

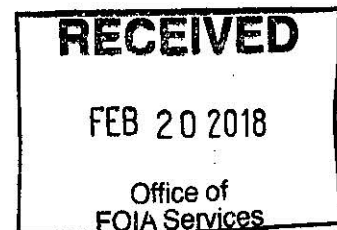
18-02590-E

Debra Smetana  
ktMINE  
940 West Adams  
Suite 100  
Chicago, IL 60607

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2/20/2018

U.S. Securities & Exchange Commission  
Office of FOIA and Privacy Act Operations  
100 F Street, NE  
Mail Stop 2465  
Washington, DC 20549-5100



Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibits 10.9 and 10.10 to the Form 8-K, as amended, filed by Tonix Pharmaceuticals Holding Corp. on 4/3/2012

We authorize \$0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

A handwritten signature in black ink, appearing to be "Debra Smetana".

Debra Smetana



UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
STATION PLACE  
100 F STREET, NE  
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 13, 2018

Ms. Debra Smetana  
ktMine  
940 West Adams, Suite 100  
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552  
Request No. 18-02590-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this Office on February 20, 2018, for Exhibits 10.9 and 10.10 to the Form 8-K, as amended, filed by Tonix Pharmaceuticals Holding Corp. on April 3, 2012.

The search for responsive records has resulted in the retrieval of 15 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me directly at [andersonc@sec.gov](mailto:andersonc@sec.gov) or (202) 551-8315. You may also contact me at [foiapa@sec.gov](mailto:foiapa@sec.gov) or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or [Archives.gov](http://Archives.gov) or via e-mail at [ogis@nara.gov](mailto:ogis@nara.gov).

Sincerely,

A handwritten signature in cursive script that reads "Clarissa Anderson".

Clarissa Anderson  
FOIA Research Specialist

Enclosure

## FEASIBILITY AND OPTION AGREEMENT

**THIS FEASIBILITY AND OPTION AGREEMENT** (the "**Agreement**") is made and entered into as of June 20, 2007 by and between **LIPOCINE, INC.**, a Delaware corporation having its principal place of business at 675 Arapeen Drive, Suite 202, Salt Lake City, UT 84108 ("**Lipocine**"), and **KRELE PHARMACEUTICALS, INC.**, a Delaware corporation having its principal place of business at 1349 Lexington Avenue, Suite 2C, New York, NY 10128 ("**Krele**"). Lipocine and Krele may be referred to herein individually as a "**Party**", or collectively as the "**Parties**".

### 1. OVERVIEW

**1.1** This Agreement provides for: (a) a feasibility and phase I study to be conducted by Lipocine with Krele funding, to study the feasibility of oral delivery of cyclobenzoprine (the "**Product**") using Lipocine's delivery technology (the "**Feasibility Study**"), and (b) the grant to Krele of an exclusive option to negotiate and enter into an exclusive license under the applicable Lipocine technology and intellectual property to develop and commercialize the Product upon payment of \$47,600 towards the cost of the Feasibility Study. The Lipocine technology that will be used in the Feasibility Study and available under such option includes Lipocine's Lip'ral™ technology for improving absorption of poorly water-soluble compounds.

### 2. FEASIBILITY PROGRAM

**2.1** Feasibility Program. Lipocine shall conduct a Feasibility Study to assess the feasibility of improved oral delivery of the Product for Krele in accordance with the Feasibility Study protocol attached to this Agreement as Exhibit I and incorporated herein (the "**Protocol**"). Lipocine shall conduct the Feasibility Study exclusively for Krele in a diligent, professional and workmanlike manner. The cost and timelines for conducting the Feasibility Study are as specified in the Protocol. Upon the completion of the Feasibility Study, Lipocine shall deliver the final report as contemplated by the Protocol (the "**Final Report**"). Krele will promptly review the results of the Feasibility Study as set forth in the Final Report. If Krele determines that it desires to proceed with its option to license, Krele will so notify Lipocine in writing no later than thirty (30) days after receipt of the Final Report).

