

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

FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

ALLENA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

45-2729920
(I.R.S. Employer
Identification Number)

One Newton Executive Park, Suite 202
Newton, Massachusetts 02462
(617) 467-4577

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Alexey Margolin
Chief Executive Officer
Allena Pharmaceuticals, Inc.
One Newton Executive Park, Suite 202
Newton, Massachusetts 02462
(617) 467-4577

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Michael H. Bison
Daniel Lang
Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
(617) 570-1000

Sophia Hudson
Joseph A. Hall
Davis Polk & Wardwell LLP
John Hancock Tower
450 Lexington Avenue
New York, New York 10017
(212) 450-4000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large Accelerated Filer

Non-Accelerated Filer (Do not check if a smaller reporting company)

Accelerated Filer

Smaller Reporting Company

Emerging Growth Company

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

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee
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Common Stock, par value \$0.001 per share

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Explanatory Note

Allena Pharmaceuticals, Inc. has prepared this Amendment No. 2 to the Draft Registration Statement on Form S-1 that was confidentially submitted to the Securities and Exchange Commission on September 28, 2017 (the "Registration Statement") solely for the purposes of filing Exhibit 10.11 to the Registration Statement and making corresponding updates to Item 16 and the Exhibit Index. This Amendment No. 2 does not modify any provision of the Prospectus that forms Part I of the Registration Statement and accordingly such Prospectus has not been included herein.

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and NASDAQ listing fee.

	<u>Amount to be Paid</u>	
SEC registration fee	\$	*
FINRA filing fee		*
NASDAQ listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Transfer Agent and fees and expenses		*
Miscellaneous expenses		*
Total	<u>\$</u>	<u>*</u>

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect at the consummation of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with certain of our executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of the Company and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that the Company's obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Exchange Act.

Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities which were not registered under the Securities Act:

1. In August 2014, we issued a warrant to purchase an aggregate of 142,856 shares of our Series A Preferred Stock at a price per share of \$0.98 to Silicon Valley Bank in connection with that certain Loan and Security Agreement dated August 18, 2014 with Silicon Valley Bank, whereby Silicon Valley Bank committed to lend us up to \$7 million pursuant to the terms therein.
2. In October 2014, we issued and sold an aggregate of 19,841,270 shares of Series B Preferred Stock at a price of \$1.26 per share.
3. In November 2015 and December 2015, we issued and sold an aggregate of 20,000,000 shares of Series C Preferred Stock at a price of \$2.65 per share.
4. In May 2016, we issued a warrant to purchase an aggregate of 37,736 shares of our Series C Preferred Stock at a price per share of \$2.65 to Silicon Valley Bank in connection with that certain Second Amendment to Loan and Security Agreement dated May 2, 2016 with Silicon Valley Bank, whereby Silicon Valley Bank committed to lend us up to \$10 million pursuant to the terms therein.
5. Since January 1, 2014, we granted stock options to purchase an aggregate of 5,807,690 shares of our common stock, with exercise prices ranging from \$0.18 to \$1.17 per share, to our employees, directors and consultants pursuant to our 2011 Stock Incentive Plan.
6. Since January 1, 2014, we sold an aggregate of 182,767 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of \$28,235 upon the exercise of stock options and stock awards.

We deemed the offers, sales and issuances of the securities described in paragraphs (1) through (4) and paragraph (6) above to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not be registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

We deemed the grants of stock options described in paragraph (5) as exempt pursuant to Section 4(a)(2) of the Securities Act or to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration had either received or had adequate access, through employment, business or other relationships, to information about us.

All certificates representing the securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transaction set forth in this Item 15.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

(b) Financial statement schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes:

- (1) That for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities

Act shall be deemed to be part of this registration statement as of the time it was declared effective.

- (2) That for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Exhibit Index</u>
1.1*	Form of Underwriting Agreement
3.1*	Form of Restated Certificate of Incorporation (to be effective upon pricing of this offering).
3.2*	Form of Restated Certificate of Incorporation (to be effective upon closing of this offering).
3.3**	By-laws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant (to be effective upon closing of this offering).
4.1*	Form of Common Stock certificate.
4.2**	Second Amended and Restated Investor Rights Agreement, by and between the Registrant and the Investors named therein, dated as November 25, 2015.
4.3**	Warrant to Purchase Stock issued to Silicon Valley Bank, dated May 2, 2016.
4.4**	Warrant to Purchase Stock issued to Silicon Valley Bank, dated August 18, 2014.
5.1*	Opinion of Goodwin Procter LLP
10.1+**	2011 Stock Incentive Plan and forms of agreements thereunder.
10.2+*	2017 Stock Option and Incentive Plan and forms of agreement thereunder (to be effective upon closing of this offering).
10.3+*	2017 Employee Stock Purchase Plan (to be effective upon closing of this offering).
10.4+*	Senior Executive Cash Incentive Bonus Plan (to be effective upon closing of this offering).
10.5+*	Employment Agreement by and between the Registrant and Alexey Margolin.
10.6+*	Employment Agreement by and between the Registrant and Edward Wholihan.
10.7+*	Employment Agreement by and between the Registrant and Louis Brenner.
10.8*	Form of Indemnification Agreement, to be entered into between the Registrant and its directors and officers (to be effective upon closing of this offering).
10.9**	Lease Agreement, by and between the Registrant and Newton Executive Park Limited Partnership, dated August 29, 2011, as amended.
10.10**	Commercial Lease, by and between the Registrant and Cummings Properties, LLC, dated August 18, 2016, as amended.

10.11#	License Agreement dated March 22, 2012, as amended, by and between the Registrant and Ajinomoto Althea, Inc. (f/k/a Althea Technologies, Inc.).
10.12**	Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, dated August 18, 2014, as amended.
10.13†*	Non-Employee Director Compensation Policy.
21.1**	Subsidiaries.
23.1*	Consent of Ernst & Young LLP.
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney

* To be filed by amendment

** Previously filed.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested has been filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Newton, Massachusetts on _____, 2017.

ALLENA PHARMACEUTICALS, INC.

By: _____

Name: Alexey Margolin, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Alexey Margolin, Ph.D. and Edward Wholihan, and each of them singly, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement and any subsequent registration statement filed by the Registrant pursuant to Rule 462(b) of the Securities Act of 1933, which relates to this Registration Statement, and to file the same, with all exhibits thereto, and all documents in connection herewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
Alexey Margolin, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	, 2017
Edward Wholihan	Vice President, Finance and Administration (Principal Financial and Accounting Officer)	, 2017
Axel Bolte	Director	, 2017
Stephen Kraus	Director	, 2017
Gino Santini	Director	, 2017
Robert Tepper, M.D.	Director	, 2017
James N. Topper, M.D., Ph.D.	Director	, 2017
Robert Alexander, Ph.D.	Director	, 2017

LICENSE AGREEMENT

This License Agreement (this "Agreement") is entered into as of the 22 day of March 2012 (the "Effective Date") by and between Althea Technologies, Inc., a Delaware corporation with its principal place of business at 11040 Roselle Street, San Diego, CA 92121 ("Althea"), and Allena Pharmaceuticals, Inc., a Delaware corporation with its principal place of business at One Newton Executive Park, Suite 202, Newton, MA 02462 ("Allena").

INTRODUCTION

1. Althea possesses certain intellectual property relating to ALTU-237 (as defined below), an enzyme in development for the treatment of hyperoxaluria.
2. Allena is in the business of discovering and developing pharmaceutical products.
3. Allena desires to exclusively license from Althea such intellectual property for the purpose of developing and commercializing Licensed Products (as defined below), and Althea desires to grant such a license to Allena in accordance with the terms and conditions of this Agreement.

In consideration of the mutual covenants contained herein, and other good and valuable consideration, the receipt of which is hereby acknowledged, Allena and Althea agree as follows:

1. DEFINITIONS

When used in this Agreement, each of the following terms, whether used in the singular or plural, shall have the meanings set forth in this Article I.

1.1 "Affiliate" means any Person who directly or indirectly controls or is controlled by or is under common control with another Person. For purposes of this definition, "control" or "controlled*" means ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, or status as a general partner in any partnership. The Parties acknowledge that, in the case of certain entities organized under the laws of certain countries, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence; *provided*, that such foreign investor has the power to direct the management and policies of such entity.

1.2 "Allena Indemnitees" means Allena, its Affiliates, and the agents, directors, officers and employees of Allena and its Affiliates.

1.3 "Althea Indemnitees" means Althea, its Affiliates, and the agents, directors, officers and employees of Althea and its Affiliates.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT WERE OMITTED AND REPLACED WITH "[***]". A COMPLETE VERSION OF THIS EXHIBIT HAS BEEN FILED SEPARATELY WITH THE SECRETARY OF THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO AN APPLICATION REQUESTING CONFIDENTIAL TREATMENT PURSUANT TO RULE 406 PROMULGATED UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

1.4 "Althea IP" means, collectively, Althea Know-How and Althea Patent Rights.

1.5 "Althea Know-How" means all Know-How Controlled by Althea or its controlled (within the meaning of Section 1.1) Affiliates as of the Effective Date that is necessary or useful for the Development, manufacture or Commercialization of a Product Candidate (alone or as incorporated into a Licensed Product) or Licensed Product (excluding any active ingredient that is not a Product Candidate); in each case, including any such Know-How that was assigned to Althea by Altus Pharmaceuticals Inc. ("Altus") connection with Amis' bankruptcy proceedings in May 2010.

1.6 "Althea Patent Rights" means all Patent Rights Controlled by Althea or its controlled (within the meaning of Section 1.1) Affiliates as of the Effective Date or during the Term that claim Althea Know-How or that otherwise Cover the manufacture, use, offer for sale, sale or importation of a Licensed Product The Althea Patent Rights as of the Effective Date are set forth in Exhibit A. Annually, or earlier upon request by Allena, the Parties shall update Exhibit A with current information identifying the patent applications and patents included in the Althea Patent Rights.

