HISTOGEN INC.
(Exact name of registrant as specified in its charter)

10655 Sorrento Valley Road, Suite 200, San Diego, CA 92121
(858) 526-3100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

<table>
<thead>
<tr>
<th>Title of each class</th>
<th>Trading Symbol(s)</th>
<th>Name of each exchange on which registered</th>
</tr>
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<tbody>
<tr>
<td>Common Stock, par value $0.0001 per share</td>
<td>HSTO</td>
<td>The NASDAQ Stock Market LLC</td>
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<td>(The Nasdaq Capital Market)</td>
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Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Item 1.01 Entry into a Material Definitive Agreement.

On October 26, 2020, Histogen Inc. (the “Company”) entered into a Collaborative Development and Commercialization Agreement (the “Collaboration Agreement”) with Amerimmune LLC (“Amerimmune”), pursuant to which the Company agreed to jointly develop emricasan, an orally active pan-caspase inhibitor, for the potential treatment of COVID-19 in mild COVID-19 patients. The Company retained rights to emricasan in conjunction with the close of the Merger (as defined below) and has been evaluating alternatives to create opportunities for increasing shareholder value from the legacy asset.

As previously disclosed, on May 26, 2020, the Company acquired Histogen Therapeutics, Inc. (formerly known as Histogen Inc.) through its merger with a wholly owned subsidiary of the Company, with Histogen Therapeutics surviving as our wholly-owned subsidiary. As part of that transaction, the Company changed its name to Histogen Inc. (the “Merger”).

The Company filed and received approval for an Investigational New Drug (“IND”) from the United States Food and Drug Administration (“FDA”) to initiate a Phase 1 study of emricasan in mild-Covid-19 patients to assess safety and tolerability. Under the Collaboration Agreement, Amerimmune, at its expense and in collaboration with the Company, shall use commercially reasonable efforts to lead develop activities and conducting clinical trials for emricasan. Amerimmune is pursuing non-dilutive funding in order to support the clinical program and anticipates initiating the Phase 1 study as early as the end of 2020. The Company has agreed to provide reasonable quantities of emricasan for the clinical trials and believes its current supply of emricasan is sufficient to support clinical trials through any Phase 2 study. Until such time as a potential strategic partner assumes responsibility, the Company, in collaboration with Amerimmune, shall be responsible for and shall control all regulatory interactions relating to emricasan. The parties shall establish a joint development committee to oversee the development of emricasan and a joint partnering committee to oversee commercialization activities for emricasan. Each party shall retain ownership of their existing intellectual property and responsibility for ongoing prosecution and maintenance costs.

In addition, the Company granted Amerimmune an exclusive option to commercialize emricasan under certain conditions for the sole purpose of supporting future third-party partnering transactions. Should any such partnering transaction emerge, the Company and Amerimmune shall equally share the profits.

The foregoing description of the Collaboration Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Collaboration Agreement, which is filed as Exhibits 10.1 and incorporated herein by reference.

Item 8.01 Other Events.

On October 27, 2020, the Company issued a press release announcing the transaction with Amerimmune. A copy of the press release is furnished as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits.

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1</td>
<td>Collaborative Development and Commercialization Agreement, dated as of October 26, 2020, by and between the Company and Amerimmune LLC</td>
</tr>
<tr>
<td>99.1</td>
<td>Press Release, dated October 27, 2020</td>
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</tbody>
</table>

* * *

2
Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HISTOGEN INC.

Date: October 27, 2020

/s/ Richard W. Pascoe
Richard W. Pascoe
President and Chief Executive Officer
COLLABORATIVE DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

between

AMERIMMUNE LLC

and

HISTOGEN, INC.

Dated as of 26 October 2020
This Collaborative Development and Commercialization Agreement (the “Agreement”) is entered into as of 26 October 2020 (the “Effective Date”) by and between Amerimmune LLC, a Virginia limited liability company with a place of business at 11212 Waples Mill Rd, Suite 100, Fairfax, Virginia 22030 (“Amerimmune”), and Histogen, Inc., a Delaware corporation with a place of business at 16745 West Bernardo Drive, Suite 200, San Diego, California 92127 (“Histogen”). Amerimmune and Histogen may each be referred to herein by name or as a “Party,” or, collectively, as the “Parties.”

BACKGROUND

Histogen is a clinical-stage regenerative medicine company with a novel biological platform that replaces and regenerates tissues in the human body. On or about 27 May 2020, Histogen, through a reverse merger with Conatus Pharmaceuticals, Inc. (“Conatus”), acquired the assets of Conatus, including that certain pan-caspase inhibitor known as Emricasan (as defined below).

Amerimmune is a clinical laboratory engaged in research related to human disease. Amerimmune has recently invented technologies for the treatment of COVID-19 using caspase inhibitors, including Emricasan.

Amerimmune and Histogen now wish to collaborate to undertake a clinical development program using Emricasan to determine if Emricasan is safe and efficacious in treating COVID-19.

In view of the foregoing and the following terms and condition set forth below, and for other good and valuable consideration, the receipt and sufficiency of which the Parties acknowledge, Amerimmune and Histogen agree as follows:

ARTICLE I
DEFINITIONS

1.1 Terms. Capitalized and underlined terms in this Agreement (including its Schedules) shall be defined as indicated, including those terms set out below.

1.1.1 “Accounting Standards” means GAAP (United States Generally Accepted Accounting Principles), consistently applied.

1.1.2 “Additional Revenue” means the sum of (a) any payments or income (other than Net Sales) received by a Party or its Affiliates that are attributable to a Product, including any and all payments or income (other than Net Sales) received from a Strategic Partner pursuant to a Strategic Partnership, and (b) recoveries pursuant to Section 6.4 of this Agreement; provided, however, that such amount does not include an amount received from any Third Party (i) for issuance of equity securities, (ii) pursuant to a bona fide loan, (iii) for any payment made or reimbursement provided for Development, (iv) for any payment made or reimbursement provided for Patent Costs, (v) for acquisition of a Party or any of its Affiliates, or an assignee or successor of a Party or any of its Affiliates, or (vi) for acquisition of any of the assets of a Party or any of its Affiliates, or an assignee or successor of a Party or any of its Affiliates.

1.1.3 “Advertising and Market Research Expenses” means, with respect to a Product, those expenses incurred related to: (a) conducting and monitoring professional and consumer appraisals of any Products in the Territory, such as market share services (e.g., IMS data), pricing analysis, special research testing and focus groups; and (b) advertising and promotion of such Product in the Territory through any means, including (i) television and radio advertisements; (ii) advertisements appearing in journals, newspapers, magazines or other media; (iii) seminars, symposia and conventions; (iv) packaging design; (v) programs for education of health care professionals; (vi) product samples; (vii) visual aids and other selling materials; (viii) hospital formulary committee presentations; (ix) presentations to state and other governmental formulary committees; and (x) all media costs associated with product advertising.
1.1.4 “Affiliate” means, as to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Person, as the case may be, for so long as such control exists. As used in this Section 1.1.2, “control” means: (a) to possess, directly or indirectly, the power to direct affirmatively the management and policies of such Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; (b) in the case of a corporate entity, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors; or (c) in the case of a non-corporate entity, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entity, or in each case (b) and (c) such lesser percentage which is the maximum allowed to be owned by a foreign corporation or non-corporate entity in a particular jurisdiction.

1.1.5 “Alliance Manager” has the meaning set forth in Section 3.4.

1.1.6 “Amended and Restated CDA” means that certain “Amended and Restated Confidential Disclosure Agreement” entered into by the Parties on 23 July 2020 and effective as of 5 May 2020.

1.1.7 “Amerimmune Indemnified Party” has the meaning set forth in Section 10.2, below.

1.1.8 “Amerimmune Intellectual Property” means Amerimmune Know-How and Amerimmune Patents, collectively.

1.1.9 “Amerimmune Know-How” means any Know-How that is (a) Controlled by Amerimmune as of the Effective Date or during the Term, and (b) necessary or useful for the Development, Manufacture and/or Commercialization of any Product in the Field.

1.1.10 “Amerimmune Manufacturing Responsibilities” has the meaning set forth in Section 5.4, below.

1.1.11 “Amerimmune Patents” means any and all Patents that (a) are owned or controlled by Amerimmune as of the Effective Date or during the Term, and (b) concern the Development, Manufacture, and/or Commercialization of any Product (including the composition of matter, manufacture, or any use thereof) in the Field. The Amerimmune Patents include those Patents listed on attached Schedule 1.

1.1.12 “Amerimmune Profit Allocation” means the percentage of Profits to which Amerimmune is entitled.

1.1.13 “Bankruptcy Code” has the meaning set forth in Section 5.1.5, below.

1.1.14 “Calendar Quarter” means a calendar quarter ending on the last day of March, June, September or December; provided, however, that (a) the first Calendar Quarter shall begin on the Effective Date and end on 30 September 2020, and (b) the final Calendar Quarter shall end on the last day of the Term.

1.1.15 “Calendar Year” means a period of time commencing on January 1 and ending on the following December 31; provided, however, that (a) the first Calendar Year shall begin on the Effective Date and end on December 31, 2020, and (b) the final Calendar Year shall end on the last day of the Term.

1.1.16 “Change of Control” of a Party means any of the following, in a single transaction or a series of related transactions: (a) the sale or disposition of all or substantially all of the assets of such Party to a Third Party; (b) the direct or indirect acquisition by a Third Party (other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates) of beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party or any direct or indirect entity which holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party, or (c) the acquisition, merger, or consolidation of such Party with or into a Third Party, unless, following such acquisition, merger, or consolidation.
1.1.17 “Chemistry, Manufacturing and Controls” or “CMC” means the part of pharmaceutical development that is directed to the Development and Manufacture of products, the specifications therefor, and other parameters which indicate that the finished drug or biologic product and the manufacturing process are consistent and controlled, in each case, as specified by the FDA or other applicable Regulatory Authorities in the chemistry, manufacturing and controls section of an IND or other regulatory filing in the United States, or the equivalent section of regulatory filings made outside of the United States.

1.1.18 “Claims” means any and all suits, claims, actions, proceedings, or demands brought by a Third Party.

1.1.19 “Clinical Trial” means a Phase I Study, a Phase II Study, a Phase III Study, a Pivotal Clinical Trial, a Phase IV Study, or a combination of any of the foregoing studies.

1.1.20 “Collaboration” has the meaning set forth in Section 2.1, below.

1.1.21 “Committee” means the JDC or JPC, as the context requires.

1.1.22 “Commercialization” or “Commercialize” means any activities directed to using, marketing, promoting, distributing, importing, offering to sell, and/or selling a Product, after or in expectation of receipt of Regulatory Approval for such Product (but excluding Development).

1.1.23 “Commercial Field” means the treatment, prophylaxis, or amelioration of any condition, disease, or disorder in humans.

1.1.24 “Competitive Product” means any Product or other compound that has as its primary mode of action modulation of one or more caspase enzyme activities.

1.1.25 “Confidential Information” means (a) all confidential or proprietary information relating to any Product, including all pre-clinical and clinical data, and (b) all other confidential or proprietary documents, technology, Know-How, or other information (whether or not patentable) actually disclosed by one Party to the other pursuant to this Agreement or Amended and Restated Confidentiality Agreement, including information regarding a Party’s technology, products, business information or objectives and reports under Section 2.7, and all proprietary biological materials of a Party.

1.1.26 “Contingent Payments” mean the consideration received or receivable by Amerimmune, its employees, former or current equity holders and/or any other parties in the form of deferred performance or retention-based payments, earn-outs, or other contingent payments based upon the occurrence of future events. Any part of the sales proceeds held pursuant to an escrow account established before or in connection with the consummation of a Transaction shall be deemed paid or received and not contingent.

1.1.27 “Control” or “Controlled” means, with respect to any (a) Know-How or other information or materials, (b) any compounds, or (c) intellectual property right, the possession (whether by license (other than a license granted under this Agreement) or ownership) by a Party of the ability to grant to the other Party access and/or a license, as provided herein, without violating the terms of any agreement with any Third Party existing as of the Effective Date or thereafter during the Term.

1.1.28 “Cure Period” has the meaning set forth in Section 11.4.1, below.

1.1.29 “Damages” means all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney’s fees), or judgments, whether for money or equitable relief, of any kind and is not limited to matters asserted by Third Parties against a Party, but includes claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney’s fees) or judgments incurred or sustained by a Party in the absence of Third Party claims; provided, that no Party shall be liable to hold harmless or indemnify the Amerimmune Indemnified Parties or Histogen Indemnified Parties, as applicable, for any claims,
threatened claims, damages, losses, suits, proceedings, liabilities, costs or judgments for punitive or exemplary damages, except to the extent the Party seeking indemnification is actually liable to a Third Party for such punitive or exemplary damages in connection with a claim by such Third Party.

1.1.30 “Data” means any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, market research, clinical data (including investigator reports (both preliminary and final), results, conclusions, statistical analyses, expert opinions and reports, safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by applicable Laws), and the like, in each case created, generated, or directed to, or used in, the Development, Manufacture or Commercialization of any Product(s).

1.1.31 “Develop” or “Development” means discovery, research, preclinical, non-clinical and clinical development activities, including activities relating to screening, assays, test method development and stability testing, toxicology, pharmacology, formulation, quality assurance/quality control development, Clinical Trials, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, report writing and other pre-Regulatory Approval activities.

1.1.32 “Development Costs” means with respect to a Product, the costs and expenses that are actually incurred by or on behalf of a Party and specifically and directly attributable to the Development of such Product. “Development Costs” of a Party with respect to the Product shall include, without duplication:

(a) the FTE Costs of the Party or its Affiliates with respect to such Development;
(b) all Out-of-Pocket Costs incurred by the Party or its Affiliates, including payments made to Third Parties, with respect to such Development (except to the extent that such costs have been included in FTE Costs), including the costs and expenses of conducting Clinical Trials;
(c) Regulatory Expenses other than Regulatory Maintenance Costs;
(d) the cost of contract research organizations;
(e) Manufacturing Costs for clinical supply, including:
   (i) costs of packaging of drug products and distribution of drug products used in Clinical Trials;
   (ii) expenses incurred to purchase or package comparator drugs;
   (iii) costs and expenses of disposal of clinical samples; and
   (iv) costs and expenses incurred in scaling up Manufacturing activities related to pre-clinical or clinical supply, including formulation development activities;
(f) Manufacturing Scale-Up Costs; and
(g) Third Party License Costs.

Development Costs for a Product shall not include any Damages and other liabilities incurred by a Party as a result of such Party’s negligence, gross negligence, illegal conduct, willful misconduct, or breach of such Party’s representations and warranties made hereunder and any such Damages and other liabilities will be treated as the sole and exclusive responsibility of the Party whose actions or omissions gave rise to such Damages and other liabilities.

All of such costs shall be as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with Accounting Standards. For purposes of clarity, no general corporate
overhead or fixed charges, such as depreciation, shall constitute Development Costs (except as otherwise provided under the definition of Manufacturing Costs).

1.1.33 “Development Plan” means a development plan outlining the clinical program to be pursued in Developing a Product.

1.1.34 “Disclosing Party” has the meaning set forth in Section 7.1, below.

1.1.35 “Dispute” has the meaning set forth in Section 11.1, below.

1.1.36 “Electronic Delivery” has the meaning set forth in Section 12.12, below.

1.1.37 “EMA” means the European Medicines Agency, or any successor agency thereof.

1.1.38 “Emricasan” means (a) in the Research Field, an irreversible orally active pan-caspase inhibitor formerly known as IDN-6556, PF-03491390; with an IUPAC name of (3S)-3-[(2S)-2-[(2-tert-butylanilino)-2-oxoacetyl]amino]propanoylamino]-4-oxo-5-(2,3,5,6-tetrafluorophenoxy)pentanoic acid; and (b) in the Commercial Field, an irreversible orally active pan-caspase inhibitor formerly known as IDN-6556, PF-03491390; with an IUPAC name of (3S)-3-[(2S)-2-[(2-tert-butylanilino)-2-oxoacetyl]amino]propanoylamino]-4-oxo-5-(2,3,5,6-tetrafluorophenoxy)pentanoic acid, alone or in any dosage form or delivery system, including pro-drugs, hydrates, hemihydrates, polymorphs, acids, bases, analogs, homologs, derivatives, and isomers, including stereoisomers, structural and geometric isomers, diastereomers, enantiomers, racemic mixtures, and chiral versions.

1.1.39 “Existing Third Party Agreement” means a Third Party agreement existing as of the Effective Date regarding the acquisition, licensing, or other grant of rights to or under any Patent or Know-How owned or controlled by a Third Party that are necessary or useful for the Development, Manufacture or Commercialization of one or more Products.

1.1.40 “FDA” means the United States Food and Drug Administration, or any successor agency thereof.

1.1.41 “FDCA” means the United States Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, each as amended from time to time.

1.1.42 “Field” means the Research Field and/or the Commercial Field, as the context requires.

1.1.43 “FTE” means the equivalent of the work of one (1) full-time employee of a Party or its Affiliates for one (1) year (consisting of One Thousand Nine Hundred Fifty (1,950) hours per year) in directly conducting Development, Manufacturing, and/or as Pre-Commercialization Expenses hereunder. For the avoidance of doubt, “FTE” shall not include the work of general corporate or administrative personnel, except for the portion of such personnel’s work time actually spent on conducting scientific, technical or commercial activities directly related to the Development, Manufacture, or as Pre-Commercialization Expenses related to one or more Products.