### 3. OPTION FOR EXCLUSIVE LICENSE

#### 3.1 Option to License.

(a) Lipocine hereby grants to Krele the exclusive option (the "**Option**") to obtain an exclusive, worldwide license under the Lipocine Intellectual Property (as defined below) for the further development and commercialization of the Product, on the terms and conditions set forth in this Section 3. Krele may elect to exercise the Option by providing Lipocine written notice of such election no later than thirty (30) days after receipt of the Final Report.

(b) If Krele exercises the Option, then the Parties will meet promptly thereafter and negotiate in good faith a license agreement that grants Krele or an affiliate the

exclusive, worldwide license and rights under the Lipocine Intellectual Property to further develop, make, have made, offer for sale, sell, import and use the Product, which license agreement shall be on the terms set forth below and shall contain such other commercially reasonable terms as are customary in the industry for similar license agreements.

(c) During the term of the Feasibility Study and the Option Period (as defined in Section 3.1(d) below), Lipocine agrees to make available to Krele all data, know-how and information related to the Product and Lipocine Intellectual Property that is in Lipocine's possession or control and that is reasonably necessary or useful to Krele in order for Krele to exercise its Option and determine an appropriate regulatory strategy for the Product.

(d) The Parties understand and agree that if, despite the Parties' good faith negotiations, the Parties are not able to reach final agreement on a definitive license agreement on the terms provided herein within sixty (60) days after commencing such negotiations (or such longer period as agreed to by the Parties) (the "*Option Period*"), neither Party will be obligated to proceed further with such negotiations.

### 3.2 Scope of Exclusive License.

(a) The license rights covered by the Option will be an exclusive, worldwide license, including rights to sublicense, under the Lipocine Intellectual Property solely to develop, make, have made, offer for sale, sell, import and use the Product. Under the terms of such license, Krele, its affiliates, and/or its sublicensees will own exclusively all data, regulatory filings and regulatory approvals covering the Product. For purposes of this Agreement, "*Lipocine Intellectual Property*" means the patents and know-how rights owned or otherwise controlled by Lipocine that claim or cover, or directly relate to, the Lipocine oral delivery technology that is, or may be, used in the Product.

(b) During the term of the license agreement, in no event shall Lipocine license, transfer or sell the Lipocine Intellectual Property to a third party for the development, manufacture, use, sale or commercialization of cyclobenzaprine products.

(c) If development of the formulation selected by Krele reveals that the formulation is not optimal, in Krele's judgment, Krele has the option to have Lipocine redevelop one of the formulations from the Feasibility Study that Krele did not initially select with reimbursement of reasonably incurred costs to Lipocine.

3.3 Payments for Exclusive License. The Parties understand and agree that the payment provisions provided in this Section 3.3 relate to all Products based on cyclobenzaprine. For the avoidance of doubt, the milestone payments will be paid only once for the first Product that is bioequivalent to cyclobenzaprine 5 mg. Krele contemplates developing at least four Products that are bioequivalent to cyclobenzaprine 5 mg: for muscle spasm, sleep, generalized anxiety and fibromyalgia, and no additional milestones will be paid for such Products. If Krele develops Products that are bioequivalent to other products (for, example, a product that is bioequivalent to cyclobenzaprine 10 mg), such Products will be considered additional Products and Krele will pay fifty percent (50%) of the milestones set forth in Section 3.3(d) below for the second and third additional Products only.

(a) License Fee. In the event the Parties enter into a license agreement for the Lipocine Intellectual Property as provided herein, Krele will pay Lipocine a license fee of **\$300,000** within ten (10) days of the effective date of the license agreement.

(b) Product Development Reimbursement. If Krele decides to engage Lipocine to assist Krele in the further development of the Product, then and only then, as provided in the license agreement, Krele will reimburse Lipocine for all of Lipocine's research and development expenses relating to Lipocine's activities in support of development of the Product as directed by Krele. Such research and development expenses will be more fully defined in a product development plan approved by Krele prior to Lipocine incurring any such costs.

(c) Sublicense Payments. Krele will pay to Lipocine payments equal to **fifteen percent (15%)** of any pre-commercialization or commercialization consideration (e.g., upfront license fees, milestone payments, license maintenance fees, royalties, etc.) received by Krele from a sublicensee, including any such pre-commercialization consideration received as a result of NDA (or equivalent) approval or Product launch.

