responsibility of Licensee to keep FSURF fully apprised of the "small entity" status of Licensee and all Sublicensees with respect to the U.S. patent laws and with respect to the patent laws of any other countries, if applicable, and to inform FSURF of any changes in writing of such status, within thirty (30) days of any such change. In the event that additional licenses are granted to licensees for alternate fields-of-use, patent expenses associated with Licensed Patents will be divided proportionally between the number of existing licensees. In the case of foreign patent protection, if a licensee declines to reimburse FSURF for its proportional share of patent expenses in any particular country, then said licensee relinquishes the right to commercialize Licensed Products in the specified country.

Section 8 Infringement and Invalidity

8.1 In the event that any Licensed Patents are infringed by a third party, Licensor and joint owners of the Licensed Patents (subject to and as described in the Inter-Institutional Agreement attached as Appendix A) shall have the first right and choice, but not obligation, to defend the Licensed Patents. Licensee shall have the right, but not the obligation, to defend the Licensed Patents after Licensor and joint owners elect not to commence a suit either by formal notice to Licensee or by failure to act within the ninety (90) day period following notification of the infringer, to institute, prosecute and control any action or proceeding with respect to such infringement, by counsel of its choice, including any declaratory judgment action arising from such infringement provided, however, prior to instituting such action, Licensee shall first meet with FSURF and provide FSURF with (i) a written estimate of the expenses that would reasonably be incurred in connection with such action or proceeding and (ii) financial records reasonably sufficient to reasonably demonstrate that it has the financial wherewithal to pay such expenses as they fall due through the conclusion of such action or proceeding by means of judgment or other final, non-appealable decision or a plan to raise such funds. In the event that any Patent Rights licensed to Licensee are infringed by a third party prior to Licensee filing an investigational new drug application ("IND") for a Licensed Product, prior to any enforcement action being taken by either FSURF or Licensee regarding such infringement, FSURF and Licensee shall discuss, and will mutually agree, in writing, as to how to handle such infringement by such third party. Licensee shall be free to enter into a settlement, consent judgment, or other voluntary disposition with respect to any such action, provided that any settlement, consent judgment or other voluntary disposition thereof which (i) materially limits the scope, validity, or enforceability of patents included in the Patent Rights or (ii) admits fault or wrongdoing on the part of FSURF must be approved by FSURF, such approval not to be unreasonably withheld. Licensee's request for

such approval shall include complete copies of final settlement documents, a detailed summary of such settlement, and any other information material to such settlement. FSURF shall provide Licensee notice of its approval or denial within fifteen (15) business days of any request for such approval by Licensee, provided that (i) in the event FSURF wishes to deny such approval, such notice shall include a detailed written description of FSURF's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (ii) FSURF shall be deemed to have approved of such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) day period in accordance herewith. If Licensee recovers monetary damages in the form of lost profits from a third party infringer as a remedy for the infringement of Patent Rights licensed hereunder, then Licensee shall first apply such recovery to the costs and expenses incurred in obtaining or negotiating for such recovery (including attorneys' fees) and reimburse FSURF for the costs and expenses it reasonably incurred in obtaining or negotiating for such recovery (including attorneys' fees), and pay to FSURF the royalties on the remaining portion of such lost profits at the rate specified in Section 4.2. If Licensee recovers monetary damages in the form of a reasonable royalty as a remedy for the infringement of Patent Rights, then, after applying such royalty to the recovery of the costs and expenses incurred in obtaining or negotiating for such royalty (including attorneys' fees) and reimbursing FSURF for the costs and expenses it reasonably incurred in obtaining or negotiating for such recovery (including attorneys' fees), the remaining amount of any such royalty shall be treated as Sublicensing Royalty Revenue in accordance with Section 2.2.2.

8.2 Notwithstanding the foregoing, and in FSURF's sole discretion, FSURF shall be entitled to participate through counsel of its own choosing in any legal action involving the invention and Patent Rights. Nothing in the foregoing Sections shall be construed in any way which would limit the authority of the Florida Attorney General. FSURF and Licensee agree to notify each other promptly of each infringement or possible infringement of Licensed Patents, as well as any facts which may affect the validity, scope or enforceability of the patent rights of which any party becomes aware.

Section 9 Term and Termination

9.1 The term of this license shall begin on the Effective Date of this Agreement and continue until the date that no Licensed Patent remains an enforceable patent, unless earlier terminated as provided herein.