1.1.44 “FTE Costs” means, for any period, the FTE Rate multiplied by the number of FTEs (including fractions thereof) in such period.

1.1.45 “FTE Rate” means, during the Term, Two Hundred Fifty Thousand dollars ($250,000) per FTE.

1.1.46 “Good Clinical Practices” or “GCP” means the ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects as are required by applicable Regulatory Authorities or Law in the relevant jurisdiction. In the United States, GCP shall be based on Good Clinical Practices established through FDA guidances (including Guideline for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6)), and, outside the United States, GCP shall be based on Guideline for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6).
1.1.47 “Good Laboratory Practices” or “GLP” means the then-current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the United States, as they may be updated from time to time).

1.1.48 “Good Manufacturing Practices” or “GMP” means all applicable standards relating to manufacturing practices for fine chemicals, intermediates, bulk products and/or finished pharmaceutical products, including (a) all applicable requirements detailed in the FDA’s current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211 and “The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products”, as each may be amended from time to time, and (b) all applicable Laws promulgated by any Governmental Authority having jurisdiction over the Manufacture of any Product for the Field.

1.1.49 “Governmental Authority” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multinational organization or body; or (e) individual, entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.1.50 “Histogen Collaboration Intellectual Property” means any Patents or Know-How, or Histogen’s and/or its Affiliates’ interest therein, that is developed or generated by or on behalf of Histogen and/or its Affiliate(s) through the use of Amerimmune Know-How, Joint Collaboration Know-How, or materials disclosed or transferred by Amerimmune to Histogen in the conduct of the Collaboration during the Research Term and is necessary for the Development, Manufacture, and/or Commercialization of any Product(s) for the Field.

1.1.51 “Histogen Indemnified Party” has the meaning set forth in Section 9.1.1, below.


1.1.53 “Histogen Know-How” means any Know-How that is (a) Controlled by Histogen as of the Effective Date or during the Term, and (b) necessary or useful for the Development, Manufacture or Commercialization of any Product in the Field.

1.1.54 “Histogen Patents” means any and all Patents that (a) are owned or controlled by Histogen as of the Effective Date or during the Term, and (b) concern the Development, Manufacture or Commercialization of any Product (including the composition of matter, manufacture, or any use thereof) in the Field. The Histogen Patents include those Patents listed on attached Schedule 2.

1.1.55 “Histogen Profit Allocation” means the percentage of Profits to which Histogen is entitled.

1.1.56 “IND” means any Investigational New Drug application, filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any supplements or amendments thereto. Prior to exercise of the Option, references herein to “IND” shall mean the Research IND; in the event the Option is exercised, “IND” shall include any IND owned or controlled by either Party for a Product in the Field, and shall include, to the extent applicable, any comparable filing(s) outside the United States (such as a Clinical Trial Application (“CTA”) in the countries that are officially recognized as member states of the EU).

1.1.57 “Indication” means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease, condition or syndrome.

1.1.58 “Initial Trial” has the meaning set forth in Section 2.1.1, below.
1.1.59 “Initial Trial Report” has the meaning set forth in Section 2.5.2, below.

1.1.60 “Inventions” means all inventions, whether or not patentable, that are designed, discovered, generated, invented or conceived by or on behalf of either Party or its respective Affiliates or both Parties or their respective Affiliates, whether solely or jointly with any Third Party, in the course of activities performed under this Agreement in the Field.

1.1.61 “Joint Collaboration IP” means, collectively:
   (a) “Joint Collaboration Know-How,” which means all Know-How related to the Field, including physical embodiments of a Product, that is jointly created, invented, or otherwise made by or on behalf of both Parties or their respective Affiliates by at least one employee, consultant, or agent of Amerimmune and at least one employee, consultant, or agent of Histogen, whether solely or jointly with any Third Party, pursuant to the conduct of activities under the Collaboration at any time during the Research Term; and
   (b) “Joint Collaboration Patents,” which means Patents that cover any Joint Collaboration Know-How.

1.1.62 “Joint Development Committee” or “JDC” has the meaning set forth in Section 3.1.1, below.

1.1.63 “Joint Partnering Committee” or “JPC” has the meaning set forth in Section 3.3, below.

1.1.64 “Know-How” means any tangible or intangible trade secrets, know-how, expertise, discoveries, information, Inventions, data or materials, including ideas, concepts, formulas, methods, procedures, designs, technologies, compositions, plans, applications, scientific or technical data, assays, manufacturing information or data, samples, chemical and biological materials and all derivatives, modifications, and improvements of any of the foregoing, as well as financial and commercial data, business and commercial information, and non-public information about or belonging to a Party’s customers, collaborators, suppliers, employees, agents, or other representatives.

1.1.65 “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, as from time to time enacted, repealed or amended, including Good Clinical Practices and adverse event reporting requirements, guidance from the International Conference on Harmonization or other generally accepted conventions, the FDCA and similar laws and regulations in countries outside the United States, and all other rules, regulations and requirements of the FDA and other applicable Regulatory Authorities.

1.1.66 “License Effective Date” has the meaning set forth in Section 5.1.1, below.

1.1.67 “Manufacture” or “Manufacturing” means, as applicable, all activities associated with the production, manufacture, processing, filling, packaging, labeling, shipping and storage of a drug product or drug substance in the Field, and/or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, preclinical, clinical and commercial manufacture and analytical methods development and validation, product characterization, quality assurance and quality control development, testing and release.

1.1.68 “Manufacturing Costs” means, with respect to a Product, the reasonable FTE Costs and Out-of-Pocket Costs of a Party or any of its Affiliates or sublicensees incurred in Manufacturing a Product, excluding Manufacturing Scale-Up Costs, but including:
   (a) to the extent that a Product is manufactured by a Party or any of its Affiliates or sublicensees, direct material and direct labor costs, plus manufacturing overhead attributable to the Product (including facility start-up costs, all directly incurred manufacturing variances, and a reasonable allocation
of related manufacturing administrative and facilities costs (including depreciation) and a reasonable allocation of the costs of failed batches to be further described in the applicable supply agreement, to be provided for a Product, but excluding costs associated with excess capacity), all determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with Accounting Standards; and

(b) to the extent that a Product is Manufactured by a Third Party manufacturer, the Out-of-Pocket Costs paid by a Party or any of its Affiliates or sublicensees to the Third Party for the manufacture, supply, packaging, and labeling of a Product, and any reasonable Out-of-Pocket Costs and direct labor costs actually incurred by such Party or any of its Affiliates or sublicensees in managing or overseeing the Third Party relationship, determined in accordance with the books and records of the applicable Party or its Affiliates or sublicensees maintained in accordance with Accounting Standards.

1.1.69 “Manufacturing Scale-Up Costs” means, with respect to a Product, the reasonable FTE Costs and Out-of-Pocket Costs of a Party or any of its Affiliates or sublicensees incurred in scaling up Manufacturing activities related to a Product for clinical supply, including (a) costs for process development work, analytical method optimization, and process validation, (b) costs for complete technology transfer to a commercial site (including costs for Manufacturing of demonstration batches on a suitable scale), and (c) Regulatory Expenses associated with such Manufacturing activities.

1.1.70 “Marketing Expenses” means, with respect to a Product, the sum of Marketing Management Expenses, Advertising and Market Research Expenses, and Medical Education Expenses relating to such Product.

1.1.71 “Marketing Management Expenses” means, with respect to a Product, FTE Costs arising from the management of marketing activities for such Product, including management and administration of managed care and national accounts and other activities associated with developing overall sales and marketing strategies; Product-related advertising, market research, and public relations; relationship maintenance with opinion leaders, professional societies, contract pricing administrators, and market information systems; education programs for health care professionals; governmental affairs activities for reimbursement; formulary acceptance; and other activities directly related to the marketing or promotion of such Product anywhere in the Territory.

1.1.72 “Material Breach” has the meaning set forth in Section 11.4.1, below.

1.1.73 “Medical Education Expenses” means, with respect to a Product, all Out-of-Pocket Costs specifically incurred to educate health care professionals licensed to practice in one or more jurisdictions in the Territory with respect to the Product through any means not covered as an Advertising and Marketing Research Expense, but including articles appearing in journals, newspapers, magazines, or other media; seminars, scientific exhibits, and conventions; and symposia, advisory boards, and opinion leader development activities; medical science liaison and medical affairs activities, and education grant programs.

1.1.74 “NDA” means an application submitted to a Regulatory Authority for the marketing approval of a Product, including (a) a New Drug Application, Product License Application or Biologics License Application (as such capitalized terms are used in C.F.R. Title 21) filed with FDA or any successor applications or procedures, (b) a foreign equivalent of a US New Drug Application, Product License Application or Biologics License Application or any successor applications or procedures, including a Marketing Authorization Application in the European Union, and (c) all supplements and amendments that may be filed with respect to the foregoing.

1.1.75 “Net Sales” means, with respect to any Product, the gross amounts received by the Parties, their respective Affiliates, or Strategic Partners from Third Parties (that are not Strategic Partners) for the sale or other commercial disposition of such Product anywhere within the Territory (each, a “Selling Party”) to Third Party customers for sales of such Product, less the following deductions actually incurred, allowed, paid, accrued or specifically allocated in its financial statements in accordance with (as applicable to the Selling Party) Accounting Standards, for: (i) customary discounts allowed; (ii) sales tariffs, duties, taxes (including value added taxes), or the like required to be paid; (iii) amounts allowed or credited on returns; (iv) rebates and chargebacks or
If non-monetary consideration is received by a Selling Party for any Product in the relevant country, Net Sales will be calculated based on the average price charged for such Product, as applicable, during the preceding royalty period, or in the absence of such sales, the fair market value of the Product, as applicable, as determined by the Parties in good faith. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Products, as applicable, for use in Clinical Trials, non-clinical development activities or other development activities with respect to Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate use or for Product samples, if no monetary consideration is received for such transfers.

If a Product is sold as part of a Combination Product (as defined below), Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

“A” is the gross invoice price in such country of the Product comprising a Compound as the sole therapeutically active ingredient; and

“B” is the gross invoice price in such country of the other therapeutically active ingredients contained in the Combination Product.

If “A” or “B” cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product. As used in this definition of “Net Sales,” “Combination Product” means a Product that contains one or more additional active ingredients (whether co-formulated or co-packaged) that are neither Compounds nor generic or other non-proprietary compositions of matter. Pharmaceutical dosage forms, adjuvants, and excipients shall be deemed not to be “active ingredients”.

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate Net Sales. Subject to the foregoing, the calculations set forth in this definition of Net Sales shall be determined in accordance with Accounting Standards so as to arrive at Net Sales as reported by the Selling Party in such Person’s financial statements.

1.1.76 “Option” has the meaning set forth in Section 4.1.1, below.

1.1.77 “Option Exercise Notice” has the meaning set forth in Section 4.1.2, below.

1.1.78 “Option Exercise Window” has the meaning set forth in Section 4.1.1, below.

1.1.79 “Option Term” means the period commencing on the Effective Date and ending on the first to occur of (a) Amerimmune’s exercise of the Option in accordance with Section 4.1, below, or (b) the expiration of the Research Term; provided, however, the Option Term shall not extend after 31 December 2022.

1.1.80 “Out-of-Pocket Costs” means, with respect to a Product, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for the Collaboration hereunder and have been recorded in accordance with the Accounting Standards.

1.1.81 “Partnering” means any activity directed at identifying, negotiating, and concluding a commercial relationship with a Third Party to further Develop a Product in the Field for the ultimate purpose of Commercializing such Product in the Field after or in expectation of receipt of Regulatory Approval for such Product.
1.1.82 "Patent" means (a) patents and patent applications anywhere in the world, (b) all divisionals, continuations, continuations in-part thereof or any other patent application claiming priority, or entitled to claim priority, directly or indirectly to (i) any such patents or patent applications or (ii) any patent or patent application from which such patents or patent applications claim, or is entitled to claim, direct or indirect priority, and (c) all patents issuing on any of the foregoing anywhere in the world, together with all registrations, reissues, re-examinations, patents of addition, renewals, patent term extensions, supplemental protection certificates, or extensions of any of the foregoing anywhere in the world.

1.1.83 "Patent Costs" means costs incurred by a Party pursuant to Article VI of this Agreement.

1.1.84 “Pre-Commercialization Expenses” means, with respect to a Product, those expenses incurred by either Party or its Affiliates (as detailed below) for the purpose of Developing the Product or reasonable out of pocket expenses directly connected to identifying Strategic Partners for a Product, and shall consist of the following expenses with respect to such Product: (a) expenses related to Development, including any Clinical Trial expenses; (b) Manufacturing Costs for supply of the Product; (c) Marketing Expenses; (d) other Pre-Commercialization costs; (e) Patent Costs; (f) Regulatory Maintenance Costs; and (g) Third Party License Costs.

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

1.1.86 “Phase I Study” means a human clinical trial of a product, the principal purpose of which is a preliminary determination of safety, tolerability, and pharmacokinetics in study subjects where potential pharmacological activity may be determined or similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(a), as amended (or the non-United States equivalent thereof).

1.1.87 “Phase II Study” means a human clinical trial intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise, including for example the trials referred to in 21 C.F.R. §312.21(b), as amended (or the non-United States equivalent thereof).

1.1.88 “Phase III Study” means a human clinical trial of a product in any country that would satisfy the requirements of 21 C.F.R. §312.21(c), as amended (or the non-United States equivalent thereof) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

1.1.89 “Phase IV Study” means a human clinical trial of a product which is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained from an appropriate Regulatory Authority for enhancing marketing or scientific knowledge of an approved indication.

1.1.90 “Pivotal Clinical Trial” means a human clinical trial of a Product on a sufficient number of subjects that, prior to commencement of the trial, satisfies both of the following: such trial (a) is designed to establish that such Product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such Product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such Product by the FDA or EMA, and (b) such trial is a registration trial designed to be sufficient to support the filing of an application for a Regulatory Approval for such Product in the U.S. or another country or some or all of an extra-national territory, as evidenced by (i) an agreement with or statement from the FDA or the EMA on a special protocol assessment or equivalent, or (ii) other guidance or minutes issued by the FDA or EMA, for such registration trial.
1.1.91 “Press Release” has the meaning set forth in Section 8.5.1, below, a mutually agreed form of which is attached hereto as Exhibit A.

1.1.92 “Product” means any pharmaceutical preparation, dosage form, or delivery system containing as an active pharmaceutical ingredient (i) Emricasan or (ii) any other caspase modulator owned or controlled by Histogen as of the Effective Date or at any time during the Term, in each case alone or in combination with another active pharmaceutical ingredient except as identified on Schedule 1.172, as it may be amended by Histogen from time to time to reflect caspase modulators first owned or controlled by Histogen after the Effective Date.

1.1.93 “Profits” means, with respect to any Calendar Quarter or Calendar Year: the sum of (x) any and all profits resulting from Strategic Partnering and/or the Development and Commercialization of a Product, which shall be equal to (a) the sum of (i) Net Sales of Products, plus (ii) Additional Revenue, less (to the extent not previously allocated) (b) (i) Development Costs, (ii) Pre-Commercialization Expenses, (iii) for any Product that is Commercialized, Manufacturing Costs, (iv) Manufacturing Scale-Up Costs, (v) Marketing Expenses, (vi) Regulatory Maintenance Costs, and (vii) Third Party License Costs; and (y) the Transaction Value from any Transaction.

1.1.94 “Profit Allocation” means the Histogen Profit Allocation or the Amerimmune Profit Allocation, as applicable.

1.1.95 “Prosecution” or “Prosecute” means the filing, preparation, prosecution and maintenance of Patents, including any and all pre-grant proceedings before any patent authority, such as interferences.

1.1.96 “Publication” means any publication in a scientific journal, any scientific abstract to be presented to any audience, any presentation at any scientific conference, including slides and texts of oral or other public presentations, any other scientific presentation and any other oral, written or electronic scientific disclosure directed to any audience that pertains to any Product, or the use of any of Product, or the data or results from any work under the Research Program.

1.1.97 “Qualifying Strategic Partnership” means a Strategic Partnership pursuant to which the Third Party who is Partnering with Amerimmune is obligated to pay to Amerimmune consideration that equals or exceeds One Million dollars ($1,000,000), exclusive of any payment or reimbursement to Amerimmune for past, current, or future expenses incurred by or on behalf of Amerimmune in connection with the Development or Manufacturing of the Product(s) that are the subject of such Strategic Partnership.

1.1.98 “Receiving Party” has the meaning set forth in Section 8.1, below.

1.1.99 “Regulatory Interactions” means (i) monitoring and coordinating all regulatory actions, preparing, submitting, and coordinating all communications and filings with, and submissions to, any Regulatory Authority with respect to Emricasan or any other Product, and (ii) interfacing, corresponding, and meeting with any Regulatory Authority with respect to Emricasan and other Products.

1.1.100 “Regulatory Approval” means all approvals of the applicable Regulatory Authority necessary for the commercial marketing and sale of a product for a particular indication in a country (including separate Regulatory Authority pricing or reimbursement approvals whether or not legally required in order to sell the product in such country, it being understood that, as of the Effective Date, no such Regulatory Authority pricing or reimbursement approval requirement is applicable in the United States).