(d) Milestones. Krele will pay Lipocine milestone payments for the following events:

- 1) **\$500,000 at NDA Filing for the first Product**
- 2) **\$1,000,000 at NDA Approval for the first Product**

In addition, as provided in Section 3.3 above, if Krele develops Products that are bioequivalent to products other than cyclobenzaprine 5 mg, such Products will be considered additional Products and Krele will pay **fifty percent (50%)** of the milestones set forth above for the second and third additional Products only.

(e) Royalties. Krele will pay to Lipocine royalties based on sales of Product by Krele and its affiliates, which royalties equate to **3%** of net sales.

**3.4** Understandings. The Parties understand and agree that consummation of the above proposed licensing transaction is contingent upon execution and delivery of the contemplated license agreement in a form satisfactory to both of the Parties, which will include the terms and conditions of Section 3.3 above as well as additional terms and conditions customary for a transaction of this nature, including without limitation, technology transfer provisions, customary representations and warranties, indemnification provisions and intellectual property prosecution and enforcement provisions, and neither Party shall be bound (except to negotiate in good faith and as otherwise provided herein) unless and until such license agreement is finally agreed upon and executed by both Parties.

#### **4. INTELLECTUAL PROPERTY MATTERS**

**4.1** Prior Intellectual Property. All patents, trade secrets, information, know-how,

inventions, technology, data and other intellectual property rights owned by either Party prior to the Effective Date shall remain the sole property of the respective Party. For the avoidance of doubt, Krele shall retain all or its and its affiliates' rights in patents, trade secrets, information, know-how, inventions, technology, data and other intellectual property rights that relate to very low dose cyclobenzoprine (VLD-cyclo) (the "**Krele Intellectual Property**").

**4.2 Developed Intellectual Property.** All patents, trade secrets, inventions, technology, and other intellectual property rights (collectively, "**Intellectual Property**") arising from the performance of the Feasibility Study shall be jointly owned by Krele and Lipocine. Each of the Parties shall have the sole right to file patent applications related to their respective Intellectual Property and the Parties shall mutually determine which Party shall file patent applications for jointly-owned Intellectual Property. Each Party shall execute such assignments and other documents as the other Party may reasonably request to enable the Parties to perfect assignments to the other Party of the Intellectual Property as provided herein and to protect the Intellectual Property.

**4.3 No Implied or Express License.** Unless and until Krele exercises the Option and the Parties enter into the license agreement contemplated by such Option, Krele shall obtain no license or other rights under, and Lipocine grants no implied or express license to Krele under, the Lipocine Intellectual Property for any use or purpose. In addition, Lipocine shall have no license or other rights under, and Krele grants no implied or express license to Lipocine under, the Krele Intellectual Property for any use or purpose other than performance of the Feasibility Study on behalf of Krele as contemplated by the Protocol and this Agreement.

**4.4 Use of Study Data and Name.** Lipocine shall have the rights to use the data and results of the Feasibility Study (the "**Study Data**") for internal and marketing purposes (and not drug development), such as use of the Study Data in proposals, presentations and similar materials supplied by Lipocine to its prospective partners or business partners for promotional or marketing purposes only; provided, however, that Lipocine shall redact all references to Krele and Krele Intellectual Property and any confidential or proprietary information from any Study Data supplied to the prospective customers or business partners of Lipocine and such prospective customers and business partners will not be granted any rights or licenses (implied or express) in the Krele Intellectual Property or Study Data. Upon execution of the license agreement, Krele shall have the right, but not any obligation, to use the name "Lipocine" and "Lip'ral" on internal and marketing materials related to the Feasibility Study and the results thereof, including any Products.

**4.5 Ownership of Study Data.** Notwithstanding anything to the contract in Section 4.2, Krele shall own all work product, information and data arising from the Feasibility Study regardless of whether the Option is exercised.

## **5. TERM AND TERMINATION**

**5.1 Agreement Term.** Unless terminated earlier by either Party pursuant to this Section 3, this Agreement shall become effective upon the Effective Date and shall terminate on the earlier of expiration of the Option. This Agreement may be extended by written agreement signed by the Parties.