9.2 Licensee may terminate this Agreement at any time by giving at least sixty (60) days written notice of such termination to FSURF. Such a notice shall be accompanied by a statement of the reasons for termination.

9.3 FSURF may terminate this Agreement by giving Licensee at least thirty (30) days written notice if Licensee:

9.3.1 is delinquent on any report or payment;

9.3.2 is not diligently developing and commercializing Licensed Product and Licensed Process;

9.3.3 is in breach of any provision;

9.3.4 provides any false report;

9.3.5 goes into bankruptcy, liquidation or proposes having a receiver control any assets;

9.3.6 violates any laws or regulations of applicable government entities;

9.3.6 shall cease to carry on its business pertaining to Licensed Patents; or

9.3.8 fails for more than two (2) calendar quarters to make payments of earned royalties under Section 4.2.

Termination under this Section 9.3 will take effect thirty (30) days after written notice by FSURF unless Licensee remedies the problem in that 30-day period.

9.4 FSURF may immediately terminate this Agreement upon the occurrence of the second separate default by Licensee within any consecutive three-year period for failure to pay royalties, patent or any other expenses when due.

9.5 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Licensee shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination, and any minimum royalties shall be prorated as of the date of termination by the number of days elapsed in the applicable calendar year. Licensee may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that Licensee shall remain obligated to provide an accounting for and to pay running royalties thereon.

9.6 Licensee shall be obligated to deliver to FSURF, within ninety (90) days of the date of termination of this agreement, complete and unredacted copies of all documentation prepared for or submitted for all regulatory approvals of Licensed Products or Licensed Processes.

Section 10 Assignability

This Agreement may not be transferred or assigned by Licensee except with the prior written consent of FSURF, which will not be unreasonably withheld. Licensee may, on written notice to FSURF and with FSURF's consent, assign this Agreement to an acquirer of all or substantially all of Licensee's stock or assets, in which case assignee assumes all responsibilities under this license, however Licensee shall not be released of its obligations that matured prior to assignment.

Section 11 Dispute Resolution Procedures

11.1 Mandatory Procedures.

In the event either party intends to file a lawsuit against the other with respect to any matter in connection with this Agreement, compliance with the procedures set forth in this Section shall be a condition precedent to the filing of such lawsuit, other than for injunctive relief. Either party may terminate this Agreement as provided in this Agreement without following the procedures set forth in this section.

11.1.1 When a party intends to invoke the procedures set forth in this section, written notice shall be provided to the other party. Within thirty (30) days of the date of such notice, the parties agree that representatives designated by the parties shall meet at mutually agreeable times and engage in good faith negotiations at a mutually convenient location to resolve such dispute.

11.1.2 If the parties fail to meet within the time period set forth in Section 11.1.1 above or if either party subsequently determines that negotiations between the representatives of the parties are at an impasse, the party declaring that the negotiations are at an impasse shall give notice to the other party stating with particularity the issues that remain in dispute.

11.1.3 Not more than fifteen (15) days after the giving of such notice of issues, each party shall deliver to the other party a list of the names and addresses of at least three individuals, any one of whom would be acceptable as a neutral advisor in the dispute (the "Neutral Advisor") to the party delivering the list. Any individual proposed as a Neutral Advisor shall have experience in determining, mediating, evaluating, or trying intellectual property litigation and shall not be affiliated with the party that is proposing such individual.

11.1.4 Within ten (10) days after delivery of such lists, the parties shall agree on a Neutral Advisor. If they are unable to so agree within that time, within five (5) days, they shall each select one individual from the lists. Within five (5) days, the individuals so selected shall meet and appoint a third individual from the lists to serve as the Neutral Advisor. Within thirty (30) days after the selection of a Neutral Advisor:

- (a) The parties shall each provide a written statement of the issues in dispute to the Neutral Advisor.
- (b) The parties shall meet with the Neutral Advisor in Tallahassee, Florida on a date and time established by the Neutral Advisor. The meeting must be attended by persons authorized to make final decisions on behalf of each party with respect to the dispute. At the meeting, each party shall make a presentation with respect to its position concerning the dispute. The Neutral Advisor will then discuss the issues separately with each party and attempt to resolve all issues in the dispute. At the meeting, the parties will enter into a written settlement agreement with respect to all issues that are resolved. Such settlement agreement shall be final and binding with respect to such resolved issues and may not be the subject of any lawsuit between the parties, other than a suit for enforcement of the settlement agreement.