1.1.101 “Regulatory Authority” means a federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing or sale (including pricing and reimbursement approval) of a product in a country or territory.
1.1.102 “Regulatory Documentation” means, with respect to the Collaboration, all INDs, NDAs, and other regulatory applications submitted to any Regulatory Authority, Regulatory Approvals (if any), pre-clinical and clinical data and information, 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 data, reports, records, regulatory correspondence and other materials relating to Development or Regulatory Approval of the Licensed Products, or required to Manufacture, distribute or sell the Licensed Products, including any information that relates to pharmacology, toxicology, CMC, Manufacturing and controls data, batch records, safety and efficacy, and any safety database.

1.1.103 “Regulatory Expenses” means, with respect to a Product, all Out-of-Pocket Costs incurred by or on behalf of a Party in connection with the preparation and filing of regulatory submissions for a Product and obtaining of Regulatory Approvals and any applicable governmental price and reimbursement approvals.

1.1.104 “Regulatory Maintenance Costs” means Out-of-Pocket Costs and FTE Costs for maintenance fees relating to Regulatory Approvals for a Product, and personnel engaged in the filing and maintenance of Regulatory Approvals.

1.1.105 “Representative” has the meaning set forth in Section 3.5.1, below.

1.1.106 “Research Field” means the treatment, prophylaxis, or amelioration of COVID-19 (caused by SARS-CoV-2) in humans.

1.1.107 “Research IND” means the IND filed by and in the name of Histogen on or before the Effective Date concerning the use of Emricasan in the Research Field, and any extension thereof (i) filed by and in the name of Histogen if filed prior to consummation of a Qualifying Strategic Partnership or (ii) by and in the name of a Strategic Partner after consummation of a Qualifying Strategic Partnership.

1.1.108 “Research Program” means a program comprising Development activities by and on behalf of Amerimmune, Histogen, and their Affiliates directed to Emricasan solely in the Field.

1.1.109 “Research Term” means the period commencing on the Effective Date and, unless earlier terminated in accordance with this Agreement, ending on the earlier of (a) one hundred eighty (180) days after Amerimmune delivers the final Phase 2 Initial Trial Report to the JDC, (b) December 31, 2022, or any permitted extension thereto, and (c) discontinuation of the Research Program.

1.1.110 “Research Term Extension” has the meaning set forth in Section 2.1.2, below.

1.1.111 “Right of Reference or Use” means a “Right of Reference or Use” as that term is defined in 21 C.F.R. §314.3(b), and any non-United States equivalents.

1.1.112 “Strategic Partner” means any Third Party to whom Amerimmune or any of its Affiliates or any other Strategic Partner grants a sublicense under this Agreement with respect to the Development, Manufacture, or Commercialization of a Product, in each case excluding (a) Third Party contractors and (b) wholesale distributors or any other Third Party that purchases a Product in an arm’s-length transaction to Develop, Manufacture or Commercialize the Product.

1.1.113 “Strategic Partnership” means a written agreement between Amerimmune and a Third Party regarding Partnering of one or more Products in the Research Field and/or Commercial Field in any country in the Territory pursuant to which the Third Party is obligated to pay to Amerimmune consideration.

1.1.114 “Suspension Period” means a period not to exceed one hundred twenty (120) days after execution of this Agreement during which Amerimmune shall have the right to cease its Development activities under the Research Program.
1.1.115 “Term” has the meaning set forth in Section 11.1, below.

1.1.116 “Term Sheet” means that certain “Term Sheet” entered into by the Parties and effective as of 21 July 2020.

1.1.117 “Territory” means the entire world.

1.1.118 “Third Party” means any Person other than a Party or any of a Party’s respective Affiliates.

1.1.119 “Third Party License” has the meaning set forth in Section 7.5.2, below.

1.1.120 “Third Party License Costs” means Out-of-Pocket Costs paid to Third Parties pursuant to Section 7.5.3 of this Agreement for a Product.

1.1.121 “Transaction” means any direct or indirect merger, consolidation, joint venture, partnership (including any Strategic Partnership), spin-off, split-off, business combination, tender or exchange offer, recapitalization, acquisition, sale, distribution, transfer or other disposition of assets or equity interests, or other transaction, involving all or a substantial portion of the business, assets or equity interests of Amerimmune and/or any of its Affiliates, or any right or option to acquire any of the foregoing, in one or more transactions.

1.1.122 “Transaction Value” means the total proceeds and other consideration paid or received, or to be paid or received, directly or indirectly, in connection with or in anticipation of a Transaction (which consideration shall be deemed to include amounts in escrow), including, without limitation, cash, notes, securities, and other property received or to be received by Amerimmune or any of its Affiliates, creditors or security holders (including, without limitation, the holders of convertible securities, options, warrants, stock appreciation rights or similar rights, whether or not vested); deferred non-contingent payments (such as installment payments); amounts payable under consulting agreements, above-market employment contracts, non-compete or severance agreements, employee benefit plans, reimbursement for taxes or similar arrangements; Contingent Payments (as defined below); and, in the case of a partnership, joint venture or similar structure, the gross value of all cash, securities, assets and other consideration contributed, invested, committed, or otherwise made available by Amerimmune or any other parties to such partnership, joint venture or similar structure. The Transaction Value shall be calculated as if 100% of the equity interests of Amerimmune on a fully diluted basis had been sold by dividing the total consideration involved in a Transaction by the percentage of ownership which is sold. The Transaction Value shall include the aggregate principal amount of any debt, pension liabilities, guarantees and any other liabilities or obligations of Amerimmune or any of its affiliates or security holders (i) retired, refinanced, restructured, redeemed, decreased, repaid or extinguished in connection with or anticipation of a Transaction or (ii) assumed in an acquisition of assets or which remain outstanding at the time of closing in all other cases. If any cash or other assets of Amerimmune and/or any of its subsidiaries or affiliates are sold or otherwise transferred to another party after the date hereof (including, without limitation, any dividends, distributions or other amounts paid to option or other security holders, amounts paid to repurchase any securities, or transaction-related bonus payments made to employees), or are retained after the consummation of the Transaction, then the Transaction Value will be increased to reflect the fair market value of any such assets.

1.1.123 “Trial Results” means any Data or other results generated during the performance of or in connection with a Clinical Trial conducted as part of the Research Program, including the Initial Trials.

1.1.124 “United States” or “U.S.” means the United States of America and all of its territories and possessions, including Puerto Rico.

1.2 Interpretation; Construction. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement, unless the context requires otherwise, (a) the word “including” shall be deemed to be followed by the phrase “without limitation” or like expression, whether or not followed by the same; (b) references to the singular shall include the plural and vice versa; (c) references to
male, feminine, and neuter pronouns and expressions shall be interchangeable; (d) the words “herein” or “hereunder” relate to this Agreement; (e) “or” is disjunctive but not necessarily exclusive; (f) the word “will” shall be construed to have the same meaning and effect as the word “shall”; and (g) all references to “dollars” or “$” herein shall mean U.S. Dollars. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

ARTICLE II
COLLABORATIVE DEVELOPMENT; RESEARCH PROGRAM; RESEARCH LICENSE

2.1 Scope and Collaboration Overview. Pursuant to this Agreement and as further provided in this Article II, during the Research Term, Amerimmune, at its expense and in collaboration with Histogen, (a) shall conduct the Research Program in the Research Field using commercially reasonable efforts and shall provide regular updates to Histogen at JDC meetings in accordance with Article IV below, together with all material data and information in Amerimmune’s possession relating to Emricasan, and (b) subject to oversight by the JDC and Article III below, shall be responsible for the research strategy and the conduct of activities under each Research Program. The activities conducted pursuant to this Article II and the activities performed by a Party or the Parties relating to the Research Program, and any Commercialization as permitted and overseen by the JPC or a Strategic Partner pursuant to Strategic Partnership, shall be the “Collaboration”.

2.1.1 Amerimmune Responsibility for Development.

(a) Commencing on the Effective Date, during the Research Term Amerimmune, will lead the Development activities in collaboration with Histogen, conduct Development activities with respect to Emricasan with the goal of progressing Emricasan through a Phase I Study and a Phase 2 Study in the Research Field (the “Initial Trials”).

(b) Amerimmune shall be responsible for conducting the Clinical Trials, including, the Initial Trials, and including providing human resources, coordinating with its network of clinical investigators, establishing study sites, engaging a clinical research organization, if part of the clinical development plan, and patient enrollment, pursuant to a Development Plan for Emricasan. Amerimmune, in collaboration with Histogen, shall prepare and submit to the JDC for approval a Development Plan for the Initial Trials. Once approved, a Development Plan may be amended from time to time by the JDC or otherwise by agreement of the Parties. Furthermore, Amerimmune may amend a Development Plan from time to time, provided that such amendment would not impose any obligation on Histogen beyond those for which Histogen is responsible or otherwise diminish Histogen’s rights under this Agreement or the then-current Development Plan.

(c) Amerimmune shall have the right, after discussing in the JDC and by so informing Histogen in writing in advance, to cease or suspend its Research Program activities at any time during the Research Term for one Suspension Period; provided, however, that a cessation or suspension for longer than the Suspension Period shall automatically terminate this Agreement with immediate effect on the day following the last day of the Suspension Period. If Amerimmune ends the Suspension Period before the 120th of the Suspension Period and continues to conduct, without stoppage, the Research Program, then the Research Term shall be deemed to be in progress until it expires or is otherwise terminated in accordance with this Agreement.

(d) During the Research Term, in accordance with Article III below, Amerimmune shall collaborate with Histogen, on a regular basis at JDC meetings, the status of the Research Program, progress made to date thereunder, and future plans under the Research Program, including discussing with Histogen material developments in or new data or information in Amerimmune’s possession relating to the Research Program made since the preceding JDC meeting.

2.1.2 Extension of Research Term. Amerimmune may, at its election and after discussing in the JDC, as long as both parties are in mutual agreement, extend the Research Term for up to three (3) one (1) year
extension periods (each being a "Research Term Extension", and each to run consecutively after the end of the then-current Research Term) by giving notice to Amerimmune of each such election at least thirty (30) days prior to the expiration of the then-current Research Term.

2.2 [intentionally left blank]

2.3 Supply of Emricasan.

2.3.1 Initial Trials. To facilitate conduct of the Initial Trials, after the Effective Date and promptly following a written request from Amerimmune, Histogen shall provide Amerimmune (or clinical trial sites designated by Amerimmune), at no cost to Amerimmune, with reasonable quantities of clinical Emricasan to conduct the Initial Trials, subject to the availability of Emricasan to Histogen.

2.3.2 Additional Development. To facilitate conduct of the Research Program beyond the conduct of the Initial Trials, if available and promptly following a written request from Amerimmune, Histogen shall provide Amerimmune with reasonable quantities of clinical Emricasan for the conduct of such additional Clinical Trials as the JDC approves. Histogen shall be entitled to charge Amerimmune a reasonable price for such additional Emricasan for such additional Clinical Trials (not to exceed Histogen’s documented costs for each dose from a Third Party supplier, plus Twenty Five percent (25%) of Histogen’s documented cost for each dose), absent the Parties entering into a written agreement to the contrary.

2.3.3 Limitations. Amerimmune agrees that Emricasan provided by Histogen shall be used only in furtherance of the Research Program and pursuant to Amerimmune’s rights and obligations under this Agreement. The Parties agree that Emricasan shall be used in compliance with applicable Law and the terms and conditions of this Agreement. Notwithstanding anything to the contrary herein, Histogen’s obligation to provide clinical Emricasan under this Agreement shall not extend to more Emricasan than is reasonably available to Histogen.

2.4 Regulatory Matters.

2.4.1 Initial Trial IND. To facilitate conduct of the Initial Trial, prior to the start of the Research Program, Histogen, in collaboration with Amerimmune, shall have filed a Research IND with the FDA seeking approval of a clinical trial protocol to govern the conduct of the Initial Trial.

2.4.2 Research Program. During the Research Program and until such time as a Strategic Partner assumes responsibility pursuant to a Qualifying Strategic Partnership, Histogen, in collaboration with Amerimmune, shall be responsible for and shall control all Regulatory Interactions relating to any Phase I or Phase II Study of Emricasan conducted pursuant to the Research Program, including the Initial Trials.

2.4.3 Transfer of Regulatory Interactions. After Amerimmune exercises the Option and a Strategic Partner assumes responsibility for Development of Emricasan pursuant to a Qualifying Strategic Partnership, the Parties shall each transfer any IND(s) for the Field to such Strategic Partner and promptly complete all relevant activities related to such IND(s) as required for the Strategic Partner to assume regulatory ownership thereof. Each of Histogen and Amerimmune shall provide such Strategic Partner in a Qualifying Strategic Partnership with all relevant clinical and non-clinical data reasonably requested by the Strategic Partner or a Regulatory Authority, including CMC, pharmacology, and toxicology data in its possession with respect to any Product, including Emricasan. Such Strategic Partner shall be deemed a third party beneficiary with respect to this Agreement.

2.4.4 Review of Regulatory Documentation. During the Research Term, for so long as Histogen has responsibility under Section 2.4.2, above, for Regulatory Interactions, Histogen shall (i) keep the JDC reasonably informed of all material Regulatory Interactions, preparation of regulatory documentation, Regulatory Authority review thereof, annual reports, and the like, and (ii) afford Amerimmune a reasonable opportunity to review and comment thereon and to provide meaningful input with respect to responses to any Regulatory Authority. Once any of Histogen’s responsibility under Section 2.4.2, above, is transferred to Amerimmune or a
Strategic Partner, Amerimmune or the Strategic Partner, as the case may be, shall (i) keep Histogen reasonably informed of all material Regulatory Interactions, preparation of regulatory documentation, Regulatory Authority review thereof, annual reports, and the like, and (ii) provide Histogen with a reasonable opportunity to review and comment thereon and to provide meaningful input with respect to responses to any Regulatory Authority.

2.4.5 Meeting Participation. Amerimmune shall have the right to have an experienced representative participate as an observer in material or scheduled meetings, video conferences, and any teleconferences with any Regulatory Authority, and shall be provided with advance access to Histogen’s material documentation prepared for such meetings. Histogen shall have the same right to participate as an observer and have advance access to material documentation prepared for such meetings after it makes a transfer of any regulatory authority or responsibility under Section 2.4.3, above.

2.4.6 Submission Review. While Histogen maintains responsibility for Regulatory Interactions, prior to submission of material correspondence to any Regulatory Authority with respect to a Product, Histogen shall, sufficiently in advance for Amerimmune to review and comment, provide Amerimmune any material correspondence intended for submission to the Regulatory Authority. Histogen shall also provide Amerimmune with a copy of any material correspondence with a Regulatory Authority relating to Development of any Products, and consider and respond within a reasonable time frame to all reasonable inquiries made by Amerimmune with respect thereto. After it makes a transfer of any regulatory authority or responsibility under Section 2.4.3, above, Histogen shall have the same right to review and comment on any material correspondence intended for submission to the Regulatory Authority, and Histogen shall receive a copy of any material correspondence with a Regulatory Authority relating to Development of any Products and shall consider and respond within a reasonable time frame to all reasonable inquiries with respect thereto.

2.5 Reports; Results.

2.5.1 Records. Amerimmune shall maintain, and shall require its Third Party contractors to maintain in all material respects, complete, current, and accurate records of all Development activities conducted by it under this Agreement, and all Trial Results and other data and information resulting from the Research Program and any Clinical Trials, including all Phase I or Phase II Studies conducted pursuant thereto. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and patent purposes. Amerimmune shall document in writing all non-clinical studies and Clinical Trials conducted pursuant to the Research Program, and Histogen shall have the right to review and copy such records at reasonable times, as reasonably requested by Histogen.

2.5.2 Reports. At each meeting of the JDC held pursuant to Section 3.5, below, Amerimmune shall provide the Histogen a written progress report summary on the status of its activities under the Research Program, including data summaries of Trial Results, it being understood that Histogen may reasonably request additional information regarding any such written progress report summary. Upon the conclusion of any Clinical Trial conducted pursuant to the Research Program, including the Initial Trials, Amerimmune shall promptly prepare and submit to the JDC for review and approval a final report detailing the conduct of and the Trial Results obtained, and conclusions drawn, from such Clinical Trial, including the Initial Trials (as relates to either of the Initial Trials, the “Initial Trial Report(s)”).

2.5.3 Trial Results as Confidential information. Trial Results will be deemed to be the Confidential Information of each Party. In the absence of a written agreement to the contrary, upon the expiration or termination of the Term, either Party shall be free to use the Trial Results as they would use other Confidential Information owned by them, subject to each Party’s Intellectual Property rights therein.

2.6 No Representation. Neither Party makes any representation, warranty, or guarantee that the Collaboration will be successful, or that any other particular results will be achieved with respect to the Collaboration or Research Program or any Product.

2.7 Subcontracting. Subject to the terms of this Agreement, as applicable, Amerimmune shall have the right to engage Affiliates or Third Party subcontractors to perform some or all of its obligations under this Agreement. Any such Affiliate or subcontractor shall meet the qualifications typically required by such Party for
the performance of work similar in scope and complexity to the subcontracted activity and perform such work consistent with the terms of this Agreement; provided, however, that Amerimmune shall remain fully responsible and obligated for any activities it subcontracts under this Agreement. Amerimmune will inform the JDC in the event it elects to subcontract any of its obligations in connection with the Research Program, and if requested by Histogen, Amerimmune agrees to provide Histogen further information regarding any subcontractor. Any subcontract of all or substantially all of Amerimmune’s obligations under the Agreement must be unanimously approved by the JDC.