**5.2 Termination for Uncured Breach.** If a Party breaches a material obligation, the other Party may give written notice to such breaching Party specifying the breach and its intention to terminate this Agreement if such breach is not cured. If the breaching Party does not cure the breach within sixty (60) days of receipt of such notice, the other Party may terminate the Agreement upon written notice to the breaching Party.

**5.3 Consequences of Termination.** Termination or expiration of this Agreement will not relieve either Party of any obligations under this Agreement accrued prior to any such termination or expiration. The obligations of the Parties pursuant to Sections 4.1, 4.2, 4.3 and 6 shall survive expiration or termination of this Agreement for the period set forth therein, and if no period is set forth, perpetually.

**5.4 Early Termination.** Upon early termination of the Feasibility Study, for reasons other than safety concerns of study subjects or other reasonable scientific or regulatory concerns, or for uncured breach of the payment terms thereunder, the Option to license shall not survive.

## **6. CONFIDENTIALITY**

**6.1 Confidential Treatment.** All Information of a Party that is disclosed by such Party to the other Party pursuant to this Agreement and labeled “confidential” or the equivalent (the “*Confidential Information*”) shall be maintained in confidence by the recipient Party and its respective officers, employees, agents, assignees, and subcontractors for a period of ten (10) years from the date of termination of the Agreement. During such period, recipient Party shall not publish or otherwise disclose the Confidential Information of the disclosing Party to any other Party or entity and shall not use the Confidential Information of the disclosing Party for purposes other than as expressly permitted in this Agreement, without the written consent of the other Party.

**6.2 Limited Third Party Disclosure.** Each Party may disclose the Confidential Information of the other Party to a third party only after obtaining the prior written approval of the Party owning such Confidential Information for such disclosure and provided that each such Third Party shall have agreed in writing to be bound by obligations of non-use and nondisclosure equivalent in all respects to those assumed by the Parties hereunder.

**6.3 Information Excluded from Confidentiality Provision.** The foregoing obligations of confidentiality and non-use shall not apply to materials and information that the receiving Party can demonstrate:

(a) are or become publicly known or available through no fault or omission of the recipient;

(b) are learned or obtained by the recipient from a third party entitled to disclose or transfer such materials or information;

(c) are already known or possessed by the recipient before receipt or transfer from the disclosing Party, as shown by the recipient's prior written records; or

(d) are developed independently by an employee or consultant of the recipient with no knowledge of the Confidential Information disclosed hereunder.

**6.4 Other Permitted Disclosure.** Notwithstanding any other provision of this Agreement, a Party may disclose the Confidential Information of the other Party to the limited extent that such disclosure:

(a) is in response to a valid order of a court or other governmental body;

or

(b) is required by law or regulation;

provided, however, that such Party shall first have given reasonable prior notice to the other Party and shall have made a reasonable effort, or shall cooperate with the other Party's efforts, as applicable, to obtain a protective order limiting the extent of such disclosure and requiring that the Confidential Information so disclosed be used only for the purposes for which such order was issued or as required by such law or regulation.

## **7. MISCELLANEOUS PROVISIONS**

**7.1 Execution in Counterparts.** This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

**7.2 Entire Agreement.** This Agreement constitutes, on and as of the Effective Date, the entire agreement between the Parties with respect to the subject matter hereof, and all prior understanding and agreements, whether written or oral, between the Parties with respect to such subject matter are hereby superseded in their entireties.

**7.3 Governing Law.** This Agreement shall in all respects be governed by, and construed and enforced in accordance with, the laws of the State of New York without regard to its conflict of laws principles.

**7.4 Relationship of the Parties.** The Parties to this Agreement are independent contractors and not joint venturers or partners. Neither Party shall be deemed to be an agent of the other Party as a result of any transaction under or related to this Agreement nor shall in any way pledge the other Party's credit or incur any obligation on behalf of the other Party.

