

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20649

Form 10-Q/A

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2015

or

TRANSACTION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 1-10113

Acura Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

New York

(State or other Jurisdiction of
incorporation or organization)

11-0853640

(I.R.S. Employer Identification No.)

**616 N. North Court, Suite 120
Palatine, Illinois**

(Address of Principal Executive Offices)

60067

(Zip Code)

847 705 7709

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report.)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 S-T (§232.405 of this charter) during the preceding 12 months (or to such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of July 30, 2015 the registrant had 59,006,817 shares of common stock, \$.01 par value, outstanding.

EXPLANATORY NOTE

Acura Pharmaceuticals, Inc. (also referred to as the “Company,” “we,” or “our”) is filing this amendment (Amendment No. 1) to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (the June 30, 2015 Form 10-Q), originally filed with the Securities and Exchange Commission on August 3, 2015, for the sole purpose of providing a revised copy of Exhibit 10.1 to restore certain information following correspondence with the Securities and Exchange Commission that was previously omitted from Exhibit 10.1 pursuant to a request for confidential treatment. All other items of the June 30, 2015 Form 10-Q are unaffected by the change described above and have been omitted from this Amendment No. 1. As required, the Company is filing with this Amendment No. 1 updated certifications of its Chief Executive Officer and Chief Financial Officer as Exhibits 31.1 and 31.2, which, in accordance with published guidance of the staff of the Securities and Exchange Commission, are abbreviated from the certifications filed with the original Form 10-Q in light of the limited scope of this Amendment No. 1.

This Amendment No. 1 does not reflect events occurring after the filing of the June 30, 2015 Form 10-Q or modify or update those disclosures. In particular, the number of shares of common stock outstanding on the cover page does not reflect a 1 for 5 reverse stock split effected on or about August 27, 2015 or any shares issued after July 31, 2015. Accordingly, this Amendment No. 1 should be read in conjunction with our filings made with the SEC subsequent to the filing of the June 30, 2015 Form 10-Q, including any amendments to those filings.

Item 6. Exhibits

The Exhibit Index listed under Item 6 of Part II of the June 30, 2015 Form 10-Q is hereby amended such that Exhibit 10.1 is replaced in its entirety by the document attached as Exhibit 10.1 to this Amendment No. 1, which is hereby included as an exhibit to the June 30, 2015 Form 10-Q.

- 10.1 License and Development Agreement dated as of June 5, 2015 between the Registrant and Bayer HealthCare LLC (certain information has been omitted and filed separately with the Securities and Exchange Commission and confidential treatment has been requested with respect to the omitted portion).
- 31.1 Certification of Periodic Report by Chief Executive Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- 31.2 Certification of Periodic Report by Chief Financial Officer pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934.
- *32.1 Certification of Periodic Report by the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- *101.INS XBRL Instance Document
- *101.SCH XBRL Taxonomy Extension Schema Document
- *101.CAL XBRL Taxonomy Extension Calculation Linkbase
- *101.LAB XBRL Taxonomy Extension Label Linkbase
- *101.PRE XBRL Taxonomy Extension Presentation Linkbase
- *101.DEF XBRL Taxonomy Extension Definition Linkbase

*** Filed as an Exhibit to the Form 10-Q for the quarter ending June 30, 2015 on August 3, 2015**

Signatures

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

February 16, 2016

ACURA PHARMACEUTICALS, INC.

/s/ Robert B. Jones
Robert B. Jones
Chief Executive Officer

/s/ Peter A. Clemens
Peter A. Clemens
Senior VP & Chief Financial Officer

LICENSE AND DEVELOPMENT AGREEMENT

This License and Development Agreement (“Agreement”) is made and entered into as of this June 5, 2015 (the “Effective Date”) by and between Bayer HealthCare LLC, with offices at 100 Bayer Blvd., Whippany, NJ 07981 (“Bayer”), and Acura Pharmaceuticals, Inc., with offices at 616 N. North Court, Palatine IL 60067 (“Acura”). Bayer and Acura each are referred to herein as a “Party” and collectively as the “Parties.”