2.8 Research License. Histogen hereby grants Amerimmune, and Amerimmune accepts, a fully-paid, exclusive research license under Histogen Intellectual Property to Develop Emricasan in the Research Field throughout the Territory during the Research Term (the “Research License”). Upon expiration or termination of the Research Term or this Agreement, the Research License shall automatically terminate. Except as otherwise provided under this Agreement, any Emricasan delivered by Histogen to Amerimmune shall remain the sole property of Histogen, shall only be used only in furtherance of the Research Program, and shall be returned to Histogen or destroyed, in Histogen’s sole discretion, upon the first to occur of: termination of this Agreement (subject to Article X, below); or upon the discontinuation of the Research Program. Amerimmune shall not permit Emricasan to be used by or delivered to or for the benefit of any Third Party without the prior written consent of Histogen unless such Third Party is a Strategic Partner under a Qualifying Strategic Partnership or Third Party subcontractor as set forth above.

2.9 Tech Transfer. As soon as reasonably practical after the Effective Date and thereafter upon Amerimmune’s reasonable request during the Research Term, Histogen shall transfer to Amerimmune, at no cost to Amerimmune, copies of all Histogen Know-How that are related to the Product and necessary for the Clinical Trial(s), to the extent not previously transferred to Amerimmune. In addition, Histogen shall provide reasonable assistance, including making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to Amerimmune with respect to Development and regulatory matters and the use of such transferred Know-How in the Development of Products. The Out-of-Pocket Costs, as indicated with reasonable supporting evidence, incurred by Histogen in connection with such assistance shall be reimbursed to Histogen from any monies from Third Parties (including without limitation, any grants).

2.10 Grant Applications. During the Research Term, Amerimmune and Histogen agree to cooperate with regard to submitting grant applications or the like to Third Party funding agencies in order to obtain financial support for the Research Program, including the conduct of the Initial Trials and such additional Clinical Trials as the Parties mutually agree to undertake.

ARTICLE III
GOVERNANCE; COLLABORATION

3.1 General.

3.1.1 Governance Committees. The Parties shall establish (a) a Joint Development Committee (“JDC”) to oversee Development of Emricasan in the Research Field during the Research Term and (b) a Joint Partnering Committee (“JPC”) to oversee Commercialization activities for the Products. The JDC and JPC shall have decision-making authority with respect to the matters within its purview to the extent expressly and as more specifically provided herein, it being understood and agreed that with respect to any Product that becomes subject to a Qualifying Strategic Partnership, neither the JDC nor JPC shall have any review or decision-making authority as of the effective date thereof with respect to such Product(s).

3.1.2 Subcommittees. From time to time, each Committee may establish subcommittees to oversee particular projects or activities, as it deems necessary or advisable (each, a “Subcommittee”). Each Subcommittee shall consist of such number of members as the applicable Committee determines is appropriate from time to time. Such members shall be individuals with expertise and responsibilities in the subject matter area(s) to be overseen by the particular Subcommittee. Any Subcommittee shall operate under the same principles as set forth in this Article III for its governing Committee.
3.2 Joint Development Committee.

3.2.1 Establishment. Within ten (10) days following the Effective Date, Amerimmune and Histogen shall establish the JDC. The JDC shall have oversight over all Development activities conducted by or on behalf of Amerimmune as part of the Research Program, subject to Sections 3.6 and 3.7, below.

3.2.2 Duties. The JDC shall:

(a) manage the strategic direction of the Research Program, and to update the same from time to time as mutually agreed;

(b) oversee implementation of the Research Program in accordance with this Agreement;

(c) provide a forum for the Parties (i) to discuss the objectives of the Research Program; and (ii) to exchange and review scientific information and data relating to the activities being conducted under the Research Program;

(d) review and approve all Development plans for the Research Program and any proposed updates or amendments to such Development plans in the Research Field, and propose revisions to each of such Development plans in the Research Field as needed;

(e) oversee the implementation of the Research Program and Development of Emricasan (including evaluation of clinical trial protocols and review of the conduct of Clinical Trials conducted pursuant to the Research Program);

(f) oversee and approve the overall strategy and positioning of all material submissions and filings for Emricasan with the applicable Regulatory Authorities in the Research Field;

(g) review and approve the content of any IND for Emricasan or other clinical trial protocol or other submission to the FDA in respect of a Phase I or Phase II Study to be conducted pursuant to the Research Program;

(h) provide a forum for the Parties to share information with respect to Development of Emricasan in the Research Field, including reviewing and commenting on updates on such Development;

(i) review and monitor progress of the Research Program and serve as a forum for exchanging information and facilitating discussions regarding the conduct of the Research Program;

(j) provide a forum for the Parties to discuss whether to conduct additional Development activities for a Product other than Emricasan in the Research Field;

(k) oversee, review, and coordinate process research and development activities (including Manufacturing and formulation development activities) for Emricasan in the Research Field;

(l) oversee, review and coordinate the Parties’ activities with respect to Manufacturing of Emricasan for Development purposes in the Research Field, including discussion, review, and implementation of any supply plans pursuant to which, if necessary, a Third Party will Manufacture and supply Emricasan to Amerimmune for purposes of conducting the Research Program;

(m) develop and approve a publication plan for any Publication concerning use of Emricasan in the Research Field in accordance with Section 8.6, below, and review and approve in advance of the submission any such proposed Publication;
review and approve any grant application or the like that is prepared by Amerimmune or Amerimmune and Histogen to seek funding or other award from a Third Party in order to obtain financial support for the Research Program, including the conduct of the Initial Trials and/or such additional Clinical Trials as the Parties mutually agree to undertake;

(o) discuss and attempt to resolve any disputes in the JDC; and

(p) perform such other duties as are specifically assigned to the JDC under this Agreement.

3.2.3 Dissolution. Unless the Parties otherwise agree in writing, the JDC shall be dissolved and its activities and authority terminated upon the first to occur of (i) expiration or termination of the Research Program or (ii) a Strategic Partner assumes responsibility for Development of Emricasan pursuant to a Qualifying Strategic Partnership and all other tasks of the JDC have been discharged or are no longer needed.

3.3 Joint Partnering Committee.

3.3.1 Establishment. Within thirty (30) days of the Effective Date, the Parties shall establish the JPC. The Parties intend that the JPC shall have the responsibility for overseeing the Partnering of Products pursuant to the terms of this Agreement.

3.3.2 Duties. The JPC shall:

(a) review and approve Partnering plans presented from time to time by Amerimmune or Histogen with respect to Products in the Field;

(b) oversee implementation of any Partnering plan in the Field;

(c) review and coordinate the Partnering activities of Histogen and Amerimmune in the Field with respect to Products;

(d) review and unanimously approve in writing any proposed Strategic Partnership in the Commercial Field with respect to Products, and any deadlock or other failure to achieve unanimity with regard to any proposed Strategic Partnership shall not be subject to any dispute resolution mechanism provided in this Agreement, except that either Party may elect to escalate the matter to the Chief Executive Officers of the Parties for attempted resolution in accordance with Section 12.1, below; provided, however, that if such Chief Executive Officers are unable to approve the proposed Strategic Partnership, the proposed Strategic Partnership will be deemed to not approved;

(e) have such other Partnering responsibilities as may be mutually agreed by the Parties from time to time. For purposes of clarity, the JPC shall not have any authority beyond the specific matters set forth in this Section. In any case where a matter within the JPC’s authority arises, the JPC shall convene a meeting and consider such matter as soon as reasonably practicable, but in no event later than ten (10) business days after the matter is first brought to the JPC’s attention (or, if earlier, at the next regularly scheduled JPC meeting); and

(f) identify Third Parties that may assist with identifying one or more Strategic Partners.

3.4 Alliance Managers. Each Party shall appoint one designated representative to serve as an alliance manager (“Alliance Manager”) with responsibility for being the primary point of contact between the Parties with respect to the Collaboration. The Alliance Managers shall attend JDC and JPC meetings, as necessary, as non-voting observers. Nothing herein shall prohibit a Party from appointing its Alliance Manager as a member of one or more Committees.
3.5 General Committee Membership and Procedures.

3.5.1 Committee Membership. The JDC and JPC shall each be composed of two (2) representatives from each of Histogen and Amerimmune (each a “Representative”). Each Committee representative shall be of the seniority and experience appropriate for service on the applicable Committee in light of the functions, responsibilities, and authority of the Committee. Each Party may replace any of its Representatives on any Committee at any time by so informing the other Party in writing at least five (5) business days in advance of the next meeting of the particular Committee. Each Committee shall appoint a Committee member as chairperson from among its members. Within ten (10) business days following each Committee meeting, the chairperson of each Committee shall circulate to all members of that Committee a draft of the minutes of such meeting. The Representatives of that Committee shall then have five (5) business days after receiving such draft minutes to provide comments in writing to the Committee chairperson. If Representatives of that Committee do not submit comments within the applicable comment period, then the draft minutes shall be deemed final. If comments are timely submitted, then following incorporation or resolution of such comments, the chairperson of that Committee shall issue final minutes.

3.5.2 Committee Meetings.

(a) The JDC and JPC shall hold an initial joint meeting within ten (10) business days after the Effective Date or as otherwise agreed by the Parties. Thereafter, each Committee shall meet at least monthly, unless the respective Committee members otherwise agree. All Committee meetings shall be conducted in person or by telephone or televideo conference, unless otherwise determined by the applicable Committee.

(b) Unless otherwise agreed by the Parties, all in-person meetings for any Committee shall be held at such locations as the Committee chairperson determines. A reasonable number of other representatives of a Party (not to exceed three (3)) may attend any Committee meeting as non-voting observers; provided, that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in Article VIII, below; and provided further that the Parties, reasonably in advance of the applicable Committee meeting, approve the list of non-voting observers to attend such meeting. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in Committee meetings. The first scheduled meeting of the JPC shall be held no later than thirty (30) days after the Effective Date unless otherwise agreed by the Parties. The JPC shall disband upon the last to occur of: expiration or termination of the Research Program; expiration or termination of this Agreement; or the date that the Parties have received any and all consideration due under the last Strategic Partnership.

(c) Each Party shall be responsible for all expenses, as well as travel and related costs and expenses, for its Representatives to attend or otherwise participate in Committee meetings.

3.6 Responsibilities after Strategic Partnering. After a Strategic Partnership approved by the JPC has been consummated to govern the Development and Commercialization of a Product in the Commercial Field, no Committee shall have any review or decision-making authority under this Agreement with respect to such Product(s).

3.7 Decision-Making.

3.7.1 Committee; Referral to Executive Officers. All decisions of each Committee shall be made by consensus, with each Party’s Representatives collectively having one (1) vote, and shall be set forth in minutes approved in writing by both Parties. Upon five (5) business days prior written notice, either Party may convene a special meeting of a Committee for the purpose of resolving any failure to reach consensus on a matter within the scope of the authority and responsibility of such Committee. No Committee shall have the authority to resolve any dispute involving the breach or alleged breach of this Agreement and shall not have any power to amend, modify, expand the scope of, or waive the terms of, this Agreement, or to alter, increase, expand, or waive compliance by a Party with, a Party’s obligations under this Agreement. If the JDC or JPC is unable to achieve
consensus on any matter so referred to it for resolution by one or both Parties within ten (10) business days after the matter is so referred to it, such matter shall be referred to the Chief Executive Officers of the Parties for resolution.

3.7.2 Decision-Making Authority. If the matter is not resolved by the Executive Officers after discussions between them within ten (10) business days (or such longer period as the Parties agree) after referral to the Executive Officers, then the Executive Officer of Amerimmune shall have the right to decide the unresolved matter.

3.7.3 Notwithstanding the foregoing, neither Party shall have the right to finally and unilaterally resolve a dispute subject to this Section 3.7:

(i) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement;
(ii) in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement;
(iii) to resolve any dispute involving the breach or alleged breach of this Agreement;
(iv) to resolve a matter if the provisions of this Agreement specify that unanimous or mutual agreement of the Parties or a Committee, or consent of the other Party, is required for such matter;
(v) in a manner that would require the other Party to perform any act that is inconsistent with any Law; or
(vi) otherwise expand a Party’s rights or reduce a Party’s obligations under this Agreement.

3.8 Scope of Governance. Notwithstanding the creation of each the Committees, each Party shall retain the rights, powers, and discretion granted to it under this Agreement, and no Committee shall be delegated or vested with rights, powers, or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by a particular Committee are only those specific issues that are expressly provided in this Agreement to be decided by such Committee, as applicable.

ARTICLE IV
OPTION; OPTION EXERCISE; TECH TRANSFER

4.1 Option Grant and Exercise.

4.1.1 Option Grant by Histogen. Subject to the terms and conditions of this Agreement, Histogen hereby grants to Amerimmune, and Amerimmune accepts, an exclusive option (the “Option”), exercisable at any time during the period commencing on the first to occur of (i) the date the JPC agrees that Amerimmune shall have the right to exercise the Option, and (ii) the date that the JPC approves a Strategic Partnership, and in any case ending upon the end of the Research Term (the “Option Exercise Window”), to obtain an exclusive license to Develop and Commercialize Products in the Research and Commercial Fields throughout the Territory during the Term (the “Commercial License”). After exercise of the Option, Amerimmune, alone or in conjunction with one or more Strategic Partners, will use its commercially reasonable efforts to Develop, Manufacture, and Commercialize a Product for Profit, and to identify and support a Strategic Partner to Develop, Manufacture, and Commercialize a Product for Profit; it being understood and agreed that Amerimmune shall have satisfied this diligence obligation as of the date the first Qualifying Strategic Partnership becomes effective.
4.1.2 **Option Exercise.** Amerimmune shall have the right, but not the obligation, to exercise the Option by delivering written notice of such exercise to Histogen (the “Option Exercise Notice”) during the Option Exercise Window.

4.1.3 **Expiration of Option Exercise Window.** Unless otherwise agreed by the Parties in writing, if Amerimmune does not exercise the Option during the Option Exercise Window, then all rights in the Histogen Intellectual Property shall revert to Histogen, and this Agreement shall automatically and concurrently terminate with the expiration of the Option Exercise Window.

4.2 **Data.** Notwithstanding anything to the contrary in this Agreement, in the event Amerimmune timely exercises the Option, Histogen shall promptly provide to Amerimmune, free of charge, copies of and Rights of Reference to and use of all Data related to the Products that is relevant to or necessary to address issues relating to: (i) the safety of any Product, including Data that is related to adverse effects experienced with a Product, and/or (ii) all activities relating to CMC regarding Products.

4.3 **Tech Transfer.** In the event Amerimmune timely exercises the Option, and periodically thereafter following a reasonable request from Amerimmune, as soon as reasonably practical Histogen shall transfer to Amerimmune, at no cost to Histogen, copies of all Histogen Know-How and Histogen Collaboration Intellectual Property to the extent not previously provided to Amerimmune. In addition, Histogen shall provide reasonable assistance, including making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to Amerimmune with respect to the use of such transferred Know-How in the Development, Manufacture, and Commercialization of Products. The costs and expense incurred by either Party in connection with such assistance shall constitute Development Costs.

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**ARTICLE V**

**COMMERCIAL LICENSE; EXCLUSIVITY**

5.1 **Commercial License.**

5.1.1 **Exclusive License.** Subject to the terms and conditions of this Agreement, in the event Amerimmune provides Histogen an Option Exercise Notice during the Option Exercise Window, Histogen hereby grants to Amerimmune, and Amerimmune accepts as of the date of the Option Exercise Notice (the “License Effective Date”), an exclusive, royalty-free right and license, including the right to grant and authorize sublicenses (subject to Section 5.1.2, below), under the Histogen Intellectual Property and Histogen Collaboration Intellectual Property to the extent not previously provided to Amerimmune. In the event of early termination of this Agreement, the Commercial License shall terminate as of the date of termination of this Agreement.

5.1.2 **Sublicenses.** Amerimmune shall have the right to grant and authorize sublicenses under the Commercial License, provided that any such sublicense granted by Amerimmune shall be (i) included only within a Strategic Partnership that has been unanimously approved in writing in advance by the JPC and (ii) subject to and consistent with the terms and conditions of this Agreement. Amerimmune agrees to promptly provide Histogen with an unredacted copy of any such sublicense. It is understood and agreed that a Strategic Partnership may grant the Strategic Partner the unrestricted right to grant and authorize further sublicenses pursuant to and consistent with the terms and conditions of the Strategic Partnership, and provided that to the extent at the time any such further sublicense is granted the Strategic Partner then owes one or more obligations to Amerimmune, the Strategic Partnership shall require that the Strategic Partner promptly provide an unredacted copy of such further sublicense to Amerimmune, and Amerimmune shall promptly share that unredacted copy of such sublicense with Histogen.

5.1.3 **Rights Retained by the Parties.** For purposes of clarity, each Party retains all rights under Know-How and Patents Controlled by such Party not expressly granted to the other Party pursuant to this Agreement.
5.1.4 Limitation. For purposes of clarity, the Parties expect that further Development beyond the Research Program and any Commercialization of a Product will be carried out by a Third Party pursuant to a Qualifying Strategic Partnership. It is the intention of the Parties, subject to any Strategic Partnership entered into as provided herein, to structure Partnering with respect to such Strategic Partnership (i) as a collaborative endeavor whereby Amerimmune shall be the lead party for Partnering and (ii) whereby the Parties will mutually make decisions regarding Partnering through the JPC. It is understood and agreed that, unless agreed in a separate writing by the Parties, (i) no Product shall be Developed outside of the Research Field prior to a Qualifying Strategic Partnership being consummated, and (ii) no Product shall be Commercialized by Amerimmune without the prior written consent of Histogen; it being understood and agreed, however, that any activities undertaken by either Amerimmune or Histogen during the Term to identify a Third Party to support the Research Program and Development of Products under this Agreement, shall not be deemed Commercialization of any Product.