1.7 "ALTU-237" means the product candidate known as ALTU-237, as further described in the Patent Rights listed in Exhibit A.

1.8 "ALTU-237 IND" means U.S. IND No. [***], including all amendments and supplements thereto.

1.9 "Annual Net Sales" means the aggregate Net Sales in the Territory during a Calendar Year.

1.10 "Broad Patent Rights" means Althea Patent Rights other than Product Patent Rights.

1.11 "Business Day" means any day other than a Saturday or a Sunday on which the banks in both Boston, Massachusetts and San Diego, California are open for business.

1.12 "Calendar Quarter" means a calendar quarter ending on the last day of March, June, September or December.

1.13 "Calendar Year" means a period of time commencing on January 1 and ending on the following December 31.

1.14 "Commercialization" or "Commercialize" means any activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product).

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1.15 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party with respect to any objective, exerting such efforts and employing such resources as would normally be exerted or employed by such Party for a product of similar market potential, profit potential and strategic value at a similar stage of its product life, taking into account efficacy, safety, approved labeling, the competitiveness of the relevant marketplace, the patent, intellectual property and development positions of Third Parties, applicable regulatory factors, the commercial viability of the product and other relevant Development and Commercialization factors based upon then-prevailing conditions.

1.16 “Confidential Information” means, with respect to a Party (the “Disclosing Party”), information, regardless of the form in which that information is constituted, which (a) is treated by the Disclosing Party as confidential; and (b) relates either directly or indirectly to the business of such Disclosing Party or its Affiliates or the Third Party from whom the Disclosing Party received such information. The terms of this Agreement shall be deemed the Confidential Information of both Parties.

Confidential Information of the Disclosing Party excludes any information that the other Party (the “Receiving Party”) can establish by written records:

- (i) was known by the Receiving Party prior to the receipt from the Disclosing Party;
- (ii) was disclosed to the Receiving Party on a non-confidential basis by a Third Party having the right to do so;
- (iii) was, or subsequently became, publicly known through no act or omission of the Receiving Party, its Affiliates or any of the officers, directors, employees or agents of the Receiving Party or its Affiliates, in breach of this Agreement; or
- (iv) was concurrently or subsequently developed by personnel of the Receiving Party without having had access to the Disclosing Party’s Confidential Information.

1.17 “Control” or “Controlled” means, with respect to any item of Know-How, Patent Right or any other intellectual property right, the possession of the right (whether by ownership, license or otherwise (other than pursuant to a license granted under this Agreement)), to assign, or grant a license, sublicense or other right to or under, such Know-How, Patent Right or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.18 “Cover”, “Covered” or “Covering” means, (a) with respect to a patent, that, in the absence of a license granted to a Person under a Valid Claim included in such patent, the practice by such Person of an invention claimed in such patent would infringe such Valid Claim, or (b) with respect to a patent application, that, in the absence of a license granted to a Person under a Valid Claim included in such patent application, the practice by such Person of an invention claimed in such patent application would infringe such Valid Claim if such patent application were to issue as a patent.

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1.19 “Develop” or “Development” means activities conducted for the purpose of evaluating and progressing compounds, products, or processes for submission of information to a Regulatory Authority for the purpose of obtaining or maintaining Regulatory Approval of a product, and establishing manufacturing capabilities for products. For a particular Product Candidate or Licensed Product, Development includes non-clinical activities, pharmacology studies, toxicology studies, formulation, chemical analysis, bioanalytical analysis, material performance studies (such as measurements of stability, physical form, dissolution, or visual or spectroscopic analysis, and the like), manufacturing process development and scale-up (including API and drug product production), quality assurance and quality control, technical support, pharmacokinetic studies, clinical studies, biomarker and companion diagnostic discovery and development, regulatory affairs activities, and all other activities relating to seeking, obtaining or maintaining any Regulatory Approvals from the FDA or any other applicable Regulatory Authority.

1.20 “EMA” means the European Medicines Agency or any successor agency thereto having the same or similar functions.

1.21 “Executive Officer” means, with respect to a Party, the Chief Executive Officer of such Party (or the officer or employee of such Party then serving in a substantially equivalent capacity) or his/her designee who reports directly to such Chief Executive Officer.

1.22 “FDA” means the United States Food and Drug Administration or any successor agency thereto having the same or similar functions.

1.23 “Field” means all fields.

1.24 “First Commercial Sale” means, with respect to a Licensed Product in a country in the Territory, the first sale for use or consumption by the general public of such Licensed Product in such country. Sales or transfers of Licensed Products which are not for value, and sales or transfers of reasonable quantities of Licensed Products for clinical trial purposes or for compassionate or similar non-commercial use, shall not be considered a First Commercial Sale.

1.25 “GAAP” means United States Generally Accepted Accounting Principles, consistently applied.

1.26 “Generic Launch” mean the first commercial sale of a Generic Product in any country.

1.27 “Generic Product” or “Generic Products” means, with respect to a particular Licensed Product Commercialized by Allena or any of its Affiliates or Sublicensees in a particular country, any product Commercialized by a Third Party (excluding a Sublicensee) in such country that:

[***]

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In the event that such Licensed Product is regulated as a biologic in a particular jurisdiction, the term Generic Product shall be defined using comparable terms applicable to a follow-on biologic or biosimilar product approved through a similarly abbreviated Regulatory Approval process.

1.28 “Governmental Authority” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.29 “Health Canada” means the Therapeutic Products Directorate of Health Canada or any successor agency thereto having the same or similar functions.

1.30 “IND” means an application submitted to a Regulatory Authority to initiate human clinical trials, including (a) an Investigational New Drug application or any successor application or procedure filed with the FDA; (b) any non-United States equivalent of a United States Investigational New Drug application; and (c) all supplements and amendments that may be filed with respect to the foregoing.

1.31 “Know-How” means any information, ideas, data, inventions, works of authorship, materials (including biological and chemical materials), trade secrets or technology (excluding intellectual property rights therein), whether or not proprietary or patentable, including documents and other media (including paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, trays and containers and any other media) containing or storing any of the foregoing, and whether stored or transmitted in oral, documentary, electronic or other form, including all Regulatory Documentation.

1.32 “Law” means any law, statute, rule, regulation, ordinance or other pronouncement having the effect of law, of any federal, national, multinational, state, provincial, county, city or other political subdivision.

1.33 “Licensed Product” means a pharmaceutical product or composition containing a Product Candidate in any form or formulation.

1.34 “Major EU Country” means any of [***]

1.35 “Major ROW Country” means any of [***]

1.36 “NDA” means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq. (or its successor regulation), a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601 (or its successor regulation), and any equivalent application submitted in any country in the Territory, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

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1.37 “**Net Sales**” means the gross amounts invoiced by Allena, its Affiliates and Sublicensees for sales of Licensed Products to Third Parties that are not Affiliates or Sublicensees of the selling party (unless such Affiliate or Sublicensee is the end user of such Product, in which case the amount billed therefor shall be deemed to be the amount that would be billed to a Third Party end user in an arm’s-length transaction), less the following items, as allocable to Licensed Products (if not previously deducted in calculating the amount invoiced):

[***]

Net Sales shall be determined from books and records maintained in accordance with GAAP.

Licensed Products distributed as free promotional samples or in any compassionate use program, donated to non-profit institutions or government agencies, or used in research or Development, including clinical studies, by Allena, its Affiliate or Sublicensee, for which, in each case, no monetary or other consideration is paid to or received by Allena, its Affiliate or Sublicensee, shall be disregarded in determining Net Sales.

If Allena or any of its Affiliates or Sublicensees effects a sale, disposition or other transfer of a Licensed Product to a customer in a particular country at a price that is not an arm’s-length sales price, the Net Sales of such Licensed Product to such customer shall be deemed to be the weighted average sale price of such Licensed Product for arm’s-length sales of such Licensed Product in such country during the Calendar Quarter immediately preceding such sale, disposition or other transfer by the selling party.

In the event that the Licensed Product is sold as part of a Combination Product (as defined below) in a country in a Calendar Quarter, the Net Sales from the Combination Product in such country in such Calendar Quarter, for the purposes of determining royalty payments and sales milestone payments, shall be determined by multiplying the Net Sales of the Combination Product as determined in accordance with the preceding provisions of this Section 1.37 in such country during such Calendar Quarter, by the [***]

As used above, the term “Combination Product” means any Licensed Product sold in a single finished dosage or co-packaged form that contains (a) a Product Candidate and (b) one or more active ingredients that are not Product Candidates or Licensed Products.

1.38 “**Oxalate Oxidase**” means the enzyme known as oxalate oxidase, as further described in the Patent Rights listed in Exhibit A.

1.39 “**Party**” means Althea or Allena and “**Parties**” means Althea and Allena.

1.40 “**Patent Rights**” means (a) patent applications’, (b) any patents issuing from such patent applications (including certificates of invention); (c) all patents and patent applications based on, corresponding to or claiming the priority date(s) of any of the foregoing; and (d) any substitutions, extensions (including supplemental protection certificates), registrations, confirmations, reissues, divisionals, continuations, continuations-in-part, re-examinations, renewals and foreign counterparts thereof.

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1.41 “Person” means any individual, corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, or any other entity or body.

1.42 “Pricing Approval” means, with respect to a product, the approval, agreement, determination or governmental decision establishing the price or level of reimbursement for such product, as required in a given jurisdiction prior to sale of such product in such jurisdiction.

1.43 “Product Candidates” means (a) ALTU-237; (b) Oxalate Oxidase; and (c) any other enzyme for which Allena, its Affiliates or Sublicensees reference data included in the Althea Know-How in a filing with a Regulatory Authority.