WITNESSETH:

WHEREAS, Acura has developed Impede® Technology designed to prevent extraction of pseudoephedrine from tablets and to disrupt the direct conversion of pseudoephedrine from tablets into methamphetamine;

WHEREAS, Bayer and its Affiliates have substantial expertise in the distribution, sales and marketing of healthcare products worldwide;

WHEREAS, Acura wishes to grant to Bayer, and Bayer wishes to obtain, the rights to (i) make, have made, distribute, have distributed, sell, have sold, market, have marketed, commercialize, and have commercialized the Developed Product(s) utilizing the Impede® Technology in the Field in the Territory, on the terms and conditions set forth herein (as each such term in defined herein);

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

ARTICLE I – DEFINITIONS

1.1 “**Affiliate**” means any corporation or other entity, which directly or indirectly controls, is controlled by or is under common control with a Party. A corporation or other entity shall be regarded as in control of another corporation or entity if it owns or directly or indirectly controls more than Fifty Percent (50%) of the voting stock or other ownership interest of the other corporation or entity, or if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than Fifty Percent (50%) of the members of the governing body of the corporation or other entity. Notwithstanding the foregoing, a private equity or venture capital firm with an ownership interest in an entity shall not be an Affiliate by reason of such ownership and portfolio companies of a private equity firm or a venture capital firm shall not be Affiliates or a Party by virtue of the private equity firm or venture capital firm being Affiliates of a Party.

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

- 1.2 “**Allergy Product**” means [*****].
- 1.3 “**Applicable Law**” means, with respect to any Person, any domestic or foreign, federal, state or local statute, treaty, law, ordinance, rule, regulation, administrative interpretation, order, writ, injunction, judicial decision, decree or other requirement of any governmental authority, including any rules, regulations or other requirements of the Regulatory Authorities in the Territory, applicable to such Person or any of such Person’s respective properties, assets, officers, directors, employees, consultants or agents.
- 1.4 “**Budget**” is the budget for the proposed development of the Developed Product as set forth in Exhibit B, and as amended in writing by the DC.
- 1.5 “**Commercialization Condition**” [*****].
- 1.6 “**Commercially Reasonable Efforts**” means with respect to a Party, the efforts and resources which would be used (including the promptness in which such efforts and resources would be applied) by that Party consistent with its normal business practices and in compliance with Applicable Law and the exercise of prudent scientific and business judgment, which in no event shall be less than the level of efforts and resources standard in the pharmaceutical industry for a company similar in size and scope to such Party, with respect to a product or potential product at a similar stage in its development and with similar market potential or product life cycle taking into account efficacy, safety, commercial value, the competitiveness of alternative products of Third Parties that are in the marketplace, and the Patent Rights and other proprietary position of such product.
- 1.7 “**Confidential Information**” is defined in Section 7.1 herein below.
- 1.8 “**Competing Product**” means [*****].
- 1.9 “**Control**” means, with respect to Intellectual Property Rights, ownership or the possession of the ability by license or otherwise to assign or grant a license or sublicense to or disclose such Intellectual Property Rights without violating the terms of any agreement or other arrangement, express or implied, with any Third Party.
- 1.10 “**DC**” means a Development Committee.
- 1.11 “**Delivery**” has the meaning set forth in Section 5.2.

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- 1.12 “**Development Plan**” means the plan for the development of the Developed Product set forth in Exhibit A, as the same may be amended by the Parties in writing.
- 1.13 “**Developed Product(s)**” means a [*****] product [*****].
- 1.14 “**Effective Date**” has the meaning set forth above.
- 1.15 “**FDA**” means the United States Food and Drug Administration, or any successor thereto.
- 1.16 “**Field**” means over-the-counter (non-prescription) (“OTC”) and prescription (“Rx”) products.
- 1.17 “**FTE Expense**” means [*****].
- 1.18 “**GAAP**” means generally accepted accounting principles in effect in the United States from time to time applied on a consistent basis.
- 1.19 “**Gross Sales**” means [*****].
- 1.20 “**Impede® Patent Rights**” means [*****].
- 1.21 “**Impede® Technology**” means [*****].
- 1.22 “**Information**” means any development data, results, records, reports, and technical information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, technical, reports, specifications, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.
- 1.23 “**Infringing Competing Product**” means [*****].
- 1.24 “**Intellectual Property Rights**” means Know-How, registered trademarks, trademark applications, unregistered trademarks, trade dress, copyrights, and Patent Rights.
- 1.25 “**Know-How**” means all Information that is Controlled by a Party, including but not limited to ideas, concepts, discoveries, inventions, developments, and improvements.
- 1.26 “**Know-How Royalty Payment**” is defined in Section 4.2.1