5.1.5 Section 365(n) of the Bankruptcy Code. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to “intellectual property” as defined in Section 101 of such Code. Each Party, as licensee, may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, if a Party elects to retain its rights as a licensee under any Bankruptcy Code, such Party shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to the licensee Party not later than: (a) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under the Agreement; or (b) if not delivered under clause (a), upon the rejection of this Agreement by or on behalf of the licensor, upon written request. Any agreement(s) supplemental hereto will be deemed to be “agreement(s) supplementary to” this Agreement for purposes of Section 365(n) of the Bankruptcy Code. As used herein, “Bankruptcy Code” means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

5.2 Exclusivity.

5.2.1 Amerimmune; Histogen. During the Research Term, except as expressly permitted in this Agreement or mutually agreed in writing by the Parties, neither Party nor any of its Affiliates shall, directly or indirectly, Develop, Manufacture, or Commercialize any Competitive Product for any use or purpose.

5.2.2 Certain Exceptions. Section 5.2.1, above, shall not apply if, during Research Term, either Party or any of its Affiliates merges or consolidates with, or otherwise acquires or is acquired by, a Third Party that is then engaged in activities that would otherwise constitute a breach of this Section 5.2 by a Party or its Affiliates.

5.3 Government Approvals. To the extent required, each of Amerimmune and Histogen will use its commercially reasonable good faith efforts to eliminate any concern on the part of any Governmental Authority regarding the granting, scope, or exercise of the Commercial License, including, if required by Governmental Authorities, promptly taking all steps to remove any and all impediments to consummation of the transactions contemplated by this Agreement, including obtaining government antitrust clearance, cooperating in good faith with any Governmental Authority investigation, promptly producing any documents and information and providing witness testimony if requested by a Governmental Authority. Subject to this Section 5.3, Amerimmune and Histogen shall cooperate and use respectively all reasonable efforts to make all other registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications, authorizations, permits and waivers, if any, and to do all other thing necessary or desirable for the consummation of the transactions as contemplated hereby.

5.4 Post-Exercise Clinical, Commercial Supply. In the event Amerimmune timely exercises the Option, thereafter Amerimmune (or, following consummation of a Strategic Partnership, the Strategic Partner), itself or through one or more Third Party manufacturers, shall be responsible for all drug product manufacturing and processing and filling of Products for all subsequent Clinical Trials and for Commercialization of Products (collectively, the “Amerimmune Manufacturing Responsibilities”). In order to assist Amerimmune (or the Strategic Partner) to perform the Amerimmune Manufacturing Responsibilities, Histogen shall (a) transfer, or have transferred, to Amerimmune (or the Strategic Partner), pursuant to a technology transfer plan to be mutually agreed by the Parties, all Manufacturing technology Controlled by Histogen and used in Manufacturing Products at the time.
5.5 Diligence; Compliance with Laws. Each Party shall use commercially reasonable efforts to perform all Development and, if any, all Manufacturing obligations under this Agreement in compliance with the applicable Development Plan, including any budget(s) and timeframe(s) set forth therein and including making available those resources set forth in any applicable Development Plan and the terms of this Agreement. In addition, each Party shall perform its obligations under this Agreement in a scientifically sound and workmanlike manner and carry out all work done in the course of the Collaboration in compliance with all applicable Laws governing the conduct of such work.

ARTICLE VI
FINANCIAL TERMS

6.1 [intentionally left blank]

6.2 Amerimmune Responsibility. Amerimmune shall be responsible for all costs associated with the Research Program, including all Clinical Trials conducted as part of the Research Program, unless a Strategic Partner has assumed such costs.

6.3 Profit Sharing.

6.3.1 The Parties shall equally share in Profits generated directly or indirectly (including through one or more Third Parties) in the course of Developing, preparing to Commercialize, and Commercializing Products subject to this Agreement, whether pursuant to and in accordance with any Strategic Partnership or through the acquisition (by sale, merger, or otherwise) of Amerimmune, subject first to deductions for costs and expenses a Party incurs in connection with such activities. For the avoidance of doubt, Profits would be net of costs and expenses that each Party incurs in connection with such activities. Profits shall also include Profit generated in a Transaction. For clarity, regardless of specific reference in an applicable definition in this Agreement, (i) all costs and expenses that a Party incurs in connection with this Agreement shall be as determined from the books and records of the applicable Party and its Affiliates maintained in accordance with Accounting Standards, and (ii) no costs and expenses shall be double-counted.

6.3.2 Beginning with the first Calendar Quarter in which Profits accrue under this Agreement, and for each Calendar Quarter thereafter during the Term in which Profits accrue, the Profit Allocation shall be as follows:

(a) the Amerimmune Profit Allocation shall be Fifty Percent (50%) of Profits accrued during such Calendar Quarter; and
(b) the Histogen Profit Allocation shall be Fifty Percent (50%) of Profits accrued during such Calendar Quarter.

6.4 Reports of Revenue, Profits; Payment. Beginning with the Calendar Quarter in which a Strategic Partnership or other Commercialization is entered into with a Third Party, within forty-five (45) days after the end of each Calendar Quarter, Amerimmune shall provide Histogen with a report stating the Profits received by Amerimmune during the applicable quarter. If no amount is payable to Histogen for a particular Calendar Quarter, the corresponding report shall so state. Concurrently with providing such report, Amerimmune shall pay the amounts specified in such report, if any, to Histogen. If a Transaction occurs, then the Report and Profits shall be provided and paid to Histogen at the closing of such Transaction.

6.5 Development Costs and Manufacturing Costs. In addition to receipt of its respective Profit Allocation in accordance with Section 6.3, above, each Party shall also be entitled to recover all of its documented, unallocated (i) Development Costs, (ii) Pre-Commercialization Expenses, (iii) Manufacturing Costs,
Manufacturing Scale-Up Costs, (v) Regulatory Expenses, (vi) Regulatory Maintenance Costs, and (vii) Third Party License Costs from proceeds received from a Strategic Partnership or the sale or acquisition of Amerimmune.

6.6 Financial Records. Amerimmune shall keep, and shall require its Affiliates and Strategic Partners or other Third Parties involved in any Commercialization to keep, complete and accurate books and records containing all data reasonably required for the calculation and verification of amounts payable to Histogen under this Article in accordance with the applicable Accounting Standards. Amerimmune shall keep, and shall require its Affiliates and Strategic Partners to keep, such books and records for at least three (3) years following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. With respect to any royalties that may be payable to Amerimmune from a Strategic Partner in respect of a Strategic Partnership or by a Third Party for any Commercialization, such records shall be in sufficient detail to support calculations of the equal share thereof due to Histogen. Amerimmune shall also keep, and require its Affiliates and Strategic Partners to keep, complete and accurate records and books of accounts containing all data reasonably required for the calculation and verification of Development Costs, including FTEs, Profit or Loss and, if applicable, Net Sales.

6.7 Inspection Rights. For a period of three (3) years from the end of a Calendar Quarter in which a payment is due to Histogen under this Agreement, upon thirty (30) days prior notice, Amerimmune agrees to make, and to cause its Affiliates to make, such records relating to the expenditure of all Third Party monies (including, without limitation, all grants) available, during regular business hours and not more often than once each calendar year, for examination by an independent certified public accountant selected by Histogen, for the purpose of verifying the accuracy of the financial reports and expenditures made by Amerimmune pursuant to this Agreement. The results of any such inspection shall be shared by the auditor with both Parties and shall be considered Confidential Information of both Parties. Histogen shall bear the full cost of such inspection unless the audit reveals an underpayment in an amount in excess of the cost of the audit due Histogen for the period under examination, in which case, Amerimmune shall bear the full cost of such audit.

6.8 Underpayment. In the event an examination conducted pursuant to Section 6.7, above, reveals a deficiency in Amerimmune’s payments to Histogen for the period under examination, Amerimmune shall promptly (and in no event within five Business Days) rectify such deficiency and, in addition, pay to Histogen interest on the amount of the deficiency, calculated at a rate per annum equal to ten percent (10%), calculated on the number of days such payments are paid after the date such payments were due, compounded annually.

6.9 Tax Matters.

6.9.1 Income Taxes; Withholding Taxes.

(a) Each Party shall be responsible for payment of any income or withholding taxes in connection with amounts received by such Party in connection with this Agreement. Notwithstanding the foregoing, Amerimmune shall be entitled to deduct and withhold from any amounts payable to Histogen under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of applicable Law, in which event Amerimmune: (i) deduct those taxes from such payment; (ii) timely remit the taxes to the proper taxing authority; and (iii) if requested by Histogen, send evidence of the obligation together with proof of tax payment to Histogen. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty or other applicable Law which is in effect to ensure that any amounts required to be withheld pursuant to this Section 6.9.1(a) are reduced in amount to the fullest extent permitted by applicable Law. In addition, the Parties shall co-operate in accordance with applicable Laws to minimize income taxes payable by either Party in connection with this Agreement, as applicable.

(b) Tax Documentation. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by the other Party or as required by applicable Law, properly completed and duly executed documentation as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes, and the applicable payment shall be made without (or at a reduced rate of) withholding to the extent permitted by such documentation, as reasonably determined by Amerimmune.
6.9.2 **Tax Cooperation.** Upon request, each Party shall use Commercially Reasonable Efforts to cooperate with the other Party to mitigate, reduce, or eliminate adverse tax consequences to such other Party from changes in applicable Law, the use of present or future Affiliates of either Party to engage in transactions described in or contemplated by this Agreement, or from other activities or transactions described in or contemplated by this Agreement.

6.10 **Payments; Currency Exchange.** Payments of all amounts payable under this Article shall be made directly by Amerimmune to the bank account as designated in writing by Histogen from time to time during the Term. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments made under, this Agreement shall be in United States dollars. Conversion of sales recorded in local currencies to United States dollars shall be performed in a manner consistent with commercially reasonable business practices.

6.11 **Late Payments.** Amerimmune shall pay interest to Histogen on any payments due to Histogen that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to ten percent (10%), calculated on the number of days such payments are paid after the date such payments were due, compounded annually.

### ARTICLE VII

**INTELLECTUAL PROPERTY**

7.1 **IP Ownership.**

7.1.1 **Amerimmune IP.** Except as expressly provided herein or otherwise agreed in writing by the Parties, during the Term Amerimmune shall retain ownership of all Amerimmune Intellectual Property owned or Controlled by Amerimmune as of the Effective Date or during the Term.

7.1.2 **Histogen IP.** Except as expressly provided herein or otherwise agreed in writing by the Parties, during the Term Histogen shall retain ownership of all Histogen Intellectual Property owned or Controlled by Histogen as of the Effective Date or during the Term.

7.1.3 **Joint Collaboration IP.** Except as expressly provided herein or otherwise agreed in writing by the Parties, during the Term Amerimmune and Histogen shall jointly own all Joint Collaboration IP discovered, invented, created, or made during the Research Term, without any duty to account to the other except as provided herein.

7.1.4 **Inventorship.** Inventorship of Inventions shall be determined by application of U.S. patent law pertaining to inventorship, and ownership shall follow inventorship. All such Inventions shall be deemed the Intellectual Property of the Party that owns it/them.

7.2 **Prosecution of Patents.**

7.2.1 **Before Strategic Partnering.** As between the Parties, during the Term until such time as a Qualifying Strategic Partnership is entered into, the Party that owns a Patent subject to this Agreement shall have the sole right (but not the obligation) to Prosecute such Patent, at such Party’s sole discretion and expense using patent counsel of its choice, and unless otherwise explicitly agreed in writing by the Parties, Amerimmune shall have the first right (but not the obligation) to Prosecute any Patent within the Joint Collaboration Patents (if any), at its sole expense. If Amerimmune determines not to prosecute any such Collaboration Patent(s), then such right and Invention shall be assigned, and is hereby assigned, to Histogen and such patent shall thereafter be Histogen Intellectual Property.

7.2.2 **After Strategic Partnering.** If during the Term a Qualifying Strategic Partnership is consummated, then the Qualifying Strategic Partnership may provide that the Strategic Partner may assume responsibility to Prosecute any Patent within the Amerimmune Patents, Histogen Patents, or Joint Collaboration Patents, in which event the Strategic Partner shall thereafter have the sole right to Prosecute any and all such Patents, subject to the terms of the Qualifying Strategic Partnership.

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7.2.3 Cooperation. During the Term, each Party agrees to keep the other Party reasonably informed of all material developments with respect to the Prosecution of any and all Patents for which it has Prosecution responsibility under this Agreement, including by providing copies of all substantive office actions or any other substantive documents in connection with such Patent(s) that such Party, though its patent counsel, receives from any patent office, and (y) provide the other Party with a reasonable opportunity to comment substantively on the Prosecution thereof prior to taking material actions (including the filing of applications, designating countries for national/regional stage entry, for validation, or the like), and will in good faith consider any comments made by and actions recommended by the other Party, provided, however, that the other Party does so promptly and consistently sufficiently prior to any applicable filing deadlines (but in no event after the date the Party having Prosecution Responsibility thereof reasonably designates).

7.3 Defense of Claims Brought by Third Parties. If a Party becomes aware of any actual or potential claim that the Development, Manufacture or Commercialization of any Product may infringe or misappropriate the intellectual property rights of any Third Party, such Party shall promptly notify the other Party.

7.4 Enforcement and Defense of Patents. The Party owning a Patent subject to this Agreement shall have the sole right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to any infringement or defense of any Patent subject to this Agreement, using counsel of its choice, in its own name, and under its direction, control and expense. In the event the Party owning the Patent elects to abandon a Patent applicable to a Product or the Research Program, the other Party shall have the option to receive an assignment of the Patent for the same consideration provided to the Patent owner for such assignment, if possible. Upon receipt of such consideration, the Party owning the Patent shall promptly assign the Patent to the other Party at the other Party’s sole cost and expense.

7.5 Third Party Licenses.

7.5.1 Notice. On a Product-by-Product basis, if, at any time during the Term Amerimmune or Histogen reasonably determines that the Development, Manufacture, or Commercialization of any Product subject to this Agreement may infringe one or more Patents or utilize Know-How, in either case owned or controlled by a Third Party, then the Party making such determination shall so inform the other Party in writing and request that an emergency session of the JPC be convened in order to consider the issue, which issue shall then be deemed to be within the purview of the for so long as the issue remains unresolved.

7.5.2 Third Party License. If the JPC determines that resolution of a matter referred to the JPC pursuant to Section 7.5.1, above, may require obtaining one or more licenses, on commercially reasonable terms, from one or more Third Parties for the Development, Manufacture, or Commercialization of a Product subject to this Agreement (in each case, a “Third Party License”), thereafter Amerimmune shall have the right, but not the obligation, at its sole discretion but after consultation with the JPC, to obtain a Third Party License on commercially reasonable terms.

7.5.3 Costs. Subject to Section 6.3, above, unless otherwise agreed by the Parties in writing, the costs associated with negotiating and obtaining rights under any Third Party License obtained under this Section 7.5 shall be borne by the Party entering into such Third Party License.

ARTICLE VIII
CONFIDENTIALITY

8.1 Confidential Information. Each Party agrees that a Party receiving Confidential Information (the “Receiving Party”) of the other Party (the “Disclosing Party”) shall (x) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort, (y) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (z) not use such Confidential Information for any purpose except those permitted by this Agreement (it being understood that this clause (z) shall not create or imply any rights or licenses not expressly granted under this Agreement). No Confidential Information of the Disclosing Party shall be used by
the Receiving Party except in performing its obligations or exercising rights explicitly granted under this Agreement, except to the extent that the Confidential Information:

(a) was known by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party, as evidenced by the Receiving Party’s written records at the time of disclosure; or

(b) is lawfully disclosed to the Receiving Party or its Affiliates by a Third Party other than the Disclosing Party rightfully in possession of the Confidential Information; or

(c) becomes published or generally known to the public through no fault or omission on the part of the Receiving Party or its Affiliates; or

(d) is independently developed by or for the Receiving Party or its Affiliates without reference to or reliance upon such Confidential Information, as evidenced by the Receiving Party’s written records at the time of disclosure.

8.2 Ownership. Unless otherwise expressly provided in this Agreement, Amerimmune and Histogen shall at all times remain the sole owner of its respective Confidential Information.