**7.5 Waiver.** The failure of either Party to insist upon strict compliance with any of the terms, covenants, or conditions herein shall not be deemed a waiver by such Party of such terms, covenants or conditions, nor shall any waiver or relinquishment of any right at any one or more times be deemed a waiver or relinquishment of such right at any other times, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or a future exercise thereof or the exercise of any other right or remedy granted hereby or by any related document or by law.



**7.6 Severability.** The invalidity or unenforceability of any provision hereof shall in no way affect the validity or enforceability of any other provision. Any provision declared invalid or unenforceable by a court of competent jurisdiction shall be deleted and the remaining terms and conditions of this Agreement shall remain in full force and effect.

**IN WITNESS WHEREOF,** the Parties hereto have caused this Agreement to be executed by their authorized representatives.

**LIPOCINE, INC.**

**KRELE PHARMACEUTICALS, INC.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: Seth Lederman

Title: \_\_\_\_\_

Title: Chairman

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**Attachment A**

**Proposal for Feasibility Evaluation of  
Improved Oral Delivery of Cyclobenzaprine**

March 30, 2007

Submitted By:

Lipocine, Inc.  
675 Arapeen Drive Suite 202  
Salt Lake City, Utah 84108

Submitted To:

Krele Pharmaceuticals, Inc.

## **Improved Oral Delivery of Cyclobenzaprine - Feasibility Proposal**

### **Background**

Lipocine Inc. (Lipocine) has proprietary technology, Lip'ral™, for improved oral absorption of poorly water soluble drugs and elimination of food effects on absorption. The technology has been validated in clinical and preclinical studies with several different poorly water soluble drugs, and is protected by issued and pending patents.

Krele Pharmaceuticals (Krele) has contracted Lipocine to conduct a feasibility evaluation for the improved oral delivery of Cyclobenzaprine, a muscle relaxant. Cyclobenzaprine is currently sold under the brand name Flexeril® and there are several generics. It is available as 5 mg, 7.5 mg and 10 mg tablets.

The specific objectives of the feasibility evaluation are:

1. Develop Lip'ral™ formulations of cyclobenzaprine at slightly lower strength than the marketed product; select two formulations for a Phase I study.
2. Manufacture, test and release the lots under GMP. Conduct a Phase I clinical study to determine whether the Lipocine formulations are bioequivalent to Flexeril® 5 mg tablet.

The feasibility program involves pre-formulation, formulation development and stability evaluation with the goal of selecting two formulations for a Phase I study. It also includes manufacture, testing and release of clinical lots of the selected formulation and conducting a Phase I study to determine the pharmacokinetics of the Lipocine formulations relative to Flexeril®.

The tasks, timelines and cost of the feasibility program are presented in detail below.

**Work Plan**

<b>Salient Tasks</b>	<b>FTEs</b>	<b>Timeline</b>
<b>Preformulation:</b> <ul style="list-style-type: none"> <li>▪ Develop analytical methods for assay/characterization of drug in different matrices (lipidic excipients, formulations etc.)</li> <li>▪ Determine drug solubility/compatibility in several lipidic components, and other excipients</li> <li>▪ Screen preliminary compositions for drug solubility/loading, and extent of drug solubilization upon dispersion in SGF</li> </ul>	<b>0.17</b>	<b>6 weeks</b>
<b>Formulation Development:</b> <ul style="list-style-type: none"> <li>▪ Optimize two (2) formulations to achieve target solubility enhancement, dosage form drug loading, release profile, etc.</li> <li>▪ Develop methods &amp; confirm 1 month accelerated stability of formulations</li> </ul>	<b>0.17</b>	<b>8 weeks</b>
<b>TOTAL (Stage I)</b>	<b>0.34</b>	<b>16 weeks</b>
<b>Documentation, Process, Method Development:</b> <ul style="list-style-type: none"> <li>▪ Select two (2) formulations for clinical study</li> <li>▪ Specifications and STMs for raw materials, intermediates and finished products; develop cleaning method</li> <li>▪ Manufacture one trial lot to develop/confirm process, methods and specifications for finished product</li> <li>▪ Batch records for manufacture of clinical supplies</li> <li>▪ Protocol and CRO for Phase I study and bioanalysis</li> </ul>	<b>0.25</b>	<b>3 weeks</b>
<b>Clinical Supplies, Stability:</b> <ul style="list-style-type: none"> <li>▪ Procure, test and release raw materials</li> <li>▪ Manufacture, test and release two clinical lots under GMP compliance</li> <li>▪ Stage and conduct ICH stability program on the clinical lots</li> </ul>	<b>0.25</b>	<b>3 weeks</b>
<b>Conduct Phase I Studies:</b> <ul style="list-style-type: none"> <li>▪ Select CROs</li> <li>▪ Coordinate insurance, IRB review, shipping supplies, etc.</li> <li>▪ Monitor study</li> <li>▪ Complete PK and statistical analysis</li> <li>▪ Draft and Final clinical study reports</li> </ul>	<b>0.10</b> <b>All external costs will be passed through</b>	<b>16 weeks</b>
<b>TOTAL (Stage II)</b>	<b>0.60</b>	<b>22 weeks</b>