11.1.5 The expenses of the Neutral Advisor shall be shared by the parties equally. All other out-of-pocket costs and expenses for the alternative dispute resolution procedure required under this Section shall be paid by the party incurring the same.

11.1.6 Positions taken and statements made during this alternative dispute resolution procedure shall be deemed settlement negotiations and shall not be admissible for any purpose in any subsequent proceeding.

11.2 Failure to Resolve Dispute.

If any issue is not resolved at the meeting with the Neutral Advisor, either party may file appropriate administrative or judicial proceedings with respect to the issue that remains in dispute. No new issues may be included in the lawsuit without the mandatory

procedures set forth in this section having first been followed.

11.3 If Licensee or any of its Affiliates (i) brings a Patent Challenge against FSURF, or (ii) Licensee or any of its Affiliates assists another party in bringing a Patent Challenge against FSURF (except as required under a court order or subpoena), and (iii) FSURF does not choose to exercise its rights to terminate this Agreement pursuant to Section 9.3 then, in the event that such a Patent Challenge is successful, Licensee will have no right to recoup any consideration, including royalties, paid during the period of challenge. In the event that a Patent Challenge is unsuccessful, Licensee shall reimburse FSURF for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge.

Section 12 Product Liability; Conduct of Business

12.1 Licensee and its Sublicensee(s) shall, at all times during the term of this Agreement and thereafter, indemnify, defend and hold FSURF, the Florida Board of Governors, the Florida State University Board of Trustees, Florida State University, JHU, The Johns Hopkins Hospital, The Johns Hopkins Health System Corporation, U.S. Department of Health and Human Services, as represented by National Center for Advancing Translational Sciences (HHS) and each of their directors, officers, employees, and agents, and the inventors of the Licensed Patents "Indemnitees", regardless of whether such inventors are employed by Florida State University, and/or HHS, and/or JHU at the time of the claim, harmless against all claims and expenses, including legal expenses and reasonable attorneys' fees, whether arising from a third party claim or resulting from FSURF's enforcing this indemnification clause against Licensee, arising out of the death of or injury to any person or persons or out of any damage to property and against any other claim, proceeding, demand, expense and liability of any kind whatsoever (other than patent infringement claims) resulting from the production, manufacture, sale, use, lease, consumption, marketing, or advertisement of Licensed Products or Licensed Process(es) or arising from any right or obligation of Licensee hereunder. Notwithstanding the above, FSURF at all times reserves the right to retain counsel of its own to defend FSURF, the Florida Board of Governors', the Florida State University Board of Trustees, Florida State University, and the inventor's interests.

12.2 Licensee warrants that it now maintains and will continue to maintain liability insurance coverage at a minimum level of [***] per claim until first commercial use, and at a minimum level of [***] per claim at and continuing after first initial human testing or first commercial sale and that such insurance coverage lists Indemnitees' as additional insureds. Within ninety (90) days after the execution of this Agreement and thereafter annually between January 1 and January 31 of each year, Licensee will present evidence to FSURF that the coverage is being maintained with Indemnitees listed as additional insureds. In addition, Licensee shall provide FSURF with at least thirty (30) days prior written notice of any change in or cancellation of the insurance coverage.

Section 13 Use of Names

Licensee and its Sublicensee(s) shall not use the names of FSURF and joint owners (see Appendix A), or of Florida State University, nor of any of either institution's employees, agents, or affiliates, nor the name of any inventor of Licensed Patents, nor any adaptation of such names, in any promotional, advertising or marketing materials or any other similar form of publicity, or to suggest any endorsement by the such entities or individuals, without the prior written approval of FSURF in each case.

Section 14 Miscellaneous

14.1 This Agreement shall be construed in accordance with the internal laws of the State of Florida. Venue for any legal action shall be the state or federal courts in Leon County, Florida.

14.2 The parties hereto are independent contractors and not joint venturers or partners.

14.3 Licensee shall ensure that it applies patent markings that meet all requirements of U.S. law, 35 U.S.C. §287, with respect to all Licensed Products subject to this Agreement.