8.3 Permitted Disclosures. The Receiving Party may provide the Disclosing Party’s Confidential Information:

(a) to the Receiving Party’s respective employees, consultants, and professional advisors, and to the employees, consultants, and professional advisors of such Party’s Affiliates, who have a need to know such information for performing obligations or exercising rights expressly granted under this Agreement and who have a binding obligation to treat such information and materials as confidential;

(b) to patent offices in order to seek or obtain Patents or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to any Product, as contemplated by this Agreement; provided, however, that such disclosure may be made only following reasonable notice to and receipt of prior written approval from the Disclosing Party and then only to the extent reasonably necessary to seek or obtain such Patents or approvals;

(c) if such disclosure is required by judicial order or applicable Law or to defend or prosecute litigation or arbitration; provided, however, that prior to such disclosure, to the extent permitted by Law, the Receiving Party promptly informs the Disclosing Party in writing of such requirement, cooperates with the Disclosing Party to take whatever action it may deem appropriate to protect the confidentiality of such information, and furnishes only that portion of the Disclosing Party’s Confidential Information that the Receiving Party is legally required to furnish; or

(d) Notwithstanding anything to the contrary in this Article VIII, Amerimmune may disclose Confidential Information of Histogen (i) to Governmental Authorities (a) to the extent required to obtain or maintain INDs or Regulatory Approvals in the Research Field for Emricasan or, in the event the Option is exercised, in the Commercial Field, anywhere in the Territory for any Product, and (b) in the event it is obligated to respond to inquiries, requests, or investigations relating to this Agreement; (ii) to outside consultants, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent necessary to Develop Emricasan in the Research Field or, in the event the Option is exercised, in the Commercial Field, anywhere in the Territory for any Product; provided, that Amerimmune shall obtain the same confidentiality obligations from such Third Parties identified in (i) and (ii) above as it obtains with respect to its own similar types of Confidential Information; (iii) in connection with filing or Prosecuting Patents as permitted by this Agreement; (iv) in connection with prosecuting or defending litigation as permitted by this Agreement under a Protective Order having the same confidentiality obligations Amerimmune would seek or obtains with respect to its own similar types of Confidential Information; or (v) in connection with or included in scientific presentations and publications relating to Products, including abstracts, posters, journal articles, and the
like, and posting results of and other information about clinical trials to government and private sector websites in any country in the Territory, solely in accordance with Section 8.6 and only upon the written consent of Histogen, which consent shall not be unreasonably withheld. The Parties will coordinate in advance in connection with any such disclosures of Confidential Information of Histogen under this Section.

8.4 Acknowledgement. Amerimmune acknowledges that Histogen’s Confidential Information may represent material, non-public information of Histogen, and that Amerimmune is aware, and agrees that it will advise its employees, Affiliates, and professional advisors who are informed of the matters that are the subject of this Agreement, of the restrictions imposed by the U.S. securities laws on the purchase or sale of securities by any Person who has received material, non-public information from the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon such information.

8.5 Publicity; Terms of this Agreement; Non-Use of Names.

8.5.1 Except as required by judicial order or applicable Law or as explicitly permitted by this Article, neither Party shall make any public announcement concerning this Agreement without the other Party’s prior written consent, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, the Parties shall issue a press release, in a form mutually agreed to by the Parties (the “Press Release”), within thirty (30) days after the Effective Date. Neither Party shall use the name, trademark, trade name, or logo of the other Party, or the names of any of the other Party’s officers, directors, employees, consultants, agents, or professional advisors in any publicity or news release relating to this Agreement or its subject matter, without the prior express written permission of the other Party. For clarity, either Party may issue a press release or public announcement or make such other disclosure relating to this Agreement if the content of such press release, public announcement, or other disclosure: (i) does not consist of financial information and has previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates; or (ii) is contained in such Party’s financial statements prepared in accordance with Accounting Standards.

8.5.2 Notwithstanding the terms of this Article:

(a) Either Party shall be permitted to disclose the existence and terms of this Agreement to the extent required, in the reasonable opinion of such Party’s legal counsel, to comply with applicable Laws, including the rules and regulations promulgated by any Governmental Authority. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 8.5.2, the Parties will coordinate in advance in connection with the redaction of certain provisions of this Agreement with respect to any filings with a Governmental Authority or domestic or foreign stock exchange on which securities issued by a Party or a Party’s Affiliate are traded, and each Party will use commercially reasonable efforts to seek confidential treatment for such terms as may be reasonably requested by the other Party.

(b) Notwithstanding Section 8.1, above, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party, and Confidential Information deemed to belong to both the Disclosing Party and the Receiving Party, to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(i) subject to Section 8.5.2(g), above, complying with applicable Laws, regulations promulgated by Governmental Authorities, and with judicial process;

(ii) disclosure, solely on a “need to know basis,” to (A) Affiliates, subcontractors, advisors (including attorneys and accountants), and (B) subject to Section 8.5.2(b)(iii), below, investment bankers; provided, however, that in all cases of (A) and/or (B), prior to any such disclosure, each Person to whom such disclosure is to be made must be bound by written obligations of confidentiality, non-disclosure, and non-use no less restrictive than those set forth in this Article (provided, however, that in the case of legal advisors, no written agreement shall be required), with it being understood and agreed that in each of the above
situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 8.5.2(b)(i) to treat such Confidential Information as required under this Article; and

(iii) in the case of any disclosure of this Agreement by Amerimmune to any actual or potential acquirer, assignee, licensee, licensor, investment banker, institutional investor, lender, or other financial partner or advisor, such disclosure shall solely be made to a Third Party in connection with a proposed Strategic Partnership or transaction that would result in a Change of Control of Amerimmune.

8.6 Publications. The Parties agree that decisions regarding the timing and content of Publications shall be subject to the oversight and approval of the JDC and neither Party nor its Affiliates shall have the right to make Publications pertaining to the Research Program or any Product except as provided in this Agreement. If a Party desires to make a Publication, such Party must comply with the following procedure:

8.6.1 The publishing Party shall provide the JDC with an advance copy of the proposed Publication, and the JDC shall then have ten (10) business days prior to submission for any Publication in which to determine whether the Publication should be submitted and under what conditions, including (a) delaying sufficiently long to permit the timely preparation and filing of a patent application or (b) specifying changes the JDC reasonably believes are necessary to preserve Confidential Information contained in any unpublished Patent or Know-How belonging in whole or in part to the non-publishing Party.

8.6.2 In addition, if the non-publishing Party informs the publishing Party that such Publication, in the non-publishing Party’s reasonable judgment, discloses any Confidential Information of the non-publishing Party or could be expected to have a material adverse effect on any Know-How which is Confidential Information of the non-publishing Party, such Confidential Information or Know-How shall be deleted from the Publication.

8.6.3 Each Party shall have the right to present its Publications approved pursuant to this Section 8.6.3 at scientific conferences, including at any conferences in any country in the world, subject to any conditions imposed by the JDC in its approval.

8.6.4 For purposes of convenience, the JDC may delegate its responsibilities under this Section 8.6.4 to one or more representatives of Amerimmune or Histogen.

8.6.5 Notwithstanding any other provision of this Agreement, the Parties shall, through the JDC review and approval process set forth in this Section 8.6, seek to promptly publish in a peer-reviewed scientific journal, with Dr. Oral Alpan as the lead author, the results of any the Initial Trial following delivery of the corresponding Initial Trial Report to the JDC.

8.7 Confidentiality Period. All obligations under Sections 8.1, 8.2, 8.3, 8.5, 8.7, 8.8, 8.9, and 8.10 of this Article shall survive termination or expiration of this Agreement and shall (i) expire seven (7) years following termination or expiration of this Agreement for non-trade secret Confidential Information; and (ii) remain, for Confidential Information which rises to the level of a trade secret under applicable Law, for so long as such Confidential Information retains its status as a trade secret. Notwithstanding the preceding provisions of this Section 8.7, Section 8.9 shall survive one (1) year after termination or expiration of this Agreement.

8.8 Return of Confidential Information.

8.8.1 Upon the expiration or termination of this Agreement, should the Disclosing Party request in writing that the Receiving Party return or destroy the Disclosing Party’s Confidential Information during the seven (7) year Confidentiality Period during which the confidentiality and non-use obligations subsequently survive, the Receiving Party shall, as the case may be, return to the Disclosing Party or destroy all Confidential Information received by the Receiving Party from the Disclosing Party (and all copies and reproductions thereof).
8.8.2 Nothing in this Section 8.8 shall require the alteration, modification, deletion, or destruction of archival tapes or other electronic back-up media made in the ordinary course of business; provided, however, that regardless of any other provision of this Agreement the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article with respect to any Confidential Information contained in such archival tapes or other electronic back-up media for so long as such tapes or media are retained by the Receiving Party.

8.8.3 Notwithstanding the foregoing,

(a) the Receiving Party may retain its own notes, reports, and other documents generated by or on such Party’s behalf in accordance with the provisions of this Article that contain Disclosing Party’s Confidential Information but only:

(i) to the extent reasonably required (A) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; or (B) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or

(ii) to the extent it is impracticable to do so without incurring disproportionate cost.

Notwithstanding the return or destruction of the Disclosing Party’s Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article.

8.9 Non-Solicitation. Each Party agrees as follows:

8.9.1 Employees; Consultants. During the Research Term and for a period of eighteen (18) months thereafter, such Party shall not, directly or indirectly, solicit, induce, recruit, or encourage any of the other Party’s employees, officers, directors, consultants, agents, or professional advisors to terminate their relationship with the other Party.

8.9.2 Other Parties. During the term of this Agreement and for a period of twelve (12) months following the date of this Agreement, when in the role of a Receiving Party, such Party shall not use any Confidential Information of the Disclosing Party to negatively influence any of the Disclosing Party’s clients, licensors, licensees, or customers from purchasing products or services of the Disclosing Party or to solicit or influence or attempt to influence any client, licensor, licensee, customer, or other Person, either directly or indirectly, to direct any purchase of products and/or services to any Person in competition with the business of disclosing Party.

8.10 Common Interest. To the extent that any Confidential Information provided or made available under this Agreement may include material subject to the attorney-client privilege, work product doctrine, or any other applicable privilege concerning pending or threatened legal proceedings or governmental investigations, the Receiving Party and the Disclosing Party understand and agree that they have a commonality of interest with respect to such matters and it is their desire, intention, and mutual understanding that the sharing of such material is not intended to, and shall not, waive or diminish in any way the confidentiality of such material or its continued protection under the attorney-client privilege, work product doctrine, or other applicable privilege. All Confidential Information provided or made available by the Disclosing Party that is entitled to protection under the attorney-client privilege, work product doctrine, or other applicable privilege shall remain entitled to such protection under these privileges, this Agreement, and under the joint defense doctrine. Nothing in this Agreement obligates the Disclosing Party to reveal material subject to the attorney-client privilege, work product doctrine, or any other applicable privilege.
ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1 Mutual Representations. Amerimmune and Histogen each represents, warrants, and covenants to the other Party, as of the Effective Date, that:

9.1.1 Authority. It is duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement and to carry out its obligations hereunder, as applicable.

9.1.2 Consents. All necessary consents, approvals, and authorizations of all Government Authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery, and performance of this Agreement have been obtained.

9.1.3 No Conflict. Notwithstanding anything to the contrary in this Agreement, the execution and delivery of this Agreement, the performance of such Party’s obligations in the conduct of the Collaboration and the licenses and sublicenses to be granted pursuant to this Agreement (a) do not and will not conflict with or violate any requirement of applicable Laws existing as of the Effective Date and (b) do not and will not conflict with, violate, breach, or constitute a default under any agreement, or any contract, oral or written, to which it is a party or by which it or any of its Affiliates is bound, existing as of the Effective Date.

9.1.4 Enforceability. This Agreement has been duly executed and delivered on behalf of such Party and is a legal and valid obligation binding upon it and is enforceable in accordance with its terms.

9.1.5 Employee Obligations. To its knowledge, none of its or its Affiliates’ employees who have been, are or will be involved in the Collaboration are, as a result of the nature of such Collaboration to be conducted by the Parties, in violation of any covenant in any contract with a Third Party relating to non-disclosure of proprietary information, non-competition, or non-solicitation.

9.2 Additional Amerimmune Representations. Amerimmune represents, warrants, and covenants to Histogen, that, as of the Effective Date:

9.2.1 Amerimmune has not used, and during the Term will not knowingly use, any Know-How in the Research Program conducted by Amerimmune that is encumbered by any contractual right of or obligation to a Third Party that conflicts or interferes with any of the rights granted or to be granted to Histogen under this Agreement.

9.2.2 Amerimmune has not granted, and during the Term Amerimmune will not grant, any right or license to any Third Party relating to any Amerimmune Intellectual Property that conflicts with or limits the scope of the rights granted or to be granted to Histogen under this Agreement.

9.2.3 There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative, or other proceedings or governmental investigations pending or, to Amerimmune’s knowledge, threatened against Amerimmune, nor is Amerimmune a party to any judgment or settlement that would be reasonably expected to adversely affect or restrict the ability of Amerimmune to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Amerimmune Intellectual Property or Amerimmune’s Control thereof.

9.2.4 To Amerimmune’s knowledge, the practice of the Amerimmune Intellectual Property as contemplated under this Agreement does not (a) infringe any claim of any Patent of any Third Party or (b) misappropriate any Know-How of any Third Party.

9.2.5 None of the Amerimmune Patents are subject to any pending re-examination, opposition, interference, or litigation proceeding.

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9.2.6 There is no Existing Third Party Agreement to which Amerimmune or an Affiliate of Amerimmune is a party.

9.2.7 There is no agreement, contract, or other enforceable obligation with any Third Party to which Amerimmune or an Affiliate of Amerimmune is a party that requires payment of any fee, milestone payment, royalty, or other consideration with respect to the Development, Manufacture, or Commercialization (if any) of a Product for any purpose in the Field.

9.2.8 Neither Amerimmune nor any of its Affiliates has granted any lien or security interest in or to the Amerimmune Intellectual Property and the Amerimmune Intellectual Property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien, or charge of any kind.

9.2.9 Schedule 1 contains a complete and accurate list of all Patents owned by Amerimmune and/or its Affiliates as of the Effective Date.

9.2.10 Amerimmune and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

9.3 Additional Histogen Representations. Histogen represents, warrants, and covenants to Amerimmune, that, as of the Effective Date:

9.3.1 Histogen possesses sufficient rights, authorizations, and consents necessary to grant all rights and licenses it purports to grant to Amerimmune with respect to the Histogen Intellectual Property under this Agreement.

9.3.2 Histogen Know-How to be used by Amerimmune in conducting the Research Program is not encumbered by any contractual right of or obligation to a Third Party that conflicts or interferes with any of the rights granted or to be granted to Amerimmune under this Agreement.

9.3.3 Histogen has not granted, and during the Term Histogen will not grant, any right or license to any Third Party relating to any Histogen Intellectual Property that conflicts with or limits the scope of the rights granted or to be granted to Amerimmune under this Agreement.

9.3.4 There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative, or other proceedings or governmental investigations pending or, to Histogen’s knowledge, threatened against Histogen, nor is Histogen a party to any judgment or settlement that would be reasonably expected to adversely affect or restrict the ability of Histogen to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Histogen Intellectual Property or Histogen’s Control thereof.

9.3.5 To Histogen’s knowledge, the practice of the Histogen Intellectual Property as contemplated under this Agreement does not (a) infringe any claim of any Patent of any Third Party or (b) misappropriate any Know-How of any Third Party.

9.3.6 None of the Histogen Patents are subject to any pending re-examination, opposition, interference, or litigation proceeding.

9.3.7 There is no Existing Third Party Agreement to which Histogen or an Affiliate of Histogen is a party.

9.3.8 There is no agreement, contract, or other enforceable obligation with any Third Party to which Histogen or an Affiliate of Histogen is a party that requires payment of any fee, milestone payment, royalty, or other consideration with respect to the Development, Manufacture, or Commercialization (if any) of a Product for any purpose in the Commercial Field, including the Research Field.

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9.3.9 Neither Histogen nor any of its Affiliates has granted any lien or security interest in or to the Histogen Intellectual Property and the Histogen Intellectual Property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien, or charge of any kind.

9.3.10 Schedule 2 contains a complete and accurate list of all Histogen Patents owned by Histogen and/or its Affiliates as of the Effective Date.

9.3.11 Histogen and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

9.4 Covenants.

9.4.1 Mutual Covenants. Each Party hereby covenants to the other Party that:

(a) all employees of such Party or its Affiliates or Third Party subcontractors working under this Agreement will be under appropriate confidentiality provisions at least as protective as those contained in this Agreement, and, to the extent permitted under applicable Law, the obligation to assign all right, title, and interest in and to their inventions and discoveries, whether or not patentable, to such Party as the sole owner thereof;

(b) to its knowledge, such Party will not (i) employ or use, nor hire or use any contractor or consultant that employs or uses, any individual or entity, including a clinical investigator, institution, or institutional review board that has been debarred or disqualified by the FDA (or subject to a similar sanction by any Regulatory Authority outside the United States) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding by any Regulatory Authority outside the United States), in each of subclauses (i) and (ii) of this Section in the conduct of its activities under this Agreement;

(c) neither such Party nor any of its Affiliates shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with any of the rights or licenses granted to the other Party under this Agreement; and

(d) such Party and its Affiliates shall perform its obligations pursuant to this Agreement in compliance (and shall ensure compliance by any of its subcontractors) in all material respects with all applicable Laws, including GCP, GLP, and GMP, as applicable, and with respect to the research, Development, Manufacturing, and Commercialization activities under this Agreement.

9.4.2 Additional Covenants. Except to the extent expressly permitted under Article V, above, on a Product-by-Product basis, during the Term neither Party nor its Affiliates will, other than to an Affiliate of such Party that agrees in writing to be bound by the terms and conditions of this Agreement, (a) assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b) of this Section 9.4.2), or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of this Section 9.4.2) or dispose of, any assets specifically related to such Product, including pre-clinical study or Clinical Trial results or other data specifically related to such Product, or any intellectual property specifically related to any of the foregoing, except to the extent such assignment, transfer, conveyance, encumbrance, or disposition would not fundamentally frustrate the purpose of this Agreement with respect to such Product, (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to the same if such license or grant would fundamentally frustrate the purpose of this Agreement, or (c) disclose any Confidential Information relating to the same to any Third Party if such disclosure would fundamentally frustrate the purpose of this Agreement with respect to such Product. Each Party and/or its Affiliates shall have the right to assign, transfer, convey, or dispose of any assets specifically related to such Product to any Affiliate, to the extent permitted by Section 12.4, below.