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- 1.27 “**License**” has the meaning set forth in Section 3.1.
- 1.28 “**Major Foreign Markets**” means [*****].
- 1.29 “**Milestone Payments**” is defined in Section 4.1.
- 1.30 “**Net Sales**” means [*****].
- 1.31 “**Non-Delivery Notice**” is defined in Section 5.2.
- 1.32 “**Patent Rights**” means patents and patent applications, and all divisionals, continuations, continuations in part, reissues, extensions, supplementary protection certificates and foreign counterparts thereof.
- 1.33 “**Person**” means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization.
- 1.34 “**Pilot BE Study**” means in vivo pharmacokinetic studies designed to test bioequivalence on [*****] meeting the criteria of Exhibit D.
- 1.35 “**PSE**” means pseudoephedrine or a pharmaceutically acceptable salt thereof.
- 1.36 “**Regulatory Approval**” means the license or final FDA, or equivalent foreign governmental authority, marketing approval necessary as a prerequisite for marketing the Developed Product in a country in the Territory.
- 1.37 “**Regulatory Approval Application**” means shall mean any filing(s) made with the Regulatory Authority in any country in the Territory for Regulatory Approval of the marketing, manufacture and sale (and pricing when applicable) of the Developed Product in such country.
- 1.38 “**Regulatory Authority**” means the FDA in the U.S., and any health regulatory authority(ies) in any other country in the Territory that is a counterpart to the FDA and has responsibility for granting regulatory approval for the marketing, manufacture, and sale of the Developed Product in such country, including, but not limited to, pricing and reimbursement approvals, and any successor(s) thereto, as well as any state or local health regulatory authorities having jurisdiction over any activities contemplated by the Parties.
- 1.39 “**Right of First Negotiation Product**” is defined in Section 3.7.

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- 1.40 “**Royalty Payments**” means the Standard Royalty Payments and the Know-how Royalty Payments.
- 1.41 “**Royalty Report**” is defined in Section 4.3.
- 1.42 “**Standard Royalty Payment**” is defined in Section 4.2.1
- 1.43 “**Target Product Profile**” is defined in Exhibit D.
- 1.44 “**Term**” has the meaning set forth in Section 2.1.
- 1.45 “**Territory**” means the world.
- 1.46 “**Third Party**” means any entity other than Acura and its Affiliates and Bayer and its Affiliates.
- 1.47 “**Valid**” means, with respect to a Impede® Patent Rights in a particular country, such Impede® Patent Rights have not (A) expired or been cancelled, (B) been declared invalid or unenforceable by a decision of a court or other appropriate body of competent jurisdiction, from which no appeal is or can be taken, (C) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (D) been abandoned or disclaimed either affirmatively or by operation of law.

ARTICLE II-TERM AND TERMINATION

- 2.1 Term and Expiration. The Term of this Agreement shall be on a country-by-country basis and, with respect to each country, will begin on the Effective Date and will expire on the later of the date that (i) the Impede® Patent Rights in such country are not Valid or do not claim the Developed Product; or (ii) is five years post launch of the Developed Product in such country in which there are not any Impede® Patent Rights that are both Valid and claim the Developed Product. The Agreement shall expire in its entirety when the Term has expired for all countries.
- 2.2 Termination
- 2.2.1 Before Delivery, Bayer may terminate this Agreement in its entirety immediately upon written notice to Acura. After Delivery, Bayer may terminate this Agreement at will upon six (6) months’ notice to Acura.
- 2.2.2 Acura may terminate this Agreement at any time upon sixty (60) days’ written notice to Bayer if Bayer does not launch the Developed Product in the United States [*****] Nothing in this Section 2.2.2 shall relieve Bayer of its obligations to use Commercially Reasonable Efforts to commercialize the Developed Product.

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- 2.2.3 Acura may terminate this Agreement at any time [*****] if Bayer suspends commercialization of the Developed Product in the United States for more than [*****]. Nothing in this Section 2.2.3 shall relieve Bayer of its obligations to use Commercially Reasonable Efforts to commercialize the Developed Product.
- 2.2.4 Acura may terminate this Agreement at any time upon sixty (60) days' written notice to Bayer if Bayer for an aggregate period greater than [*****] has not conducted any development of the Developed Product for the United States prior to Regulatory Approval for the United States, [*****].
- 2.2.5 With respect to each Major Foreign Market, if Bayer does not (i) initiate development of the Developed Product for such Major Foreign Market within [*****].
- 2.2.6 If Bayer or an Affiliate of Bayer files or has a Regulatory Approval Application pending or seeks Regulatory Approval of, or holds, directly or indirectly, including by way of a license, a Regulatory Approval for, or launches or assist a Third Party in the launch of an Infringing Competing Product or Competing Product in a country in the Territory, Acura may elect to terminate this Agreement with respect to such country only. Bayer shall provide written notice to Acura within [*****] days after (i) it or an Affiliate files or has pending a Regulatory Approval application for a Competing Product or an Infringing Competing Product or (ii) after receipt by it or an Affiliate of Bayer of receipt, or holding of a Regulatory Approval for the Developed Product.
- 2.2.7 Either Party may terminate the Agreement in its entirety by giving written notice of termination at any time, if the other Party fails to fulfill or breaches any material term or condition of this Agreement, and does not remedy the failure or breach within [*****] of receipt of written notice specifying such failure or breach given by the other Party; or if the other Party becomes insolvent, makes an assignment for the benefit of its creditors, is subject to proceedings in voluntary or involuntary bankruptcy instituted on behalf of or against such Party, goes into liquidation or has a receiver or trustee appointed for all or substantially all of its property.
- 2.3 Consequences of Expiration. Upon expiration of this Agreement with respect to a country, Bayer shall retain a non-exclusive, perpetual, irrevocable, fully paid-up and royalty-free license to, have made, sell, promote, or otherwise exploit the Developed Product in such country.