1.44 “Product Patent Rights” means Althea Patent Rights that claim or are directed to the composition-of-matter or method of use of any Product Candidate or Licensed Product, but do not claim, and are not directed to, the composition-of-matter or method of use of any compound or product that is neither a Product Candidate nor a Licensed Product; *provided that notwithstanding* anything to the contrary in the foregoing, the Althea Patent Rights designated in Exhibit A as Product Patent Rights shall be deemed to be Product Patent Rights.

1.45 “Regulatory Approval” means, with respect to a pharmaceutical product in a country or regulatory jurisdiction, the act of a Regulatory Authority necessary for the marketing and sale of such product in such country or regulatory jurisdiction, including, where required in order to make the marketing and sale of such product commercially practicable, Pricing Approval,

1.46 “Regulatory Authority” means any applicable government regulatory authority involved in granting approvals for the marketing and/or pricing of a pharmaceutical product in a country or regulatory jurisdiction including the FDA, and foreign equivalents thereof,

1.47 “Regulatory Documentation” means, with respect to a Product Candidate or Licensed Product, all INDs, NDAs, and other regulatory applications submitted to any Regulatory Authority, copies of Regulatory Approvals, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. §314.420 and any non-United States equivalents), and any other reports, records, regulatory correspondence, meeting minutes, telephone logs, and other materials relating to Regulatory Approval of Product Candidates or Licensed Products (including any underlying safety and effectiveness data whether or not submitted to any Regulatory Authority), or required to manufacture, distribute or sell the Licensed Product including any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database required to be maintained for Regulatory Authorities.

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1.48 “Right of Reference or Use” means a “Right of Reference or Use” as that term is defined in 21 C.F.R. §3143(b), and any non-United States equivalents.

1.49 “Royalty Term” means, with respect to a Licensed Product and a country, the period of time beginning with the First Commercial Sale of such Licensed Product in such country and continuing until the later of (a) [***] years after such First Commercial Sale of such Licensed Product in such country and (b) expiration of the last Valid Claim Covering the manufacture, use, offer for sale, sale or importation of such Licensed Product in such country.

1.50 “Sublicensee” means a Third Party to whom Allena or its Affiliate has granted a sublicense under the Althea IP in accordance with the terms of this Agreement

1.51 “Territory” means the world.

1.52 “Third Party” means any Person other than the Parties and their Affiliates.

1.53 “Valid Claim” means a claim in (a) an issued and unexpired patent within the Althea Patent Rights that has not been held unenforceable, unpatentable or invalid by a decision of a court or Governmental Authority of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise or (b) a patent application within the Althea Patent Rights that has not been irretrievably cancelled, withdrawn or abandoned or finally determined to be unallowable by a Governmental Authority (from which no appeal is or can be taken) and that has not been pending for more than [***] years from the filing date from which such claim takes priority.

1.54 Other Defined Terms. Each of the following definitions is set forth in the section of this Agreement indicated below:

<u>Definition</u>	<u>Section</u>
Additional Shares	5.1(b)
Agreement	Preamble
Allena	Preamble
Allena Patent Rights	11.3(b)
Althea	Preamble
Breaching Party	11.2(b)

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Compensatory Damages	5.3(c)(ii)
Competitive Infringement	6.2(b)
Disclosing Party	1.16
Effective Date	Preamble
Fully-Diluted Basis	5.1(b)
Indemnified Party	8.3
Indemnifying Party	8.3
Initial Shares	5.1(b)
Losses	8.1
Non-Breaching Party	11.2(b)
Receiving Party	1.16
Second Closing	5.1(b)
Second Closing Shares	5.1(b)
Securities Act	9.2(l)
Severed Clause	12.7
Shares	5.1(b)
Steering Committee	4.3
Term	11.1

1.55 Construction. In construing this Agreement, unless expressly specified otherwise;

(a) references to Sections and Exhibits are to sections of, and exhibits to, this Agreement;

(b) use of either gender includes the other gender, and use of the singular includes the plural and vice versa;

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(c) headings and titles are for convenience only and do not affect the interpretation of this Agreement;

(d) any list or examples following the word “including” shall be interpreted without limitation to the generality of the preceding words; and

(e) the language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against either Party.

2. LICENSES.

2.1 Licenses to Allena. Subject to the terms and conditions of this Agreement, Althea hereby grants to Allena an exclusive, royalty-bearing, sublicenseable (in accordance with Section 2.2), non-transferable (except in accordance with Section 12.1) license, under the Althea IP, to Develop, use, make, have made, market, offer to sell, sell, have sold, distribute, import or otherwise exploit Product Candidates and Licensed Products in the Field in the Territory.

2.2 Sublicenses. Allena shall have the right to grant to its Affiliates and to Third Parties sublicenses under the rights and licenses granted in Section 2.1. Each such sublicense shall be in writing and shall be consistent with the terms and conditions of this Agreement. Allena shall remain responsible for the performance of its Sublicensees, and shall ensure that all Sublicensees comply with the relevant provisions of this Agreement.

2.3 Negative Covenant. Allena hereby covenants not to practice, and not to permit or cause any Affiliate, Sublicensee or other Third Party to practice, any invention covered by a Valid Claim for any purpose other than as expressly authorized in this Agreement; *provided that* (a) this Section 2.3 shall not apply to activities that fall within a safe harbor existing under applicable Law that exempts unlicensed Persons from infringement liability for such activities, including 35 U.S.C. § 271(e)(1) and (b) without limiting any other remedy that Althea may have for such breach, Althea shall not have any right to terminate this Agreement pursuant to Section 11.2(b) based on any breach or alleged breach by Allena of this Section 2.3 arising from the practice of any invention covered by a Valid Claim for purposes relating to products other than Licensed Products.

2.4 Retained Rights. Except as expressly provided in Sections 2.1 and 2.2, all rights in and to the Althea IP, and any trademarks or other intellectual property rights of Althea and its Affiliates, are hereby retained by Althea and its Affiliates. For the purpose of clarity, Allena acknowledges and agrees that the rights and license granted to Allena under Althea IP pursuant to Sections 2.1 and 2.2 exclude any right to Develop, make, have made, use, sell, have sold, offer for sale or import any active ingredient other than a Product Candidate or Licensed Product.

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3. TECHNOLOGY TRANSFER.

3.1 Assignment of ALTU-237 IND. Althea hereby assigns and transfers to Allena all right, title and interest in and to the ALTU-237 IND and agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by Allena in order to further effect such assignment and transfer

3.2 Technology Transfer to Allena. On the Effective Date, Althea shall provide to Allena the data, materials, reports and other information listed on Exhibits (or true and complete copies thereof), including the ALTU-237 IND. Within [***] days after the Effective Date, Althea shall make available to Allena, in a mutually-agreed upon format, existing -and available (in recorded form) material information regarding the Althea IP, and for a period of [***] days after the Effective Date, shall make its relevant scientific and technical personnel available to Allena to answer any questions or provide instruction as reasonably requested by Allena concerning the Althea Know-How delivered pursuant to this Section 3.1.

3.3 Right of Reference or Use. Subject to the exclusive worldwide license with respect to Licensed Products granted to Allena hereunder, Allena hereby grants to Althea a non-exclusive Right of Reference or Use to the ALTU-237 IND for purposes other than Licensed Products. Allena agrees to sign, and cause its Affiliates to sign, any instruments reasonably requested by Althea in order to further effect such grant.

4. DEVELOPMENT AND COMMERCIALIZATION.

4.1 Responsibility. After the Effective Date, Allena shall be responsible for the Development and Commercialization of Product Candidates and Licensed Products, including responsibility for preparing, filing and maintaining all Regulatory Documentation and Regulatory Approvals that are required for the Development or Commercialization of Product Candidates and Licensed Products in the Field in the Territory and Allena shall otherwise be responsible for and have sole authority as to all interactions with Regulatory Authorities in the Territory with respect to the foregoing.

4.2 Diligence. Allena, with or through its Affiliates and Sublicensees, as applicable, shall use Commercially Reasonable Efforts to Develop and, after receipt of Regulatory Approval, Commercialize a Licensed Product for the treatment of hyperoxaluria.

4.3 Steering Committee.

(a) The Parties shall establish a steering committee (the "Steering Committee") as more fully described in this Section 4.3. The Steering Committee shall comprise two (2) representatives from each of Althea and Allena. Each Party may replace its representatives at any time upon written notice to the other Party.

(b) Prior to the First Commercial Sale of a Licensed Product, the Steering Committee shall meet [***] per Calendar Year, or as otherwise mutually agreed by the Parties. The Steering Committee shall review Allena's and its Affiliates' activities and progress related to the Development of Licensed Products in the Field in the Territory during the preceding [***] and serve as a forum for the exchange of information between the Parties regarding the same. Following the First Commercial Sale of a Licensed Product, the Steering Committee shall cease to meet and automatically disband.

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4.4 Future Collaboration Opportunities. During the Term, upon the written request of either Party, the Parties shall discuss potential opportunities for Allena to use the fermentation and formulation capability and capacity of Althea for future products Developed by Allena.

5. PAYMENTS.

5.1 Partial Historical Patent Costs; Shares.

(a) In partial reimbursement of Althea's out of pocket costs incurred in the prosecution and maintenance of the Althea Patent Rights prior to the Effective Date, Allena shall pay to Althea One Hundred Thousand U.S. Dollars (US \$100,000) within five (5) Business Days after the Effective Date.