9.5 Disclaimer. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR
ARTICLE X
INDEMNIFICATION; INSURANCE

10.1 **By Amerimmune.**

10.1.1 Amerimmune agrees, at Amerimmune’s cost and expense, to defend, indemnify, and hold harmless Histogen and its Affiliates and their respective directors, officers, employees, and agents (each a “Histogen Indemnified Party”) from and against any Damages arising out of any Claim relating to:

(a) any breach by Amerimmune of any of its covenants, representations, or warranties pursuant to this Agreement; or

(b) the gross negligence or willful misconduct of Amerimmune; or

(c) the Development, Manufacture, distribution, sale, offer for sale, importation, use, or other disposition of any Product by Amerimmune, its Affiliates, licensees, or sublicensees.

10.1.2 In the event of any such Claim against a Histogen Indemnified Party by any Third Party, Histogen shall promptly notify Amerimmune in writing of the Claim. Amerimmune shall have the right, exercisable by notice to Histogen within ten (10) business days after receipt of notice from Histogen of the Claim, to assume direction and control of the defense, litigation, settlement, appeal, or other disposition of the Claim (provided that such Claim is solely for monetary damages and Amerimmune agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Amerimmune to Histogen) with counsel selected by Amerimmune and reasonably acceptable to Histogen; provided, that the failure to provide timely notice of a Claim shall not limit a Histogen Indemnified Party’s right for indemnification hereunder except to the extent such failure results in actual prejudice to Amerimmune. Any Histogen Indemnified Party shall cooperate with Amerimmune and may, at its option and expense, be separately represented in any such action or proceeding. Amerimmune shall not be liable for any litigation costs or expenses incurred by a Histogen Indemnified Party without Amerimmune’s prior written authorization. In addition, Amerimmune shall not be responsible for the indemnification or defense of any Histogen Indemnified Party to the extent arising from any negligent or intentional act by any Histogen Indemnified Party or the breach by Histogen of any of its covenants, obligations, representations, or warranties under this Agreement, or any Claim compromised or settled without Amerimmune’s prior written consent, which consent will not be unreasonably withheld or delayed. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 10.1.

10.1.3 Amerimmune shall not be obligated to indemnify, defend, or hold Histogen or any Histogen Indemnified Party harmless to the extent that such Damages are the subject of Histogen’s indemnification obligations under Section 10.2, below.
10.2 **By Histogen.**

10.2.1 Histogen agrees, at Histogen’s cost and expense, to defend, indemnify, and hold harmless Amerimmune and its Affiliates and their respective directors, officers, employees, and agents (each an “Amerimmune Indemnified Party”) from and against any Damages arising out of any Claim relating to:

(a) any breach by Histogen of any of its covenants, representations, or warranties pursuant to this Agreement;

(b) the gross negligence or willful misconduct of Histogen; or

(c) the Manufacture or supply of any Product by or on behalf of Histogen pursuant to this Agreement.

10.2.2 In the event of any such Claim against an Amerimmune Indemnified Party by any Third Party, Amerimmune shall promptly notify Histogen in writing of the Claim. Histogen shall have the right, exercisable by notice to Amerimmune within ten (10) business days after receipt of notice from Amerimmune of the Claim, to assume direction and control of the defense, litigation, settlement, appeal, or other disposition of the Claim (provided that such Claim is solely for monetary damages and Histogen agrees to pay all Damages relating to such matter, as evidenced in a written confirmation delivered by Histogen to Amerimmune) with counsel selected by Histogen and reasonably acceptable to Amerimmune; provided, that the failure to provide timely notice of a Claim shall not limit an Amerimmune Indemnified Party’s right for indemnification hereunder except to the extent such failure results in actual prejudice to Histogen. Any Amerimmune Indemnified Party shall cooperate with Histogen and may, at its option and expense, be separately represented in any such action or proceeding. Histogen shall not be liable for any litigation costs or expenses incurred by an Amerimmune Indemnified Party without Histogen’s prior written authorization. In addition, Histogen shall not be responsible for the indemnification or defense of any Amerimmune Indemnified Party to the extent arising from any negligent or intentional act by any Amerimmune Indemnified Party or the breach by Amerimmune of any of its covenants, obligations, representations, or warranties under this Agreement, or any Claim compromised or settled without Histogen’s prior written consent. Each Party shall use reasonable efforts to mitigate Damages indemnified under this Section 10.2.

10.2.3 Histogen shall not be obligated to indemnify, defend, or hold Amerimmune or any Amerimmune Indemnified Party harmless to the extent that such Damages are the subject of Amerimmune’s indemnification obligations under Section 10.1, above.

10.3 **Joint Defendants.** If any suit is brought against either Party relating in any way to any Product(s), and it is not clear from the allegations in the complaint or the known facts surrounding the allegations in the complaint as to whether a Claim exists for which there is a right of indemnification pursuant to Section 10.1 or 10.2 above, then Amerimmune shall be responsible for controlling the defense of such suit in the first instance, at its expense. No settlement, consent judgment, or other voluntary final disposition of any such suit may be entered into without the prior written consent of Histogen, which consent shall not be unreasonably withheld or delayed. If, at any time in the course of such suit, it becomes apparent from discovery or otherwise that a Claim exists for which indemnification may be obtained in accordance with Section 10.1 or 10.2, above, then the indemnification provisions of either Section 10.1 or 10.2, above, whichever is applicable, shall become applicable and govern further proceedings in the suit in accordance with Section 10.1 or 10.2, above.

10.4 **Limitation of Liability.** EXCEPT WITH RESPECT TO A BREACH OF ARTICLE VIII, ABOVE, NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR OTHER INDIRECT OR REMOTE DAMAGES, OR DAMAGES FOR LOSS OF PROFITS, LOSS OF DATA, OR LOSS OF USE ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.
10.5 Insurance. During the Term, each Party shall maintain commercial general liability insurance (including product liability insurance and clinical trials insurance policy in an amount not less than what Histogen carries) from a recognized, creditworthy insurance company, with coverage limits on per claim and annual aggregate bases being commercially reasonable under the circumstances. Within thirty (30) days following written request from the other Party, each Party shall furnish to the other Party a certificate of insurance evidencing such coverage. If such coverage is modified or cancelled, the insured Party shall so inform the other Party in writing and promptly provide such other Party with a new certificate of insurance evidencing that such insured Party’s coverage meets the requirements of this Section 10.5.

ARTICLE XI
TERMINATION

11.1 Term; Expiration. Unless earlier terminated in accordance with this Article XI, the term of this Agreement (the “Term”) shall commence as of the Effective Date and remain in force until the later of the expiration of the last to expire of the following (i) the Research Term, (ii) the last to expire Patent within the Amerimmune Patents or Histogen Patents, and (iii) the date on which Amerimmune receives the last payment due pursuant to the last to expire any Strategic Partnership. Notwithstanding anything to the contrary in this Agreement, this Agreement shall terminate automatically and with immediate effect if by 31 December 2025 Profits are less than Ten Million U.S. dollars (US$10,000,000) from Development or Commercialization of a Product.

11.2 Licenses After Agreement Expiration. If Amerimmune consummated a Qualifying Strategic Partnership or has been acquired in a Transaction, in either case in which Histogen has received at least One Million dollars ($1,000,000) from Profit sharing as contemplated herein, then, concurrent with expiration of the Term (but not in the event of early termination) of this Agreement, Amerimmune’s (or a Strategic Partner’s) rights and licenses under this Agreement to surviving Histogen Intellectual Property to Develop, Manufacture, and Commercialize any Product(s) in the Commercial Field in the Territory shall convert to irrevocable, non-terminable rights and licenses, with the right to grant and authorize sublicenses, provided that following such expiration Amerimmune (or a Strategic Partner) shall be solely responsible for (i) any payment owed to any Third Party licensors of intellectual property or other assets or rights then included within Histogen Intellectual Property and (ii) for complying with the terms of any license agreements with such Third Party licensors (but only to the extent of Amerimmune’s exercise of such rights). For clarity, in the event that after expiration of this Agreement Amerimmune receives payment or other consideration (from a Strategic Partner or otherwise) in respect of Histogen Intellectual Property that survives such expiration, then Amerimmune and Histogen shall continue to share Profits derived therefrom for so long as Amerimmune receives such payment(s) or other consideration, and the provisions of Sections 6.4-6.8, above, shall survive accordingly.

11.3 Termination for Clinical Reasons. During the Research Term, either Party, or a Strategic Partner then having Development responsibility, shall have the right to terminate this Agreement in its entirety at any time upon at least thirty (30) days prior written notice to the other Party in the event that (i) a Party, or a Strategic Partner then having Development responsibility, in the exercise of its reasonable scientific judgment, determines that further Development of Emricasan for use in the Research Field is unlikely to be successful; provided, however, that if Histogen seeks to terminate this Agreement in accordance with the foregoing and Amerimmune believes in its reasonable scientific judgment that further Development of Emricasan for use in the Research Field is likely to be successful, then Amerimmune may veto such termination by notice to Histogen and committing (to Histogen) to spend at least One Million dollars ($1,000,000) in Development costs within twelve (12) months following Histogen’s written notice to terminate for clinical reasons. After entry into the first Qualifying Strategic Partnership, Amerimmune shall have the right to terminate this Agreement in its entirety at any time upon at least thirty (30) days prior written notice to Histogen in the event that such Strategic Partnership is terminated and no other Qualifying Strategic Partnership is then in effect.

11.4 Termination for Breach.

11.4.1 Material Breach. Subject to Sections 11.4.2 and 11.4.3, below, this Agreement may be terminated by either Party due to a breach of this Agreement in a manner that fundamentally frustrates the transactions contemplated by this Agreement taken as a whole (each, a “Material Breach”), provided that the breaching Party has not cured such breach within ninety (90) days after receipt of notice of such Material Breach.
or other embodiments of intellectual property from another entity. The term "embodiments" of intellectual property includes all tangible, intangible, electronic, property and all embodiments of intellectual property, and shall assist and not interfere with the Party obtaining intellectual property and all promptly delivered to it upon written request therefor by the Party, and (ii) neither Party shall interfere with the Licensed Party's rights to intellectual appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in that Party's possession, shall be
proceeding by or against that Party under the Bankruptcy Code, (i) the other Party shall be entitled to a complete duplicate of (or complete access to, as election under the Bankruptcy Code. The Parties further agree that in the event of a rejection of this Agreement by either Party in any bankruptcy Parties agree that either Party, as licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code.

11.4.2 Disagreement as to Material Breach. If the Parties reasonably and in good faith disagree as to whether there has been a Material Breach pursuant to Section 11.4.1, above, then subject to Section 12.1, below: (a) the Party that disputes that there has been a Material Breach may contest the allegation by referring such matter, within ten business (10) days after receipt of the corresponding notice of intention to terminate, for resolution to the Parties' Chief Executive Officers, who shall meet promptly to discuss the matter and determine within ten business (10) days (or such longer period as they mutually agree in writing) following referral of such matter, whether or not a Material Breach has occurred; (b) the relevant Cure Period with respect thereto shall only be tolled during the period from which a dispute is lodged and the Chief Executive Officers make a decision (including any such time as this period may be extended by mutual agreement) in accordance with the applicable provisions of this Agreement; (c) it is understood and agreed that during the pendency of any such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder); and (d) if it is finally and conclusively determined that the breaching Party committed such Material Breach, then the breaching Party shall have the right to cure such Material Breach after such determination within the remainder of the applicable Cure Period provided in Section 11.4.1, above.

11.4.3 If the Chief Executive Officers are unable to resolve a dispute within the ten (10) day period (or mutually agreed longer period) after it is referred to them, the Party allegedly in breach or default shall have the right to have the dispute resolved as provided in Section 12.1, below, during which the relevant Cure Period with respect to such dispute shall be tolled for not more than sixty (60) days.

11.5 Termination for Insolvency.

11.5.1 To the extent permitted by Law, this Agreement may be terminated by either Party upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the event of any involuntary bankruptcy or receivership proceeding, such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within ninety (90) days after the filing thereof.

11.5.2 All rights and licenses granted under or pursuant to this Agreement by Histogen are, and shall otherwise be deemed to be for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that either Party, as licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that in the event of a rejection of this Agreement by either Party in any bankruptcy proceeding by or against that Party under the Bankruptcy Code, (i) the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in that Party's possession, shall be promptly delivered to it upon written request therefor by the Party, and (ii) neither Party shall interfere with the Licensed Party's rights to intellectual property and all embodiments of intellectual property, and shall assist and not interfere with the Party obtaining intellectual property and all embodiments of intellectual property from another entity. The term "embodiments" of intellectual property includes all tangible, intangible, electronic, or other embodiments of
rights and licenses hereunder, including all Products, data, and tangible assets embodying intellectual property, filings with Regulatory Authorities and related rights, and Histogen Know-How and Amerimmune Know-How.

11.6 Effects of Termination.

11.6.1 Termination Pursuant to Section 11.3 or 11.4. In the event of termination of this Agreement by either Party pursuant to Section 11.3 or 11.4, above, notwithstanding anything to the contrary in this Agreement, upon the effective date of such termination:

(a) all rights and licenses granted herein to Amerimmune by Histogen shall terminate, Amerimmune shall cease any and all Development, Manufacture, and Commercialization activities under this Agreement (if any), and any and all rights granted by Histogen to Amerimmune shall revert to Histogen;

(b) all rights and licenses granted herein to Histogen by Amerimmune shall terminate, Histogen shall cease any and all Development, Manufacture, and Commercialization activities under this Agreement (if any), and any and all rights granted to Histogen by Amerimmune shall revert to Amerimmune; and

(c) other than as provided in Section 11.7, below, neither Party shall have any further obligation to the other Party under this Agreement.

11.7 Surviving Provisions.

11.7.1 Accrued Liabilities. Except as otherwise specifically provided herein, expiration or termination of this Agreement shall not relieve the Parties of any liability or obligation that accrued prior to the effective date of expiration or such termination, nor preclude either Party from pursuing all rights and remedies it may have under this Agreement or at law or in equity with respect to any breach of this Agreement nor prejudice either Party’s right to obtain performance of any obligation. In addition, termination of this Agreement shall not terminate provisions that provide by their respective terms for obligations or undertakings following the expiration of the term of this Agreement.

11.7.2 Survival. The rights and obligations of the Parties set forth in the following Sections and Articles shall survive the expiration or termination of this Agreement: Sections 2.2, 2.5, 5.1, 6.4, 6.5, 6.6, 6.7, 6.8, 7.1, 8.1, 8.2, 8.3, 8.5, 8.7, 8.8, 8.9, 8.10, 11.6, 11.7, 12.1, 12.2, 12.3, 12.4, and 12.5. In addition, those other terms and conditions of this Agreement that (i) by their nature are intended to survive or (b) are expressly stated to survive termination or expiration of this Agreement, shall survive.

11.7.3 Equitable Relief. Termination of this Agreement shall be in addition to, and shall not prejudice, either Party’s remedies at law or in equity, including either Party’s ability to receive Damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

11.7.4 Relationship to Other Agreements. Termination of this Agreement, in whole or with respect to any Product, shall not affect in any way the terms or provisions of any then-existing executed agreement between the Parties.

ARTICLE XII
MISCELLANEOUS

12.1 Alternative Dispute Resolution. Except for any disagreements that are within the authority of the JDC or JPC as provided in Article III, above, or unless otherwise expressly set forth herein, the Parties agree that any disputes arising with respect to the interpretation, performance, enforcement, termination, or validity of this Agreement (each, a “Dispute”) shall first be presented to the Parties’ respective Chief Executive Officers for resolution. If the Parties are unable to resolve a given dispute pursuant to this Section 12.1 after discussions
between the Chief Executive Officers within thirty (30) days (or such longer period as the Parties agree in writing) after referring such dispute to the Chief Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 12.2, below.

12.2 Binding Arbitration. Subject to Section 12.1, above, if the Parties are unable to resolve any such Dispute by negotiation and a Party wishes to pursue the matter, such Dispute shall be finally resolved by binding arbitration conducted in San Diego, California by JAMS using the JAMS Expedited Arbitration Rules for Commercial Disputes, and judgment on the arbitration award may be entered in any court having jurisdiction thereof. The arbitration shall be conducted before a single arbitrator experienced in the law, the pharmaceutical business, and pharmaceutical licensing transactions. If within twenty (20) days after initiation of arbitration the Parties are unable to agree on a qualified arbitrator, the Parties shall each nominate three (3) arbitrators and the Parties shall thereafter confidentially rank the six (6) nominees within five business (5) days, and the arbitrator with the lowest score shall be the arbitrator. In the event there is a tie and the Parties cannot agree between the candidates, JAMS shall choose the arbitrator from the tied candidates. The place of arbitration shall be mutually agreed upon by the Parties or, alternatively, selected by the arbitrator to be mutually convenient to both Parties. The Parties agree that the arbitrator shall have the authority to, but need not, permit full and complete discovery, both written and oral, by deposition, to establish reasonable additional procedures to facilitate and complete any such arbitration within ninety (90) days of the arbitrator’s appointment, and to decide any motions brought by either Party, including motions for summary judgment and/or adjudication and motions to dismiss, prior to any arbitration hearing. Either Party may also apply to the arbitrator 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 provisional relief necessary to protect such Party’s rights pending the arbitration award. The arbitrator shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrator’s and any administrative fees of arbitration; provided, however, that the arbitrator shall have the power to award any remedies, including attorneys’ fees and costs, available under applicable law. Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute would be barred by the applicable statute of limitations.