**Cost & Payment Terms**

Based on Lipocine's 2007 fully burdened reimbursement rate of \$280,000/FTE, the cost of Stage I of the feasibility program is \$95,200. The payment terms for Stage I are as follows:

50% upon signing of the agreement;

50% upon selection of two formulations for a Phase I study.

The cost for Stage II of the feasibility program is \$168,000 (plus external costs) paid according to the following schedule:

50% upon Krele's decision to proceed with Stage II

25% upon IRB approval of the Phase I study protocol

20% upon submission of the preliminary pharmacokinetic data

5% upon completion of the final clinical study report

All external costs (clinical study, liability insurance premium, bioanalytical costs, travel for clinical study monitoring) and significant (>\$500) material costs (HPLC columns, raw materials etc.) will be passed through to Krele.

Lipocine will invoice Krele for the amount due upon completion of the associated milestone. All invoices are payable net 30 days.

### **Lipocine Responsibilities**

Lipocine will purchase cyclobenzaprine API in order to complete the feasibility program.

Lipocine will develop/verify analytical method(s) for assay of cyclobenzaprine in components and formulations.

Lipocine will conduct preformulation and formulation development studies as per Stage A Work Plan.

At the conclusion of formulation development phase, Lipocine and Krele will select two (2) formulations for clinical development.

Upon a go decision from Krele, Lipocine will manufacture, test and release lots of the two (2) selected formulations for the Phase I study as per Work Plan.

Lipocine will develop the study protocols and select CROs in consultation with Krele as per Work Plan.

Lipocine will conduct the Phase I program as per Work Plan.

Lipocine will provide periodic written project reports to Krele.

Tonix Pharmaceuticals, Inc.  
250 Pehle Ave.  
Park 80 West, Plaza II - Suite 200  
Saddle Brook, NJ 07663

October 4, 2010

Lipocine, Inc.  
675 Arapeen Drive, Suite 202  
Salt Lake City, Utah 84108

Dear Mahesh:

Reference is made to a certain Feasibility and Option Agreement dated as of June 20, 2007 (the "Agreement") between Lipocine, Inc. ("Lipocine") and Tonix Pharmaceuticals, Inc. (formerly known as Krele Pharmaceuticals, Inc.) ("Tonix").

The purpose of this letter is to amend certain provisions of the Agreement. Accordingly, it is hereby agreed as follows:

1. Upon execution of this letter by both parties, Tonix shall pay Lipocine the remaining \$47,600 due for Stage I of the Feasibility Program.
2. The preamble of the Agreement shall be amended to modify Tonix's principal place of business to 2 Park 80 Plaza West, Suite 200, Saddle Brook, NJ 07633.
3. Section 2 (Feasibility Program) shall be amended as follows:
  - (a) The reference to "Exhibit 1" in Section 2.1 shall be deleted and replaced with a reference to "Attachment 1".
  - (b) The following new Section 2.2 shall be added:

**"2.2 Stage II of the Feasibility Program.** Tonix shall make a decision to proceed to Stage II of the Feasibility Study (as described in the Protocol) by providing Lipocine with a written notice (the "Stage II Notice") by no later than five business days following receipt of a mutually acceptable form of license agreement for the license rights covered by the Option consistent with the terms and conditions in Article 3 of the Agreement. Lipocine shall provide Tonix with a draft of the form of license agreement within thirty (30) days following the date of this letter, and thereafter, Tonix and Lipocine shall expeditiously negotiate the form of license agreement in good faith. Provided that Lipocine has fulfilled its obligations pursuant to the prior sentence, if Tonix has not provided Lipocine with the Stage II Notice by September 30, 2011, the Agreement shall terminate unless extended by mutual agreement in writing."