(b) Within five (5) Business Days after the Effective Date, Allena shall issue and deliver to Althea 204,992 shares of Allena's common stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting Allena's common stock) (the "Initial Shares"). The Initial Shares shall represent 1.5% of Allena's outstanding common stock on a Fully-Diluted Basis (as defined below) immediately following the issuance of the Initial Shares. In the event that Allena completes the Second Closing and/or any other closing of an equity financing transaction involving the sale and issuance of Allena's Series A Preferred Stock, Allena shall issue and deliver to Althea, within five (5) Business Days after the date of the Second Closing or such other closing, an additional number of shares of Allena's common stock (each, "Additional Shares") that when added to the Shares then held by Althea, equals 1.5% of Allena's outstanding common stock on a Fully-Diluted Basis immediately following such issuance. As used in this Agreement (i) "Shares" means the Initial Shares and any Additional Shares issued pursuant to this Section 5.1(b), (ii) "Second Closing" and "Second Closing Shares" shall have the meanings assigned to such terms in the Series A Preferred Stock Purchase Agreement dated as of September 9, 2011, among Allena and the Purchasers and Founders named therein, as it may be amended from time to time, and (iii) calculations made on a "Fully-Diluted Basis" assume the conversion into or exercise for Allena's common stock of all Preferred Stock, options, warrants or other securities that are ultimately convertible into or exercisable for Allena's common stock.

5.2 Milestone Payments.

(a) Regulatory Documentation Milestone. In partial consideration of the rights granted to Allena under Section 2.1, Allena shall pay to Althea, by wire transfer to an account designated by Althea, the milestone payment listed below within [***] days after the first achievement of the milestone event by the first Licensed Product for which Allena, its Affiliates or Sublicensees referenced the Regulatory Documentation in the NDA for such Licensed Product:

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Milestone Event:

[***]

Milestone Payment:

[***] U.S. Dollars (US \$[***])

(b) Development and Regulatory Milestones. In partial consideration of the rights granted to Allena under Section 2.1, Allena shall pay to Althea, by wire transfer to an account designated by Althea, the applicable milestone payment listed below within thirty (30) days after the first achievement of each milestone event by the first Licensed Product Covered by a Valid Claim:

(i) United States and Canada.

Milestone Event In the United States and Canada:

[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

Milestone Payment:

[***] U.S. Dollars (US \$[***])
[***] U.S. Dollars (US \$[***])

(ii) Outside of North America.

Milestone Events Outside of North America:

[***]
[***]

Milestone Payment:

[***] U.S. Dollars (US \$[***])
[***] U.S. Dollars (US \$[***])

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Milestone Events Outside of North America:

Milestone Payment:

[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])
[***]	[***] U.S. Dollars (US \$[***])

* Notwithstanding failure in a particular jurisdiction to obtain Pricing Approval that Allena initially determines is required in order to make the marketing and sale of a Licensed Product commercially practicable, if Allena (or its Affiliate or Sublicensee) subsequently begins selling such Licensed Product in such jurisdiction, then Regulatory Approval will be deemed to have been achieved effective upon First Commercial Sale in such jurisdiction, and the Regulatory Approval milestone shall be payable concurrently with the milestone payment for First Commercial Sale in such jurisdiction.

† The First Commercial Sale of a Licensed Product for an indication other than the first indication for which a Licensed Product receives NDA approval or Regulatory Approval (as applicable) shall be deemed to occur upon First Commercial Sale of Licensed Product bearing labeling that includes such subsequent indication.

(c) [***] **Net Sales Milestones.** Allena shall pay to Althea, by wire transfer to an account designated by Althea, the applicable milestone payment listed below concurrently with Allena's payment of royalties pursuant to Section 5.4 for the final Calendar Quarter of any Calendar Year during which the achievement of the event set forth below occurs with respect to a Licensed Product Covered by a Valid Claim:

Milestone Event:

Milestone Payment:

(i) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year	[***] U.S. Dollars (US \$[***])
(ii) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year	[***] U.S. Dollars (US \$[***])

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- | | |
|---|---------------------------------|
| (iii) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year | [***] U.S. Dollars (US \$[***]) |
| (iv) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year | [***] U.S. Dollars (US \$[***]) |
| (v) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year | [***] U.S. Dollars (US \$[***]) |
| (vi) First occurrence of [***] Net Sales greater than [***] U.S. Dollars (US \$[***]) in a Calendar Year | [***] U.S. Dollars (US \$[***]) |

(d) Each of the milestone payments set forth in this Section 5.2 shall be payable only once. If more than one of the milestones set forth in Section 5.2(c) are first achieved in any given Calendar Year, the milestone payments corresponding to all of such achieved milestones shall be payable with respect to [***] Net Sales in such Calendar Year.

5.3 Royalties Payable by Allena.

(a) Royalty Rate. Subject to Sections 5.3(b), 5.3(c) and 5.3(d), Allena shall pay to Althea a royalty of [***] percent ([***]%) on Net Sales of Licensed Products in the Territory.

(b) Royalty Term.

(i) Royalties shall be payable with respect to a Licensed Product and a country during the applicable Royalty Term for such Licensed Product in such country. Notwithstanding the foregoing, in the event that during any period of the Royalty Term for a Licensed Product in a country no Valid Claim Covers the manufacture, use, offer for sale, sale or importation of such Licensed Product in such country, then the royalty rate for such Licensed Product in such country shall be reduced to [***] percent ([***]%) for such period during the Royalty Term.

(ii) Upon the expiration of the applicable Royalty Term with respect to a Licensed Product in a country, Allena shall have a fully paid-up, non-exclusive, perpetual license to use the Althea Know-How to develop, use, make, have made, market, offer to sell, sell, have sold, distribute, import or otherwise exploit such Licensed Product in the Field in such country.

(c) Required Third Party Payments. If Allena obtains a license under any Third Party Patent Right that Allena determines may, in the absence of such license, be infringed by the manufacture, use, sale, offer for sale or import of the Product Candidate contained in a Licensed Product in a country in the Territory (including in connection with the settlement of a patent infringement claim), then Allena may deduct [***] percent ([***]%) of the royalties, and

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other amounts paid in lieu of royalties (e.g., upfront license fees and/or milestone payments that Allena agrees to pay in exchange for lower royalties), actually paid to such Third Party with respect to such Licensed Product in such country against royalty payments due under Section 5.3(a) with respect to Net Sales of such Licensed Product in such country; *provided, however*, that:

(i) in no event will the royalties payable to Althea with respect to such Licensed Product in such country be reduced by more than [***] percent ([***]%) in any Calendar Quarter as a result of any and all such deductions in the aggregate nor shall the effective royalty rate payable by Allena to Althea under Section 5.3(a) with respect to such Licensed Product in such country be less than [***] percent ([***]%) in any Calendar Quarter as a result of any and all such deductions in the aggregate;

(ii) if a court of competent jurisdiction determines that the manufacture, use, sale, offer for sale or import of the Product Candidate contained in a Licensed Product in a country in the Territory infringes a Third Party's Patent Rights and requires Allena to pay damages for such infringement to the Third Party, then solely that portion of such damages that (A) is determined by such court to represent a reasonable royalty on the infringing sales of such Licensed Product in such country or to compensate the Third Party for lost sales or lost profits with respect to infringing sales of such Licensed Product in such country and (B) is actually paid to such Third Party (collectively, "Compensatory Damages", shall be deemed to be "royalties" paid to such Third Party in the applicable country for purposes of the first paragraph of this Section 5.3(c) and the provisos set forth in Sections 5.3(c)(i) and 5.3(c)(iii); and

(iii) if, but for the proviso set forth in Section 5.3(c)(i), the deduction under this Section 5.3(c) would have reduced a royalty payment made by Allena by more than [***] or reduced the effective royalty rate below [***] percent ([***]%), then the amount of such deduction that would have exceeded [***] percent ([***]%) or that would have reduced the effective royalty rate below [***] percent ([***]%) will be earned over to subsequent Calendar Quarters) until the full amount that Allena would have been entitled to deduct (absent the limitation in Section 5.3(c)(i) is deducted, subject to the limitation set forth in Section 5.3(c)(i) in each such subsequent Calendar Quarter.

(d) Royalty Adjustment for Generic Competition. If one or more Generic Products exists with respect to the Licensed Product and such Generic Product(s) is (are) marketed and sold in a given country by one or more Third Parties (excluding Sublicensees) during any Calendar Quarter during the Royalty Term, then the royalty rate applicable to Net Sales of the Licensed Product in such country shall be reduced as follows:

(i) If the market share of the Licensed Product in such country during each Calendar Quarter exceed [***] percent ([***]%), on a unit basis, of the combined units of the Licensed Product and such Generic Product(s) said in such country during such Calendar Quarter, the royalty rate applicable to Net Sales of the Licensed Product in such Country shall not be reduced under this Section 5.3(d),

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(ii) If the market share of the Licensed Product in such country during such Calendar Quarter exceeds [***] percent ([***]%), but is less than or equal to [***] percent ([***]%), on a unit basis, of the combined units of the Licensed Product and such Generic Product(s) sold in such country during such Calendar Quarter, the royalty rate applicable to Net Sales of the Licensed Product in such country shall be reduced by [***] percent ([***]%); and

(iii) If the market share of the Licensed Product in such country during such Calendar Quarter is less than or equal to [***] percent ([***]%), on a unit basis, of the combined units of the Licensed Product and such Generic Product(s) sold in such country during such Calendar Quarter, the royalty rate applicable to Net Sales of the Licensed Product in such country shall be reduced by [***] percent ([***]%).

For purposes of this Section 5.3(d), the market share of a Licensed Product or Generic Product in a country shall be determined based on unit sales data provided by IMS International or, if such data is not available, such other reliable data source as mutually agreed by the Parties in good faith (such agreement not to be unreasonably withheld) in such country; *provided however*, that, in the event IMS International data (or data from another data source selected in accordance with the foregoing) is unavailable to determine the percentage market share for a country in the European Union where a Generic Product is being sold, the average market share for the countries in the European Union for which such data is available will be deemed to be the market share for such country in which such data is not available.