12.3 Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws of the State of California and, if applicable, the laws of the United States, in any case without reference to conflicts of laws principles.

12.4 Assignment.

12.4.1 Generally. This Agreement may not be assigned by any Party, nor may any Party delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, except as expressly permitted hereunder without the prior written consent of the other Party, which consent may be withheld in the Party’s sole discretion.

12.4.2 Histogen. Notwithstanding the limitations in Section 12.4.1, above, Histogen may assign all of its rights and obligations under this Agreement to (a) one or more Affiliates solely as provided in this Section 12.4.2 or (b) its successor in interest in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided, however, (a) Histogen informs Amerimmune in writing in advance of any such assignment, (ii) prior to such assignment becoming effective, the assignee agrees in writing to assume performance of all such assigned obligations, and (iii) all Histogen Intellectual Property an shall be transferred to such assignee effective as of such assignment.

12.4.3 Amerimmune. Notwithstanding the limitations in Section 12.4.1, above, Amerimmune may assign this Agreement, or all of its rights or obligations hereunder, to (a) one or more Affiliates solely as provided in this Section 12.4.3, or (b) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement; provided, however, (i) Amerimmune informs Histogen in writing in advance of any such assignment, (ii) prior to
such assignment becoming effective, the assignee agrees in writing to assume performance of all such assigned obligations, (iii) all Amerimmune Intellectual Property and Amerimmune’s interest Joint Collaboration IP shall be transferred to such assignee effective as of such assignment; (iv) the proposed assignee has not developed or sought to develop a Competitive Product, and (v) Histogen receives is share of the Profits associated with such transfer or assignment as provided in this Agreement.

12.4.4 Change of Control. Notwithstanding anything to the contrary in this Agreement, with respect to any intellectual property rights controlled by the permitted assignee of a Party or its Affiliates (if other than one of the Parties to this Agreement) involved in any Change of Control of either Party, such intellectual property rights shall not be included in the technology and intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer or its Affiliate (other than the relevant Party to this Agreement) prior to such transaction, or to the extent such technology is developed outside the scope of activities conducted with respect to the Collaboration, Research Program, or Products. The Histogen Intellectual Property and the Amerimmune Intellectual Property shall exclude any intellectual property owned or controlled by a permitted assignee or successor and not developed in connection with the Collaboration, Research Program, or Products Developed, Manufactured, or Commercialized pursuant to this Agreement.

12.4.5 All Other Assignments Null and Void. The terms of this Agreement shall be binding upon and shall inure to the benefit of the successors, heirs, administrators, and permitted assigns of the Parties. In the event of any permitted assignment by a Party of its rights and obligations under this Agreement, the permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 12.4 shall be null and void.

12.5 Force Majeure. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with, or delayed by an occurrence beyond the control of such Party (and which did not occur as a result of such Party’s financial condition, negligence, or fault), including fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions, acts of God, such Party shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference, or delay; provided, that the affected Party shall use its Commercially Reasonable Efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such cause(s) is(are) removed. For the avoidance of doubt, the coronavirus pandemic shall not qualify as a Force Majeure.

12.6 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all notices required or permitted to be given under this Agreement shall be in writing and shall be sufficient if: (a) personally delivered; (b) sent by registered or certified mail (return receipt requested and postage prepaid); (c) sent by express overnight courier service providing evidence of receipt and postage prepaid where applicable; (d) by email; or (e) sent by facsimile transmission (receipt verified and a copy promptly sent by another permissible method of providing notice described in any of clauses (a)-(d) above), to each of the address(es) designated below by the Party to be notified, which address(es) a Party may update from time-to-time during the Term by notice to the other Party:

To Amerimmune: To Histogen:
Amerimmune LLC Histogen, Inc.
11212 Waples Mill Road 16745 West Bernardo Drive
Suite 100 Suite 200
Fairfax, Virginia 22030 San Diego, California 92127
Attention: Oral Alpan, M.D. Attention: CEO
Telephone: 571.418.4824 Telephone:
Facsimile: 703.577.9065 Email:
Email: oalpan@amerimmune.com

With a copy to: With a copy to:
Amerimmune LLC Will Chuchawat, Esq.
1212 Waples Mill Road Sheppard Mullin Richter & Hampton LLP

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Any such notices shall be effective upon the date of receipt by the Party to whom it is addressed.

12.7 **Waiver.** Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. A delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party’s rights at a later time to thereafter enforce such provision. No waiver by either Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

12.8 **Severability.** If any provision of this Agreement should be adjudicated to be invalid, illegal, or unenforceable, the Parties shall negotiate in good faith a valid, legal, and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions of this Agreement shall remain in full force and effect and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. If the Parties cannot agree upon a substitute provision, the invalid, illegal, or unenforceable provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal, or unenforceable provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal, or unenforceable provision.

12.9 **Entire Agreement.** Except as set forth in this Section 12.9, this Agreement, which includes its attached Exhibits and Schedules, together with the Amended and Restated CDA, constitutes the entire agreement between the Parties relating to its subject matter, and supersedes all prior and contemporaneous agreements, representations or understandings, either written or oral, between the Parties with respect to such subject matter, including the Amended and Restated CDA and the Term Sheet, each of which are hereby terminated as of the Effective Date of this Agreement; it being understood and agreed, however, that the Amended and Restated CDA shall continue to apply to the “Confidential Information” (as such term is defined in the Amended and Restated CDA) disclosed thereunder.

12.10 **Modification.** No modification, amendment, or addition to this Agreement, or any provision hereof, shall be effective unless reduced to writing and signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted, or explained by any oral agreement, course of dealing or performance, or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

12.11 **Independent Contractors; No Intended Third Party Beneficiaries.** Nothing contained in this Agreement is intended or shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership, or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract, agreement, or undertaking with any Third Party. There are no
express or implied third party beneficiaries hereunder, except for the indemnitees identified in Sections 10.1 and 10.2, above.

12.12 Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and both of which together shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg, or similar attachment to electronic mail (any such delivery, an “Electronic Delivery”) shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Neither Party shall raise a Party’s use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a claim or defense with respect to the formation, amendment, restatement, or other modification of a contract, and each Party waives any such claim or defense, except to the extent that such claim or defense relates to lack of authenticity.

12.13 Equitable Relief. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including an injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.

12.14 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.

[remainder of page intentionally left blank]
Intending to be legally bound, the Parties have caused this Agreement to be executed below by their respective duly authorized officers as of the Effective Date.

**HISTOGEN, INC.:**

*On behalf of itself and its Affiliates*

By: /s/ Richard W. Pascoe  
Print Name: Richard W. Pascoe  
Title: President and CEO  
Date: 10/26/2020

**AMMERIMMUNE LLC:**

*On behalf of itself and its Affiliates*

By: /s/ Oral Alpan, M.D.  
Print Name: Oral Alpan, M.D.  
Title: Chief Executive Officer  
Date: 10/26/2020

SIGNATURE PAGE TO COLLABORATIVE DEVELOPMENT  
AND COMMERCIALIZATION AGREEMENT
Histogen and Amerimmune Enter into a Collaborative Development and Commercialization Agreement for Emricasan in the Treatment of COVID-19

Histogen Receives IND Approval from FDA to Initiate a Phase 1 Study of Emricasan in Mild-COVID-19 Patients to Assess Safety and Tolerability

Amerimmune to Lead Development Efforts of Emricasan in a Phase 1 Study in Mild-COVID-19 Patients Expected to Commence as Early as the End of 2020

SAN DIEGO, October 27, 2020 — Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing potential first-in-class therapeutics that ignite the body’s natural process to repair and maintain healthy biological function, today announced entering into a Collaborative Development and Commercialization Agreement with Amerimmune LLC to jointly develop emricasan, an orally active caspase inhibitor, for the treatment of COVID-19. Additionally, Histogen has received Investigational New Drug (IND) approval from the United States Food and Drug Administration (FDA) to initiate a Phase 1 study of emricasan in mild-COVID-19 patients to assess safety and tolerability. Amerimmune, which will lead the development efforts of emricasan, has selected clinical sites at two major medical centers in the New York City metropolitan area to conduct the study. Amerimmune is pursuing non-dilutive funding in order to support the clinical program and anticipates initiating the Phase 1 study as early as the end of 2020.

Under the terms of the collaboration, Histogen will retain ownership and oversight over emricasan and responsibility for all regulatory filings and maintaining its existing caspase inhibitor patent portfolio. Amerimmune, in collaboration with Histogen, will fund and lead the emricasan development efforts and maintain its own portfolio of patents for caspase inhibition and immunotherapy. Additionally, Amerimmune has been granted an option to commercialize emricasan under certain conditions for the sole purpose of supporting future third-party partnering transactions. Should any such partnering transaction emerge, Histogen and

A-1-
Amerimmune will share profits equally. The parties will manage the collaboration under a joint development and partnering committee governance structure.

“Since completing the merger with Conatus Pharmaceuticals in the second quarter, we have been evaluating opportunities to create value from the emricasan asset, which we believe can be best accomplished in partnership with Amerimmune in the potential treatment of COVID-19. The Amerimmune team brings both a strong caspase inhibitor scientific background and relevant technologies for the treatment of COVID-19 using caspase inhibitors to this collaboration,” said Richard Pascoe, President and CEO of Histogen. “With Amerimmune leading the development efforts related to emricasan, Histogen will remain focused on delivering the top line data results in the fourth quarter of 2020 for its HST-001 Phase 1b/2a trial for androgenic alopecia in men, evaluating a clinical pathway for HST-002 as a dermal filler, and continuing to progress our HST-003 program for regeneration of cartilage in the knee,” concluded Pascoe.

“We are delighted to work in collaboration with Histogen to explore the potential role of caspase inhibition as a therapy for reducing disease severity and progression of COVID-19,” said Dr. Oral Alpan, CEO of Amerimmune. “We believe our research and development efforts over the last decade have enabled us to make important advancements in our understanding of how SARS-CoV-2 compromises the immune system. We are encouraged by our progress and look forward to advancing emricasan into the clinic as early as the end of 2020,” concluded Dr. Alpan.

About Emricasan
Emricasan is a first-in-class, orally active, pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Histogen believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases. To date, emricasan has been studied in over 950 patients in 19 completed clinical trials across a broad range of liver diseases. In NASH cirrhosis patients in multiple clinical Phase II trials conducted by Conatus, emricasan demonstrated rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death. Similarly, elevated biomarkers are also believed to play a role in the severity and progression of COVID-19.

About Histogen
Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class restorative therapeutics that ignite the body’s natural process to repair and maintain healthy biological function. Histogen’s innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. Histogen’s proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including hair growth, dermal rejuvenation, joint cartilage regeneration and spinal disk repair. For more information, please visit www.histogen.com.
About Amerimmune

Amerimmune LLC is a research center and immunology laboratory with a strong focus on identifying underlying mechanisms of immune disorders. Amerimmune’s mission is to bring relevant science, data, and diagnostic and therapeutic solutions to diseases that involve the immune system. Amerimmune LLC is a spinoff of Amerimmune Diagnostics LLC, which is focused on establishing a network of physician-owned immunology labs across the United States. Amerimmune Diagnostics’ clinical approach led to the development of the innovative therapeutics technology upon which Amerimmune was founded. When the COVID-19 pandemic emerged early this year, Amerimmune brought its expertise to bear against this devastating disease. Amerimmune is a privately held development-stage company based in Fairfax, VA. For more information and to explore partnering opportunities, please visit www.amerimmune.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. For example, we are using forward-looking statements when we discuss our future operations and our ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the planned Phase 1 study of emricasan for the treatment of COVID-19; the nature, strategy and focus of our business; the sufficiency of our and Amerimmune’s cash resources and ability to commence the planned Phase 1 study of emricasan and achieve value for our stockholders; and the development and commercial potential and potential benefits of any of our product candidates and the Collaborative Development and Commercialization Agreement with Amerimmune or any other collaboration agreements. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of ours that could differ materially from those described in or implied by the statements in this press release, including: the uncertainties associated with the clinical development and regulatory approval of our product candidates and Amerimmune’s ability to further develop emricasan for the treatment of COVID-19, including the complexity and length of studies required to commercialize emricasan for COVID-19 and potential delays in the commencement, enrollment, and completion of clinical trials, such as the planned emricasan Phase 1 study for the treatment of COVID-19; the uncertainties associated with Amerimmune’s pursuit and receipt of non-dilutive capital for the advancement of emricasan, including any potential government grants; Histogen’s dependence on its collaboration partner, Amerimmune, to carry out the development of emricasan and the potential for delays in the timing of regulatory approval; competition in the COVID-19 market and other markets in which Histogen and its collaboration partner operate; risks related to business interruptions to Histogen and/or Amerimmune, including the outbreak of COVID-19 coronavirus, which could seriously harm our respective financial conditions and increase our respective costs and expenses; the potential for adverse reactions to emricasan; and market conditions. The
foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including those risks discussed in our filings with the Securities and Exchange Commission. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events, or circumstances or otherwise.
## Amerimmune Patents

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S-1-1
### EMRICASAN

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Schedule 1.172

Caspase Modulators Owned Or Controlled By Histogen Excluded From a Product

S-1.172-1
Histogen and Amerimmune Enter into a Collaborative Development and Commercialization Agreement for Emricasan in the Treatment of COVID-19

Histogen Receives IND Approval from FDA to Initiate a Phase 1 Study of Emricasan in Mild-COVID-19 Patients to Assess Safety and Tolerability

Amerimmune to Lead Development Efforts of Emricasan in a Phase 1 Study in Mild-COVID-19 Patients Expected to Commence as Early as the End of 2020

SAN DIEGO, October 27, 2020 — Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing potential first-in-class therapeutics that ignite the body’s natural process to repair and maintain healthy biological function, today announced entering into a Collaborative Development and Commercialization Agreement with Amerimmune LLC to jointly develop emricasan, an orally active caspase inhibitor, for the treatment of COVID-19. Additionally, Histogen has received Investigational New Drug (IND) approval from the United States Food and Drug Administration (FDA) to initiate a Phase 1 study of emricasan in mild-COVID-19 patients to assess safety and tolerability. Amerimmune, which will lead the development efforts of emricasan, has selected clinical sites at two major medical centers in the New York City metropolitan area to conduct the study. Amerimmune is pursuing non-dilutive funding in order to support the clinical program and anticipates initiating the Phase 1 study as early as the end of 2020.

Under the terms of the collaboration, Histogen will retain ownership and oversight over emricasan and responsibility for all regulatory filings and maintaining its existing caspase inhibitor patent portfolio. Amerimmune, in collaboration with Histogen, will fund and lead the emricasan development efforts and maintain its own portfolio of patents for caspase inhibition and immunotherapy. Additionally, Amerimmune has been granted an option to commercialize emricasan under certain conditions for the sole purpose of supporting future third-party partnering transactions. Should any such partnering transaction emerge, Histogen and Amerimmune will share profits equally. The parties will manage the collaboration under a joint development and partnering committee governance structure.

“Since completing the merger with Conatus Pharmaceuticals in the second quarter, we have been evaluating opportunities to create value from the emricasan asset, which we believe can be best accomplished in partnership with Amerimmune in the potential treatment of COVID-19. The Amerimmune team brings both a strong caspase inhibitor scientific background and...
relevant technologies for the treatment of COVID-19 using caspase inhibitors to this collaboration,” said Richard Pascoe, President and CEO of Histogen. “With Amerimmune leading the development efforts related to emricasan, Histogen will remain focused on delivering the top line data results in the fourth quarter of 2020 for its HST-001 Phase 1b/2a trial for androgenic alopecia in men, evaluating a clinical pathway for HST-002 as a dermal filler, and continuing to progress our HST-003 program for regeneration of cartilage in the knee,” concluded Pascoe.

“We are delighted to work in collaboration with Histogen to explore the potential role of caspase inhibition as a therapy for reducing disease severity and progression of COVID-19,” said Dr. Oral Alpan, CEO of Amerimmune. “We believe our research and development efforts over the last decade have enabled us to make important advancements in our understanding of how SARS-CoV-2 compromises the immune system. We are encouraged by our progress and look forward to advancing emricasan into the clinic as early as the end of 2020,” concluded Dr. Alpan.

About Emricasan

Emricasan is a first-in-class, orally active, pan-caspase inhibitor designed to reduce the activity of enzymes that mediate inflammation and apoptosis. Histogen believes that by reducing the activity of these enzymes, caspase inhibitors have the potential to interrupt the progression of a variety of diseases. To date, emricasan has been studied in over 950 patients in 19 completed clinical trials across a broad range of liver diseases. In NASH cirrhosis patients in multiple clinical Phase II trials conducted by Conatus, emricasan demonstrated rapid and sustained reductions in elevated levels of key biomarkers of inflammation and cell death. Similarly, elevated biomarkers are also believed to play a role in the severity and progression of COVID-19.

About Histogen

Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class restorative therapeutics that ignite the body’s natural process to repair and maintain healthy biological function. Histogen’s innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. Histogen’s proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including hair growth, dermal rejuvenation, joint cartilage regeneration and spinal disk repair. For more information, please visit www.histogen.com.

About Amerimmune

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