14.4 This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, shall vary or modify the written terms of this Agreement. This Agreement supercedes and replaces any and all previous agreements between the Parties. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment, or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement. Failure of either party to require performance by the other of any provision herein shall in no way affect the rights of that party to enforce same. The waiver of either party of any breach shall never be construed to be a waiver of any succeeding breach or a waiver of the provision itself.

14.5 Licensee shall not encumber or otherwise grant a security interest in any of the rights granted hereunder to any third party.

14.6 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 Contract 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. FSURF neither represents that a license is or is not required or that, if required, it shall be issued.

14.7 Licensee is responsible for any and all wire/bank fees associated with all payments due to FSURF pursuant to this agreement.

14.8 Survival.

The provisions of this Section shall survive termination of this Agreement. Upon termination of the Agreement for any reason, the following sections of the License Agreement will remain in force as non-cancelable obligations:

- Section 6 Record Keeping
- Section 9 Requirement to pay royalties on sale of Licensed Products made, and in process, at time of License Agreement termination
- Section 12 Product Liability; Conduct of Business
- Section 13 Use of Names
- Section 18 Confidentiality

14.9 This Agreement is subject to the terms and conditions of Appendix A, the terms of which are incorporated herein, which is an agreement between the U.S. Department of Health and Human Services, Johns Hopkins University, and Florida State University Research Foundation regarding technology collaboratively developed and jointly owned.

Section 15 Notices

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given

- when delivered personally, **or**
- if sent by facsimile transmission, when receipt thereof is acknowledged at the facsimile number of the recipient as set forth below, **or**
- the second day following the day on which the notice has been delivered prepaid to a national air courier service, **or**
- five (5) business days following deposit in the U.S. mail if sent certified mail, **(return receipt acknowledgement is not required to certify delivery).**

15.1 If to Florida State University Research Foundation, Inc.:

President
Florida State University Research
Foundation, Inc.
Attn: Gary K. Ostrander
2000 Levy Avenue, Suite 351
Tallahassee, FL 32310
Facsimile Number: (850) 644-3658

with a copy to:

Office of Commercialization	FSU Office of Research
Florida State University	Legal Counsel
Attn: Executive Director	3012 Westcott N. Annex
95 Chieftan Way, 312 Dittmer Bldg.	222 S. Copeland Street
Tallahassee, FL 32306-4391	Tallahassee, FL 32306-1330
	850-645-0108 (facsimile)

15.2 If to Licensee:

President
Spotlight Innovation Inc.
Attn: Cris Grunewald
6750 Westown Pkwy, Ste. 200-226
West Des Moines, Iowa 50266

Section 16 Contract Formation and Authority

The submission of this Agreement does not constitute an offer, and this document shall become effective and binding only upon the execution by duly authorized representatives of both Licensee and FSURF. Copies of this Agreement that have not been executed and delivered by both FSURF and Licensee shall not serve as a memorandum or other writing evidencing an agreement between the parties. This Agreement shall automatically terminate and be of no further force and effect, without the requirement of any notice from FSURF to Licensee, if FSURF does not receive the License Issue Fee or certificates representing shares issued to FSURF pursuant to this Agreement, as applicable, within thirty (30) days of the Effective Date.

16.1 FSURF and Licensee hereby warrant and represent that the persons signing this Agreement have authority to execute this Agreement on behalf of the party for whom they have signed.

16.2 Force Majeure.

No default, delay, or failure to perform on the part of Licensee or FSURF shall be considered a default, delay or failure to perform otherwise chargeable hereunder, if such default, delay or failure to perform is due to epidemics, war, embargoes, fire, earthquake, hurricane, flood, acts of God, or default of common carrier. In the event of such default, delay or failure to perform, any date or times by which either party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay or failure to perform.

Section 17 United States Government Interests

17.1 It is understood that the United States Government (through any of its agencies or otherwise) has funded research during the course of or under which any of the inventions of the Licensed Patents were conceived or made. The United States Government, as a co-owner of the Licensed Patents, is entitled, to certain rights, under the provisions of 35 U.S.C. §202-212 and applicable regulations of Title 37 of the Code of Federal Regulations. These include a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such Licensed Patents for governmental purposes. Any license granted to Licensee in this Agreement shall be subject to such right. FSURF shall have the right to share all Sublicensees' confidential information with JHU and HHS for the purpose of compliance with the Inter-Institutional Agreement attached as Appendix A.