5.4 Reports and Payments. Allena shall deliver to Althea, within [***] days after the end of each Calendar Quarter, a royalty report together with the required payments. Such reports shall indicate gross sales on a Licensed Product-by-Licensed Product and country-by-country basis, deductions and reductions pursuant to Sections 5.3(c) and 5.3(d) on a Licensed Product-by-Licensed Product and country-by-country basis, the calculation of Net Sales, and the calculation of royalties from Net Sales with respect thereto, each determined in accordance with GAAP. Such amounts shall be expressed in United States Dollars, and such reports shall include the rates of exchange used to convert to United States Dollars from the currency in which such sales were made or payments received. The exchange rate to be used for converting to United States Dollars shall be the simple average of the selling and buying rates of Dollars published in the East Coast Edition of The Wall Street Journal for the last Business Day of the Calendar Quarter to which the report relates. All royalty payments shall be made in United States Dollars by wire transfer to an account designated in advance by Althea.

5.5 Tax Withholding. Allena shall use all reasonable and legal efforts to reduce tax withholding with respect to payments to be made to Althea. If Allena concludes that tax withholdings under the Laws of any country in the Territory are required with respect to payments to Althea, Allena may withhold such amounts and Allena shall promptly provide Althea with original receipts or other evidence reasonably desirable and sufficient to allow Althea to document such tax withholdings for purposes of claiming foreign tax credits and similar benefits.

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5.6 Financial Records. Allena shall maintain its, and shall require its Affiliates and Sublicensees to maintain their, financial records relating to the transactions and activities contemplated by this Agreement in sufficient detail to verify compliance with the terms of this Agreement Allena shall, and shall ensure that its Affiliates and Sublicensees, maintain such records for at least [***] years after the end of the Calendar Year to which such records relate.

5.7 Audit Right. [***] during each Calendar Year, Althea may retain an independent certified public accountant, reasonably acceptable to Allena, to audit Allena's records described in Section 5.6, upon reasonable notice to Allena, during regular business hours and under an obligation of confidentiality to Allena. Althea shall bear the costs of such audit, except as provided below. The results of such audit shall be made available to both Parties. If the audit demonstrates that the payments owed under this Agreement have been understated, Allena shall pay the balance to Althea, together with interest calculated in accordance with Section 5.8. Further, if the amount of the understatement is greater than [***] percent ([***]%) of the amount owed to Althea with respect to the audited period, then Allena shall reimburse Althea for the reasonable cost of the audit. If the audit demonstrates that the amount owed to Althea has been overstated, Allena shall be entitled to credit such amount against the next royalty payment due to Althea. All payments owed by Allena under this Section 5.7 shall be made -within thirty (30) days after the results of the audit are delivered to the Parties.

5.8 Late Payments. In the event that any undisputed payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [***] as quoted on the British Banker's Association's website currently located at www.bba.org.uk (or such other source as may be mutually agreed by the Parties) [***]; *provided, however*, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Althea from exercising any other rights it may have as a consequence of the lateness of any payment

6. INTELLECTUAL PROPERTY.

6.1 Prosecution and Maintenance of Patent Rights.

(a) Product Patent Rights. As between the Parties, Allena shall have the initial right to file, prosecute and maintain the Product Patent Rights, at Allena's expense. In the event that Allena desires to abandon any Product Patent Right, or if Allena later declines responsibility for any Product Patent Right, Allena shall provide reasonable prior written notice to Althea of such intention to abandon or decline responsibility (which notice shall, in any event, be given no later than [***] days prior to the next deadline for any action that may be taken with respect to such Product Patent Right with the U.S. Patent & Trademark Office or any foreign patent office), and Althea shall have the right, at its expense, to prepare, file, prosecute, and maintain such Product Patent Right

(b) Broad Patent Rights. Althea shall have the sole right, but not the obligation, to file, prosecute and maintain the Broad Patent Rights, at Althea's expense.

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(c) Coordination of Prosecution. Each Party agrees to cooperate with the other with respect to the filing, prosecution and maintenance of the Product Patent Rights pursuant to this Section 6.1.

(i) Each Party agrees to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the Party responsible for filing, prosecuting or maintaining a Product Patent Right in accordance with Section 6.1(a) (the "Prosecuting Party") to undertake filing, prosecution and/or maintenance;

(ii) The Prosecuting Party with respect to a Product Patent Right shall provide (itself or through patent counsel) the other Party a copy of each proposed material correspondence pertaining to, substantive filing, prosecution and maintenance on the merits, reasonably in advance of any applicable filing or response deadline to allow the other Party to review and comment on the content of such proposed correspondence and, advise the Prosecuting Party as to the conduct of such filing, prosecution and/or maintenance, which comments and advice the Prosecuting Party will consider in good faith and will not unreasonably decline to follow, *provided that* doing so is consistent with the goal of obtaining optimal patent coverage for the Licensed Product;

(iii) The Prosecuting Party with respect to a Product Patent Right shall provide (itself or through patent counsel) the other Party with copies of all material correspondence pertaining to substantive prosecution and maintenance after its submission or receipt, as the case may be; and

(iv) Where Allena is the Prosecuting Party with respect to a Product Patent Right, Allena shall have the right to seek patent term extensions, adjustments, and the like wherever available for such Product Patent Right.

6.2 Enforcement.

(a) Notice. Each Party shall promptly report in writing to the other Party (i) any known or suspected infringement of any of the Althea Patent Rights, (ii) unauthorized use or misappropriation of any of the Althea Know-How of which such Party becomes aware, or (iii) any patent certification" filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions (a "Paragraph IV Certification"), or any notification under applicable Law by the sponsor of an application for Regulatory Approval of a follow-on biologic or biosimilar product, in connection with the filing of an application for the Regulatory Approval of a Generic Product intending to show that the Generic Product is biosimilar to any Licensed Product that is a reference product as to such Generic Product and for which a claim of infringement of any of the Althea Patent Rights by the manufacture or sale of the Generic Product could reasonably be asserted or (iv) any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of the Althea Patent Rights, and shall provide the other Party with all available evidence regarding such known or suspected infringement or unauthorized use.

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(b) Product Patent Rights. As between the Parties, Allena shall have the first right, but not the obligation, to enforce the Product Patent Rights against any and all actual or suspected infringements of any Product Patent Rights by Third Parties making, using or selling in the Field in the Territory a product that is or may be competitive with a Licensed Product (“Competitive Infringement”), and Althea shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Allena fails to bring any such action or proceeding within (as [***] days following the notice of alleged infringement or (b) [***] days before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such actions, whichever comes first, then Althea shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Allena shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. In the event a Party brings an infringement action in accordance with this Section 6.2(b), the other Party shall, at the enforcing Party’s expense, cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a party. Neither Party shall have the right to settle any patent infringement litigation under this Section 6.2(b) that includes any agreement or admission that any of the Product Patent Rights is invalid or unenforceable or that imposes any restriction or obligation on the other Party without the prior written consent of the other Party, which shall not be unreasonably withheld.

(c) Broad Patent Rights. Althea shall have the sole right, but not the obligation, to enforce the Broad Patent Rights against any and all actual or suspected infringements of any Broad Patent Rights by Third Parties. To the extent the actual or suspected infringement of the Broad Patent Rights constitutes Competitive Infringement, Althea agrees to consider in good faith permitting Allena to participate in any action or proceeding brought by Althea to enforce the Broad Patent Rights, but such participation shall be at Althea’s sole discretion.

(d) Allocation of Recovery. Except as otherwise agreed by the Parties as part of a cost-sharing arrangement, any damages or other recovery from an infringement action or proceeding undertaken by either Party pursuant to Section 6.2(b) or Section 6.2(c), shall first be used to reimburse the Parties for the costs and expenses incurred in such action or proceeding, and any remainder after such reimbursement shall be retained by the Party that brought and controlled such action or proceeding for purposes of this Agreement, except that:

(i) any damages or other recovery from an action undertaken by Allena pursuant to Section 6.2(b), after reimbursement of the Parties’ litigation expenses shall be allocated between the Parties as follows: (A) [***] percent ([***]%) to Althea and (B) [***] percent ([***]%) to Allena; and

(ii) that portion of any damages or other recovery from an action undertaken by Althea pursuant to Section 6.2(c) that are specifically attributable to Competitive Infringement, after reimbursement of the Parties’ litigation expenses, shall be allocated between the Parties as follows: (A) [***] percent ([***]%) to Althea and (B) [***] percent ([***]%) to Allena.

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6.3 Claimed Infringement If a Party becomes aware that the development, use, manufacture, marketing, commercialization, distribution or importation of Licensed Products in the Field in the Territory by Allena, its Affiliates or Sublicensees, infringes, or is likely or is alleged to infringe, the intellectual property rights of any Third Party, such Party shall promptly notify the other Party.

7. CONFIDENTIAL INFORMATION.

7.1 Non-Use and Non-Disclosure of Confidential Information. Each Receiving Party agrees that all Confidential Information of the Disclosing Party (a) shall not be used by the Receiving Party except to perform its obligations or exercise its rights under this Agreement, (b) shall be maintained in confidence by the Receiving Party, and (c) except as permitted by Sections 7.2,7.3 and 7.4, shall not be disclosed by the Receiving Party to any Person without the prior written consent of the Disclosing Party.