4. The second through fourth sentences of Section 3.3 (Payments for Exclusive License) shall be deleted and replaced with the following:

“For the avoidance of doubt, the milestone payments will be paid only once for the first cyclobenzaprine Product of any strength. If Tonix develops cyclobenzaprine Products of a different strength than the first Product, such Products will be considered additional Products and Tonix will pay fifty percent (50%) of the milestones set forth in Section 3.3(d) below for the second and third additional Products only.”

5. The last sentence of Section 3.3(d) (Milestones) shall be deleted and replaced with the following:

“In addition, as provided in Section 3.3 above, if Tonix develops cyclobenzaprine Products that are of a different strength than the first Product, such Products will be considered additional Products and Tonix will pay fifty percent (50%) of the milestones set forth above for the second and third additional Products only.”

6. In order to consistently reflect the modifications in paragraph 3 above, page 2 of Attachment 1 (the Protocol) shall be deleted and replaced with the attached amended page 2.

7. The second Paragraph on Page 4 of Attachment I, (Cost & Payment Terms) shall be deleted and replaced with the following:

“The cost for Stage II of the feasibility program is \$235,000 (plus external costs) with IND. The total cost (plus external costs) w/o IND is \$185,000 paid as follows:....”

8. Except as expressly provided herein, and notwithstanding any prior notices or correspondence between the Parties, all terms, covenants and conditions of the Agreement shall remain in full force and effect, and this amendment and the Agreement shall be read as one instrument.

Kindly confirm that the foregoing represents our agreement by signing and returning to the undersigned the enclosed copy hereof, whereupon this letter shall constitute an amendment to the Agreement.

Very truly yours,

TONIX PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: Seth Lederman

Title: Chairman

Date Signed: \_\_\_\_\_

ACCEPTED AND AGREED TO:

LIPOCINE, INC.

By: \_\_\_\_\_

Name: Mahesh V. Patel

Title: President and CEO

Date Signed: \_\_\_\_\_



## **Improved Oral Delivery of Cyclobenzaprine – Feasibility Proposal**

### **Background**

Lipocine Inc. (Lipocine) has proprietary technology, Lip'ral™, for improved oral absorption of poorly water soluble drugs and elimination of food effects on absorption. The technology has been validated in clinical and preclinical studies with several different poorly water soluble drugs, and is protected by issued and pending patents.

Tonix Pharmaceuticals, Inc. (formerly known as Krele Pharmaceuticals, Inc., Tonix) has contracted Lipocine to conduct a feasibility evaluation for the improved oral delivery of Cyclobenzaprine, a muscle relaxant. Cyclobenzaprine is currently sold under the brand name Flexeril® and there are several generics. It is available as 5 mg, 7.5 mg and 10 mg tablets.

The specific objectives of the feasibility evaluation are:

1. Develop Lip'ral™ formulations of Cyclobenzaprine at slightly lower strength than the marketed product; select two formulations for a Phase I study.
2. Manufacture, test and release the lots under GMP. Conduct a Phase I clinical study under a US IND to determine whether the Lipocine formulations are bioequivalent to Flexeril® 5 mg tablet or have faster absorption, faster elimination or the same or lower area under the curve (AUC) than cyclobenzaprine 5 mg.

The feasibility program involves pre-formulation, formulation development and stability evaluation with the goal of selecting two formulations for a Phase I study. It also includes manufacture, testing and release of clinical lots of the selected formulation and conducting a Phase I study to determine the pharmacokinetics of the Lipocine formulations relative to Flexeril®.

The tasks, timelines and cost of the feasibility program are presented in detail below.