17.2 Licensee agrees that for Licensed Products covered by the Licensed Patents that are subject to the non-exclusive royalty-free license to the United States Government, said Licensed Products will be manufactured substantially in the United States. Licensee further agrees that it shall abide by all the requirements and limitations of U.S. Code, Title 35, Chapter 18, and implementing regulations thereof, for all patent applications

and patents invented in whole or in part with federal money.

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential and appropriately marked "proprietary" or "confidential" (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, Sublicensees or agents. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section 18 shall extend for a period of five (5) years from termination or expiration of this Agreement.

Section 19 University Rules and Regulations

Licensee understands and agrees that Florida State University personnel who are engaged by Licensee, whether as consultants, employees or otherwise, or who possess a material financial interest in Licensee, are subject to the Florida State University's policies regarding outside activities and financial interests and, Florida State University's Intellectual Property Policy, and a monitoring plan which addresses conflicts of interests associated therewith as required by Chapter 112, Florida Statutes. Any term or condition of an agreement between Licensee and such Florida State University personnel which seeks to vary or override such personnel's obligations to Florida State University may not be enforced against such personnel, Florida State University or FSURF, without the express written consent of an individual authorized to vary or waive such obligations on behalf of Florida State University and FSURF. Furthermore, should an interest of Licensee conflict with the interest of Florida State University, Florida State University personnel are obligated to resolve such conflicts according to the guidelines and policies set forth by Florida State University.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

FLORIDA STATE UNIVERSITY RESEARCH FOUNDATION, INC.

_____, Date: _____, 2016
Gary K. Ostrander
President, Florida State University Research Foundation

LICENSEE

By: _____ Date: _____, 2016
Name and Office: _____

Appendix A - Inter-institutional Agreement

Appendix B - Development Plan

The starting point for the Development Plan will be the group of compounds previously identified by Prof. Hengli Tang and collaborators and described in Provisional Patent Application [***]. Novel compounds (prodrugs or other derivatives) will be synthesized with the aim of optimizing characteristics such as oral bioavailability, CNS penetration, pharmacodynamic (PD) and pharmacokinetic (PK) properties, and safety. The ultimate goals of the Development Program are to complete preclinical and clinical testing of one or more lead drug candidates, prepare and file a New Drug Application, obtain marketing approval, and commence product manufacturing and sales.

A. Development activities to be undertaken

(Please break activities into subunits)

1. **Testing of lead compounds in small animal and human brain organoid model for ZIKV inhibition.** We will test the efficacy of lead compounds in both IFNAR^{-/-} mice and C57BL/6 mice. Multiple assays, including body weight loss, lethality, and viral load in blood and tissues, will be used to determine if a compound is effective against ZIKV infection. We will also use the human brain organoid system as a complementary model to avoid pitfalls of species-specific differences and safeguard the success of our project.
2. **Determination of mechanism of action (this project is concurrent with other activities and not part of a sequence of activities).** We will use a combined approach of biochemistry, molecular biology, and virology to identify the compound target and dissect its mechanism of action (MOA). We will label the compound and identify its binding partner in cells and in vitro; we will map any drug resistant mutations in cell culture and determine the specific steps of the virus life cycle to which the compound targets.
3. **Optimization of lead compounds in each class.** For both classes of compounds, we will perform iterative rounds of analog synthesis and testing, typically on a biweekly or monthly schedule. The chemistry team will design and synthesize compounds; the biology team will test the compounds in assays; and the Drug Metabolism and Pharmacokinetics (DMPK) team will evaluate compound physical properties. During lead optimization, it is necessary to address ADME and toxicological liabilities and to improve the lead compound's DMPK properties. The goal lead optimization is to identify an advanced lead candidate with drug-like properties, efficacy in animal models, and low toxicity.

4. **Advanced safety testing for lead candidates.** Once advanced lead candidates are identified, we will begin to build a safety package for the compound. This in general will consist of non-GLP toxicology studies in a rodent and a non-rodent species. Upon successful completion of the exploratory toxicology studies, we will manufacture sufficient amounts of application program interface (API) under GMP conditions to support GLP toxicology studies in two species under GLP conditions, including GLP genotoxicity and safety pharmacology studies under GLP conditions. The results from these studies will form the body of the regulatory filing to open an IND with the FDA.
- B. Estimated total development time
- II. Governmental Approval
 - A. Types of submissions required
 - B. Government agency, e.g., FDA, EPA, etc.
- III. Proposed Market Approach (this may include/involve an exit strategy)

Appendix C - Development Report

When appropriate, indicate estimated start date and finish date for activities.