7.2 Permitted Disclosures. The Receiving Party may disclose the Disclosing Party's Confidential Information as expressly permitted by this Agreement, or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) to the Receiving Party's and its Affiliates' employees, consultants and advisors Who have a need to know such Confidential Information and are bound by obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information at least as stringent as the terms of this Article 7;

(b) to actual or potential Sublicensees, provided, in each case, that any such Sublicensee has agreed in writing to be bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Article 7, and that the Confidential Information so disclosed shall remain subject to this Article 7;

(c) to actual or potential Third Party investors, funding sources or acquirers in connection with due diligence or similar investigations by such Third Parties, and in confidential financing documents, provided, in each case, that any such Third Party agrees in writing to be bound by reasonable obligations of confidentiality and non-use;

(d) to patent offices in order to file, prosecute and maintain Althea Patent Rights as permitted by this Agreement;

(e) to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials of Licensed Products, or to gain Regulatory Approval of Licensed Products as provided herein;

(f) in establishing or enforcing the Receiving Party's rights under this Agreement;

(g) in prosecuting or defending litigation as permitted by this Agreement; and

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(h) in complying with a valid order of a court or other governmental body having jurisdiction or with applicable laws, rules and regulations (including by rules or regulations of any securities exchange or NASDAQ); *provided that* the Receiving Party shall, except where impracticable, give reasonable advance notice to the Disclosing Party of the required disclosure, and, at the Disclosing Party's request and expense, cooperate with the Disclosing Party's efforts to contest such required disclosure, to obtain a protective order preventing or limiting the disclosure or requiring that the Confidential Information so disclosed be used only for the purposes for which such disclosure is required, or to obtain other confidential treatment of the Confidential Information required to be disclosed. In any event, the Receiving Party shall disclose only such Confidential Information as it is required by such order or applicable law, rule or regulation to disclose and shall only disclose such Confidential Information for the purpose and to the entity(ies) required by such order or applicable law, rule or regulation.

7.3 Scientific Publications. After the Effective Date, Althea shall not, without the prior written consent of Allena, make disclosures pertaining to Licensed Products in scientific journals or other publications. Allena shall have the right to make disclosures pertaining to Licensed Products in scientific journals or other publications in accordance with this Section 7.3. Allena shall provide Althea with an advance copy of the proposed publication, and Althea shall then have [***] days in which to recommend any changes it reasonably believes are necessary to preserve any Althea Patent Rights or Althea Know-How. If Althea informs Allena that such publication, in Althea's reasonable judgment, could be expected to have a material adverse effect on any patentable invention owned or licensed, in whole or in part, to Allena or on any Althea Know-How which is Confidential Information of Althea, Allena shall delay or prevent such publication as follows: (a) with respect to a patentable invention, such publication shall be delayed sufficiently long to permit the timely preparation and filing of a patent application; and (b) with respect to Althea Know-How which is Confidential Information of Althea, such Althea Know-How shall be deleted from the publication.

7.4 Publicity. Neither Party shall have the right to make any public announcements with respect to this Agreement, nor publicly disclose the terms of this Agreement, without the prior written consent of the other Party, except as follows:

(a) Within [***] days after the Effective Date, the Parties shall issue a press release, in a form to be mutually agreed upon by the Parties, such agreement not to be unreasonably withheld.

(b) Except as set forth in Sections 7.4(c) and 7.4(e), any subsequent press release by either Party shall be subject to the other Party's prior consent, and the Parties shall consult with each other reasonably and in good faith with respect to the text and timing of subsequent press releases prior to the issuance thereof, *provided that* a Party may not unreasonably withhold consent to such releases, and that either Party may issue such press releases as it determines, based on advice of counsel, are reasonably necessary to comply with applicable law (including disclosure requirements of the U.S. Securities and Exchange Commission ("SEC")) or with the requirements of any stock exchange on which securities issued by such Party or its Affiliates are traded.

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(c) Each Party may make subsequent public disclosures of information which has previously been publicly disclosed in accordance with this Agreement.

(d) Each Party may publicly file this Agreement with the United States Securities and Exchange Commission or any other relevant securities commission in any country, and shall request, and use Commercially Reasonable Efforts to obtain confidential treatment of all terms permitted to be redacted; *provided*, that the Parties shall coordinate in advance with each other in connection with any such filing by either Party (including the proposed redactions); and *provided, further*, that the redaction of such terms is permitted by the applicable rules and regulations of the United States Securities and Exchange Commission or any such securities commission.

(e) Allena may disclose (including by issuing press releases) its own Development and Commercialization activities with respect to the Licensed Product hereunder; *provided* that, except as otherwise provided in Section 7.4(b), if Allena proposes to use Althea's name in any such disclosure, Althea shall provide Althea with a draft of such disclosure in advance and shall not make such disclosure without Althea's approval.

8. INDEMNIFICATION.

8.1 Indemnification by Allena. Allena agrees to defend the Althea Indemnitees, at Allena's cost and expense, and will indemnify and hold harmless the Althea Indemnitees from and against any and all losses, costs, damages, fees or expenses ("Losses") relating to or in connection with a Third Party claim arising out of (a) any actual or alleged death, personal bodily injury or damage to real or tangible personal property claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, any Product Candidate or Licensed Product, Developed, manufactured or Commercialized by or on behalf of Allena, its Affiliates or Sublicensees; (b) any actual or alleged infringement or unauthorized use or misappropriation of any Patent Right or other intellectual property right of a Third Party with respect to the activities of Allena, its Affiliates or Sublicensees hereunder, or (c) any breach by Allena of its representations or warranties made under this Agreement; *provided, however*, that the foregoing indemnity shall not apply to the extent that any such Losses (i) are attributable to the gross negligence or willful misconduct of the Althea Indemnitees, or (if) a breach of this Agreement by Althea.

8.2 Indemnification by Althea. Althea agrees to defend the Allena Indemnitees, at Althea's cost and expense, and will indemnify and hold harmless the Allena Indemnitees from and against any and all Losses, relating to or in connection with a Third Party claim arising out of (a) any breach by Althea of its representations or warranties made under this Agreement, or (b) any grossly negligent act or omission or willful misconduct of Althea or its Affiliates, or any of their employees, contractors or agents, in performing Althea's obligations or exercising Althea's rights under this Agreement; *provided, however*, that the foregoing indemnity shall not apply to the extent that any such Losses are attributable to (i) the gross negligence or willful misconduct of the Allena Indemnitees, or (U) a breach of this Agreement by Allena.

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8.3 Procedure.

(a) A Party entitled to indemnification under this Article 8 (an "Indemnified Party") shall give prompt written notification to the Party from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party Claim for which indemnification may be sought or, if earlier, upon the assertion of any such Claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party Claim as provided in this Section 8.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice).

(b) Within [***] days after delivery of such notification, the Indemnifying Party may, upon written notice hereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party.

(c) If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all documented costs and expenses, include reasonable attorney's fees, incurred by the Indemnified Party in defending itself within [***] days after receipt of any invoice therefor from the Indemnified Party.

(d) The Party not controlling such defense may participate therein at its own expense; *provided that*, if the Indemnifying Party assumes control of such defense and the indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party in connection with its participation in the defense action.

(e) The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto.

(f) The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party.

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8.4 Allocation. In the event a claim is based partially on an indemnified claim and partially on a non-indemnified claim or based partially on a claim indemnified by one Party and partially on a claim indemnified by the other Party, any payments in connection with such claims are to be apportioned between the Parties in accordance with the degree of cause attributable to each Party,

9. WARRANTIES AND COVENANTS.

9.1 Mutual Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

- (a) it is a corporation duly organized and in good standing under the Laws of the jurisdiction of its incorporation;
- (b) it has the full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (c) it is duly authorized to execute and deliver this Agreement and to perform its obligations under this Agreement;

(d) this Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, subject to the general principles of equity and to bankruptcy, insolvency, moratorium and other similar Laws affecting the enforcement of creditors' rights generally;

(e) all necessary consents, approvals and authorizations of all Governmental Authorities required to be obtained by it in connection with the execution and delivery of this Agreement by such Party have been obtained; and

(f) this Agreement does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it

9.2 Additional Althea Warranties. Althea represents and warrants to Allena that, as of the Effective Date:

(a) Althea has the right to grant to Allena the rights granted to Allena hereunder under the Althea IP, and Althea has not granted any right or license to any Third Party relating to any of the Althea IP, that would conflict with, or limit the scope of; any of the rights or licenses granted to Allena hereunder.

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(b) To the knowledge of Althea, the issued claims included in the Althea Patent Rights are valid and enforceable. Althea has complied with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Althea Patent Rights in the Territory.

(c) Exhibit A contains a complete and correct list of all Patent Rights owned by or otherwise Controlled by Althea and its Affiliates (and, if any such Patent Right is owned by a Person other than Althea, identifies the Person that owns such Patent Right) Covering the Development, manufacture, use, offer for sale, sale or importation of ALTU-237 or Oxalate Oxidase.

(d) Except as set forth in Exhibit A, Althea has title to and is the sole legal and beneficial owner of the Althea Patent Rights, free of any lien, encumbrance or security interest.

(e) To the knowledge of Althea, no Third Party is infringing the Althea Patent Rights or has challenged the extent, validity or enforceability of the Althea Patent Rights.

(f) Althea has not received written notice from any Third Party claiming that the manufacture, use, sale, offer for sale or importation of any Product Candidate or Licensed Product infringes the Patent Rights of any Third Party.

(g) Althea is not a party to any legal action, suit or proceeding relating to the Althea IP or any Product Candidate or Licensed Product, nor has Althea received any written communication from any Third Party threatening such action, suit or proceeding.

(h) Althea has taken reasonable measures to protect the confidentiality of the Althea Know-How.

(i) Althea has made available to Allena all material correspondence between Althea and the PDA and any other Regulatory Authorities regarding Product Candidates and Licensed Products.

(j) Althea has made available to Allena all material safety data known to it with respect to Product Candidates and Licensed Products,

(k) Althea is acquiring the Shares for its own account for investment and not with a view to, or for sale in connection with, any distribution thereof, nor with any present intention of distributing or selling the same; and Althea has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof.

(l) Althea is an “accredited investor” as defined in Rule 501(a) under the Securities Act of 1933, as amended (the “Securities Act”).

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(m) Allena has made available to Althea any and all written information which Althea has requested and has answered to Althea's satisfaction all inquiries made by Althea; and Althea has sufficient knowledge and experience in finance and business that it is capable of evaluating the risks and merits of its investment in Allena and Althea is able financially to bear the risks thereof.

(n) Neither Althea nor, to Althea's actual knowledge, any employee, agent or subcontractor of Althea involved in the Development of Licensed Products, has been debarred under Subsection (a) or (b) of Section 306 of the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) and Althea has not knowingly permitted any Person on any of the FDA clinical investigator enforcement lists (including the (A) Disqualified/Totally Restricted List, (B) Restricted List and (C) Adequate Assurances List) to participate in the Development and Commercialization of Licensed Products.

9.3 Additional Allena Representations and Warranties. Allena represents and warrants to Althea as follows:

(a) As of the Effective Date, the Initial Shares represent 1.5% of Allena's outstanding shares on a Fully-Diluted Basis (without giving effect to the potential sale by Allena of the Second Closing Shares), after giving effect to the issuance of the Initial Shares.

(b) Attached hereto as Exhibit C is a true and correct copy of Allena's capitalization table as of the Effective Date (reflecting, among other things, the issuance of the Initial Shares).

(c) The Shares are, or will be upon their issuance, validly issued, fully paid and nonassessable, and will be free of any liens or encumbrances or restrictions upon transfer, other than liens or encumbrances or restrictions upon transfer created by Althea.

(d) The issuance of the Shares is not, and will not be, subject to any preemptive rights or rights of first refusal that have not been properly waived or complied with.

(e) Assuming the accuracy of Althea's representations and warranties contained in Sections 9.2(k), 9.2(l) and 9.2(m) above, the offer and issuance of the Shares will be

(f) exempt from the registration requirements of the Securities Act, and will have been registered or qualified (or exempt from registration or qualification) under all applicable state securities laws.

9.4 Covenants.

(a) Althea hereby covenants and agrees that Althea shall not grant any right or license to any Third Party relating to any of the Althea IP, that would conflict with, or limit the scope of, any of the rights or licenses granted to Allena hereunder.

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(b) Althea shall not sell or transfer the Shares unless either (i) such sale or transfer first shall have been registered under the Securities Act, or (ii) Allena first shall have been furnished with an opinion of legal counsel, reasonably satisfactory to Allena, to the effect that such sale or transfer is exempt from the registration requirements of the Securities Act

(c) (i) No Person who is known by Allena to have been debarred under Subsection (a) or (b) of Section 306 of the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) will be employed by Allena in the performance of the Development and Commercialization of Licensed Products; and (ii) Allena will not knowingly permit any Person on any of the FDA clinical investigator enforcement lists (including the (A) Disqualified/Totally Restricted List, (B) Restricted List and (C) Adequate Assurances List) to participate in the Development and Commercialization of Licensed Products.

9.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS ARTICLE 9, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS", AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES.

10. LIMITATION OF LIABILITY.

10.1 EXCEPT FOR (A) LIABILITY FOR BREACH OF ARTICLE 7 AND (B) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY WITH RESPECT TO THIRD PARTY CLAIMS UNDER ARTICLE 8, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA, LOSS OF REVENUE, OR LOSS OF USE DAMAGES, ARISING FROM OR RELATING TO THIS AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

11. TERMINATION.

11.1 Term. This Agreement is effective as of the Effective Date and shall continue in effect until the earlier of (a) the termination of this Agreement in accordance with Section 11.2 or (b) following the First Commercial Sale of any Licensed Product, the expiration of the last-to-expire of all Royalty Terms with respect to all Licensed Products (the "Term").

11.2 Termination.

(a) Termination For Convenience. Allena shall have the right to terminate this Agreement for convenience upon [***] days prior written notice to Althea.

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(b) **Termination For Material Breach.** If either Party (the “**Non-Breaching Party**”) believes that the other Party (the “**Breaching Party**”) is in material breach of this Agreement (including any material breach of a representation or warranty made in this Agreement), then the Non-Breaching Party may deliver notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach within the [***] day period after the Breaching Party’s receipt of such notice, the Non-Breaching Party may terminate this Agreement in its entirety upon written notice to the Breaching Party.

11.3 **Effects Of Termination.**

(a) Upon any termination of this Agreement, all licenses granted by Althea to Allena hereunder shall terminate,

(b) Solely in the case of termination of this Agreement by Allena pursuant to Section 11.2(a), or termination of this Agreement by Althea pursuant to Section 11.2(b), upon Althea’s written request, Allena shall transfer and assign all right, title and interest In the ALTU-237 IND to Althea, and, effective upon such termination, Allena shall, and it hereby does grant to Althea a right of first negotiation, exercisable by written notice to Allena given within [***] days after such termination, to obtain: (i) an exclusive, worldwide, royalty-bearing license, with the right to sublicense, under Allena Patent Rights (defined below), solely to develop, make, have made, use, sell, offer for sale, have sold and import Product Candidates and Licensed Products in the Field in the Territory, (ii) access to, and the right to use and reference, all data and information in Allena’s or its Affiliates’ possession relating to any Product Candidate or Licensed Product as may be necessary to enable Althea to practice the license contemplated in the foregoing clause (i); and (iii) transfer and assignment to Althea of all INDs (other than the ALTU-237 IND), NDAs, drug dossiers and master files in Allena’s or its Affiliates’ possession with respect to any and all Product Candidates and Licensed Products and all regulatory approvals with respect to any and all Product Candidates and Licensed Products; in each case, all upon commercially reasonable terms and conditions to be negotiated in good faith by the Parties; *provided that*, if, despite good faith negotiations, the Parties do not enter into such an agreement within [***] days after Althea’s exercise of such right of first negotiation, Allena shall not have any further obligation to negotiate with Althea regarding the matters set forth in the foregoing clauses (i), (ii) and (iii). “**Allena Patent Rights**” shall mean Patent Rights Controlled by Allena that, in the absence of a license thereunder, would be infringed by the manufacture, use, sale, offer for sale or import of any Product Candidate or Licensed Product in the Field in the Territory.

(c) The following provisions shall survive the expiration or termination of this Agreement: Sections 2.3, 5.3(b)(ii), 5.4, 5.5, 5.6, 5.7, 5.8, 7.1, 7.2, 9.5, 11.3 and 11.4 and Articles 8, 10 and 12.

(d) Neither expiration nor termination of this Agreement shall relieve the Parties of any obligation accruing prior to such expiration or termination. Expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including the

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obligation to pay royalties for any Licensed Product sold prior to such termination. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

11.4 Bankruptcy Code. All rights and licenses granted under or pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code (collectively, the "Code"), licenses of rights to be "intellectual property" as defined under the Code, If a case is commenced during the Term by or against a Party under Code then, unless and until this Agreement is rejected as provided in such Code, such Party (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a case is commenced during the Term by or against a Party under the Code, this Agreement is rejected as provided in the Code and the other Party elects to retain its rights hereunder as provided in the Code, then the Party subject to such case under the Code (in any capacity, including debtor-in-possession) and its successors and assigns (including a Title 11 trustee), shall provide to the other Party copies of all Information necessary for such other Party to prosecute, maintain and enjoy its rights under the terms of this Agreement promptly upon such other Party's written request therefor. All rights, powers and remedies of the non-bankrupt Party as provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Code) in the event of the commencement of a case by or against a Party under the Code.

12. MISCELLANEOUS.

12.1 Assignment. Neither this Agreement nor any of the rights or obligations hereunder may be assigned by a Party without the prior written consent of the other Party, except (a) each Party may assign this Agreement, in whole or in part, to an Affiliate of the assigning Party, *provided* that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate; and (b) each Party may assign this Agreement, in whole, to a Person that acquires, by merger, sale of stock, sale of assets or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates, *provided* that in the event of such a sale or transfer (whether this Agreement is actually assigned or is assumed by the acquiring party by operation of law (e.g., in the context of a reverse triangular merger)), intellectual property rights of the acquiring party in such sale or transfer (if other than one of the Parties) shall not be included in the Patent Rights or Know-How licensed hereunder or otherwise subject to this Agreement Any assignment not in accordance with the foregoing shall be void. This Agreement shall be binding upon, and shall inure to the benefit of, all permitted successors and assigns.

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12.2 Force Majeure. Neither Party will be held liable or responsible to the other Party nor be deemed to have breached this Agreement for failure or delay in fulfilling or performing any provision of this Agreement when such failure or delay results from causes beyond the reasonable control of the affected Party, which may include embargoes, acts of war (whether declared or not), insurrections, riots, civil commotions, acts of terrorism, strikes, lockouts or other labor disturbances, or acts of God. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such force majeure circumstances.

12.3 Notices.

Notices to Allena shall be addressed to;

Allena Pharmaceuticals, Inc.
One Newton Executive Park
Suite 202
Newton, MA 02462
Attention: Robert Gallotto
Fax: 617-916-1871

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attention: Steven D. Barrett, Esq.
Fax: (617) 526-5000

Notices to Althea shall be addressed to:

Althea Technologies, Inc.
11040 Roselle Street
San Diego, CA 92121
Attention: CFO
Fax: 858-882-0133

With a copy to:

Cooley -4401 Eastgate Mali, San Diego, CA 92121
Attention: Jane Adams
Fax: 858-550-6420

Any Party may change its address by giving notice to the other Party in the manner provided in this Section 12.3. Any notice required or provided for by the terms of this Agreement shall be in writing, in the English language, and shall be (a) sent by certified or registered mail, return receipt requested, postage prepaid, (b) sent via a reputable overnight international courier service, (c) sent by facsimile transmission, or (d) delivered by hand. The effective date of the notice shall be the actual date of receipt by the receiving Party.