- I. Date Development Plan Initiated and Time Period Covered by this Report.
- II. Development Report.
 - A. Activities completed since last report including the object and parameters of the development, when initiated, when completed and the results.
 - B. Activities currently under investigation, i.e., ongoing activities including object and parameters of such activities, when initiated, and projected date of completion.
- III. Future Development Activities.

- A. Activities to be undertaken before next report including, but not limited to, the type and object of any studies conducted and their projected starting and completion dates.
 - B. Estimated total development time remaining before a product will be commercialized.
- IV. Changes to Initial Development Plan.
- A. Reasons for change.
 - B. Variables that may cause additional changes.
- V. Items to be Provided if Applicable:
- A. Information relating to Licensed Products or Licensed Processes that has become publicly available, e.g., published articles, competing products, patents, etc.
 - B. Development work being performed by third parties, other than Licensee, to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
 - C. Update of competitive information trends in industry, government compliance (if applicable) and market plan.
 - D. Information and copies of relevant materials evidencing the status of any patent applications or other protection relating to Licensed Products, or Licensed Processes or the Licensed Patents.

PLEASE SEND DEVELOPMENT REPORTS TO:

with a copy to:

President
Florida State University Research Foundation, Inc.
Attn: Gary K. Ostrander
2000 Levy Avenue, Suite 351
Tallahassee, FL 32310
Facsimile Number: (850) 644-3658

Office of Commercialization
Florida State University
Attn: Executive Director
95 Chieftan Way, 312 Dittmer Bldg.
Tallahassee, FL 32306-4391
Facsimile Number: (850) 644-3675

Appendix D - FSURF Royalty Report

Licensee: _____ **Agreement No.:** _____
Inventor: _____ **P#: P** _____
Period Covered: From: ____/____/2____ Through: ____/____/2____
Prepared **Date:** _____
By: _____
Approved **Date:** _____
By: _____

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

Report Type: ☐ **Single Product Line Report:** _____
☐ **Multiproduct Summary Report.** Page 1 of _____ Pages
☐ **Product Line Detail.** Line: _____ Tradename: _____ Page: _____
Report Currency: ☐ **U. S. Dollars** ☐ **Other** _____

Country	Unit Sales	Gross \$\$ Sales	* Less: Allowances	Net \$\$ Sales	Royalty Rate	Period Royalty Amount	
						This Year	Last Year

U.S.A.

Canada

Europe:

Japan

Other:

TOTAL:

Total Royalty: _____ Conversion Rate: _____ Royalty in U.S. Dollars: \$ _____

The following royalty forecast is non-binding and for FSURF's internal planning purposes only:

Royalty Forecast Under This Agreement: Next Quarter: _____ Q2: _____ Q3: _____ Q4: _____

<p>* On a separate page, please indicate the reasons for returns or other adjustments if significant. Also note any unusual occurrences that affected royalty amounts during this period. To assist FSURF's forecasting, please comment on any significant expected trends in sales volume.</p>

Appendix E – Due Diligence

Due Diligence Activity	Completion Date
Synthesis of novel analog(s) of parent compound(s) to create a First Lead Compound (“FLC”)	[***]
ZIKV inhibition testing of FLC in mice	[***]
ZIKV inhibition testing of FLC in human brain organoid system	[***]
GMP Manufacturing of FLC (small scale)	[***]
Non-GLP toxicology testing in rodents and non-rodents	[***]
Pre-IND meeting with FDA	[***]
Identification of packaging, labeling and compatibility testing	[***]
GLP toxicology testing of FLC in rodents and non-rodents	[***]
Submission of IND	[***]

Initiation of Phase 1 clinical trial	***
ADME, PK, GLP testing of FLC	***
Initiation of Phase 2 clinical trial	***
CMC development (product characterization, purity, potency, qualification, validation of analytical methods and processes, bioequivalence and bioavailability)	***
End of Phase 2 meeting with FDA	***
Two-year stability testing	***
Initiation of Phase 3 clinical trial	***
Pre-NDA meeting with FDA	***
Submission of NDA	***
Sale of first FDA-approved drug	***