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12.4 Relationship of the Parties. The Parties shall be deemed independent contractors for all purposes hereunder. This Agreement does not constitute a partnership, joint venture or agency between the Parties. Neither Party is an agent of the other Party and has no authority to represent the other Party as to any matters.

12.5 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, other than any principle of conflict or choice of laws that would cause the application of the Laws of any other jurisdiction; *provided*, that matters of intellectual property law concerning the existence, validity, ownership, infringement or enforcement of intellectual property shall be determined in accordance with the national intellectual property Laws relevant to the intellectual property in question.

12.6 Dispute Resolution. Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, shall be resolved as follows:

(a) the Executive Officers of both Parties shall meet to attempt to resolve such disputes.

(b) If the Executive Officers cannot resolve such disputes within [***] days after either Party requests such a meeting in writing, then upon written notice by either Party to the other Party, such dispute, controversy or claim shall be finally resolved by binding arbitration conducted in the English language in New York, New York under the Commercial Arbitration Rules of the American Arbitration Association, except to the extent any such Rule conflicts with the express provisions of this Section 12.6(b). Unless otherwise agreed by the Parties in writing, the arbitration shall be conducted by an arbitral tribunal of three neutral arbitrators appointed in accordance with such rules; *provided* that such arbitrators shall not be current or former employees or directors, or current stockholders, of either Party, any of their respective Affiliates or any Sublicensee; and *provided, further*, that each arbitrator shall have experience and familiarity with commercial licensing practices in the pharmaceutical and biotechnology industries. The arbitral tribunal shall permit discovery (including both the production of documents and deposition testimony) as reasonably necessary for an understanding of any legitimate issue raised in the arbitration, while also taking into account the desirability of making discovery efficient and cost-effective. The arbitral tribunal shall, in rendering an award, apply the substantive law of the State of New York, without giving effect to its principles of conflicts of law, and without giving effect to any of its rules or laws relating to arbitration. The award shall include a written statement describing the essential findings and conclusions upon which the award is based, including the calculation of any damages awarded. The arbitral tribunal's authority to award special, incidental, consequential or punitive damages shall be subject to the limitation set forth in Section 10.1, except to the extent the substantive laws of the State of New York do not permit such limitation. The award rendered by the arbitral tribunal shall be final, binding and non-appealable, and judgment upon the award may be entered in any court of competent jurisdiction. Each Party shall bear its own attorneys* fees, costs, and disbursements

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arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitration; *provided, however*, that the arbitral tribunal shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party reimbursement for any or all of its reasonable attorneys' fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), and/or the fees and costs of the administrator or the arbitral tribunal. Except to the extent necessary to confirm or enforce an award or as may be required by applicable law, neither a Party nor the arbitral tribunal may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties.

(c) Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or other equitable relief in the context of a *bona fide* emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding. In addition, either Party may bring an action in any court of competent jurisdiction to resolve disputes pertaining to the validity, construction, scope, enforceability, infringement or other violations of Patents or other intellectual property rights, and no such claim shall be subject to arbitration pursuant to Section 12.6(b). Further, no claim under any antitrust, anti-monopoly or competition law or regulation, whether or not statutory, shall be subject to arbitration pursuant to Section 12.6(b).

12.7 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement ("Severed Clause"), the Parties mutually agree that this Agreement shall endure except for the Severed Clause. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement

12.8 Entire Agreement. This Agreement constitutes the entire agreement among the Parties with respect to (the subject matter herein and supersedes all previous agreements, whether written or oral, with respect to such subject matter.

12.9 Amendment and Waiver. This Agreement may not be amended, nor any rights hereunder waived, except in a writing signed by the properly authorized representatives of each Party.

12.10 No Implied Waivers. The waiver by a Party of a breach of any provision of this Agreement by the other Party shall not be construed as a waiver of any succeeding breach of the same or any other provision, nor shall any delay or omission on the part of a Party to exercise or avail itself of any right that it has or may have hereunder operate as a waiver of any right by such Party.

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12.11 Counterparts and Facsimile Signatures. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation -which may result from the electronic transmission, storage and printing of copies from separate computers or printers. Facsimile signatures and signatures transmitted via portable document format (PDF) shall be treated as original signatures.

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IN WITNESS WHEREOF, the Parties hereto have set their hand as of the Effective Date.

ALLENA PHARMACEUTICALS, INC.

By: /s/ Alexey Margolin
Name: Alexey Margolin
Title: CEO

ALTHEA TECHNOLOGIES, INC.

By: /s/ Martha J. Demski
Name: Martha J. Demski
Title: SVP/CFO

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EXHIBIT A
ALTHEA PATENT RIGHTS

Product Patent Rights:

[***]

Broad Patent Rights:

[***]

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EXHIBIT B
TECHNOLOGY TRANSFER

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EXHIBIT C
CAPITALIZATION TABLES

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AMENDMENT NO. 1 TO LICENSE AGREEMENT

This Amendment No. 1 to the License Agreement (this "**Amendment**") is made as of MARCH 9, 2016, by and among Ajinomoto Althea, Inc., a Delaware corporation ("**Althea**") and Allena Pharmaceuticals Inc., a Delaware corporation ("**Allena**").

RECITALS

WHEREAS, Althea, Inc. and Allena entered into that certain License Agreement dated March 22, 2012 whereby Althea, Inc. licensed certain intellectual property relating to ALTU-237 to Allena (the "**License Agreement**");

WHEREAS, Althea, Inc. was acquired by Ajinomoto Co., Inc. and now operates under a new company name Ajinomoto Althea, Inc.; and

WHEREAS, Althea and Allena desire to amend the License Agreement to clarify the rights and obligations with respect to a Licensed Product under the License Agreement.

Now, THEREFORE, the parties hereto, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, intending to be legally bound, agree as follows:

1. Defined Terms. Capitalized terms used but not otherwise defined herein shall have the meanings set forth in the License Agreement.

2. Oxalate Decarboxylase Definition. The following new definition is added after Section 1.37 and before Section 1.38:

"Oxalate Decarboxylase" means the enzyme known as oxalate decarboxylase, as further described in the Patent Rights listed in Exhibit A.

3. Product Candidate Definition. Section 1.43 is deleted in its entirety and replaced with the following:

"Product Candidate" means (a) ALTU-237; (b) Oxalate Oxidase; (c) Oxalate Decarboxylase; and (d) any other enzyme for which Allena, its Affiliates or Sublicensees reference data included in the Althea Know-How in a filing with a Regulatory Authority.

4. Effect of Amendment. This Amendment shall not constitute a waiver, amendment or modification of any other provision of the License Agreement or any other provision not expressly referred to herein. Except as amended as set forth above, the License Agreement shall continue in full force and effect.

5. Entire Agreement. This Amendment and the License Agreement together constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof, and any and all other written or oral agreements relating to the subject matter hereof existing between the parties hereto are expressly superseded hereby.

6. Governing Law. This Amendment shall be governed by the laws of the State of New York, without regard to any conflicts of law principles.

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7. Counterparts. This Amendment may be executed in one or more counterparts, each of which shall be an original and all of which shall constitute together the same document.

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IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 1 to the License Agreement as of the date first set forth above.

AJINOMOTO ALTHEA, INC.

By: /s/ Martha J. Demski

Name: Martha J. Demski

Title: SVP & CFO

ALLENA PHARMACEUTICALS, INC.

By: /s/ Louis Brenner

Name: Louis Brenner

Title: COO

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June 2, 2017

Ajinomoto Althea, Inc.
11040 Roselle Street
San Diego, CA 92121
Attention: Tod Lauerma, Ph.D.

RE: License Agreement dated as of March 22, 2012 by and between Althea Technologies, Inc. (which name was changed to Ajinomoto Althea, Inc., "Ajinomoto Althea") and Allena Pharmaceuticals, Inc. ("Allena"), as amended March 9, 2016 (the "License")

Ajinomoto Althea is the assignee of U.S. Patent Application No. [***] which claims benefit of priority from U.S. Patent Application No. [***] (listed in Exhibit A of the License; now U.S. Patent No. [***]) (collectively, the "Althea U.S. Patent Rights"), which Ajinomoto Althea licensed, *inter alia*, to Allena pursuant to the License.

On [***], Ajinomoto Althea assigns all right, title and interest to the Althea U.S. Patent Rights to Allena pursuant to an assignment [***] (the "Assignment"). In consideration for the Assignment and this letter agreement, Allena agrees that:

- it will continue to comply with all of its obligations under the License in all material respects notwithstanding the Assignment, including, without limitation, payment of all royalties owed by Allena based on the Althea U.S. Patent Rights pursuant to Section 5.3 of the License, as if the Assignment had not been made;
- Allena hereby grants to Ajinomoto Althea, under the Althea U.S. Patent Rights, a fully paid-up, exclusive (even as to Allena) worldwide license to the Retained Rights as set forth in section 2.4 of the License ("Grantback"); and
- in the event the License is terminated in accordance with its terms, Allena shall assign the Althea U.S. Patent Rights back to Ajinomoto Althea and the Grantback shall terminate, and Allena agrees to use commercially reasonable efforts to execute all documentation and take all additional actions as may be necessary to vest ownership of the Althea U.S. Patent Rights in Ajinomoto Althea as if the Assignment had not been made.

This letter agreement shall be subject to the choice of law and dispute resolution provisions set forth in the License.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Parties hereto have set their hand as of the dates below:

AJINOMOTO ALTHEA, INC.

By: /s/ J. David Enloe, Jr.

Print Name: J. David Enloe, Jr.

Title: President and CEO

Date: 6/8/17

ALLENA PHARMACEUTICALS, INC.

By: /s/ Edward Wholihan

Print Name: Edward Wholihan

Title: CFO

Date: 6/14/17

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