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- 2.4 Consequences of Termination. Upon termination of this Agreement with respect to one or more countries: (i) all of Bayer's licenses with respect to Acura's trademarks and the Impede® Technology with respect to the terminated countries shall terminate; (ii) Bayer shall retain its Regulatory Approvals with respect to the Developed Product for the terminated countries; (iii) if the termination is by Bayer under Section 2.2.1, or by Acura under Sections 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6 or 2.2.7, Acura's non-compete contained in Sections 3.5 and 3.6 shall terminate immediately with respect to the terminated countries; (vi) if the termination of this Agreement is for all countries (e.g., in its entirety), Bayer shall pay [*****]; and (v) Bayer's right of reference under Section 3.4 with respect to such terminated countries shall terminate if such termination occurs prior to Delivery under Section 2.2.1.
- 2.5 Accrued Rights; Surviving Obligations.
- 2.5.1 Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.
- 2.5.2 All of the Parties' rights and obligations under Sections 2.3, 2.4, 2.5, 3.5, 4.3, 4.5.2, 4.7, 4.8, 5.6.5, and Articles 6, 7, 8, 9, 11, and 12, shall survive termination, relinquishment or expiration of this Agreement, and all other provisions reasonable construed to survive shall also survive termination or expiration. Where a provision specifies a survival period, such provision shall survive only during such survival period.

ARTICLE III-LICENSE AND COMMERCIALIZATION

- 3.1 License. Acura hereby grants Bayer an exclusive (even as to Acura), sub-licensable (subject to Section 3.8), royalty-bearing right and license under the Impede® Patent Rights to develop, manufacture, have manufactured, distribute, have distributed, sell, have sold, market, have marketed, commercialize and have commercialized the Developed Product(s) in the Field in the Territory.
- 3.2 No Other Rights and Retained Rights. This Agreement confers no right, license or interest by implication, estoppel, or otherwise under any Patent Rights, Confidential Information, Know-How or other Intellectual Property (including but not limited to trade secrets, formulations, manufacturing processes, data) that was owned by a Party prior to signing the Agreement except as expressly set forth in this **Article III**. Each Party hereby expressly retains and reserves all rights and interests with respect to patents, Confidential Information, technology or other intellectual property rights not expressly granted to the other Party hereunder.

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- 3.3 Bayer to use CRE. Bayer shall use Commercially Reasonable Efforts to market and sell Developed Product in the United States and Major Foreign Markets, after obtaining Regulatory Approval for the Developed Product in such country; provided, however, that (i) Bayer shall have sole discretion and control as to the manner and extent of such commercialization of such Developed Product and (ii) subject to Section 2.2 and 4.5.1, Bayer shall have the right to postpone or delay the commercial launch of such Developed Product or discontinue, interrupt or cease the marketing and sale of such Developed Product in Territory if the commercialization of Developed Product is reasonably determined by Bayer to be economically unviable or in the event litigation is pending or threatened with respect to such Developed Product. During the Term, Bayer shall have the sole obligation and responsibility, and at its sole cost and expense, for all aspects of manufacturing, including without limitation, testing packaging and labelling the Developed Product, and any costs associated with storage, release and Third Party logistics. As part of such responsibilities, Bayer shall have the sole responsibility to obtain or to coordinate with and provide to its contract manufacturer such information and materials as shall be reasonably necessary to obtain sufficient quota for active pharmaceutical ingredients from the Drug Enforcement Administration, and similar foreign agencies. Bayer shall be solely responsible at its cost and expense for any recalls or withdrawals of Developed Product.
- 3.4 Right of Reference. Acura grants Bayer a right of reference to [*****].
- 3.5 Non-Compete. Acura will not file a Regulatory Approval Application or seek Regulatory Approval of or launch or assist a Third Party in the launch of an Infringing Competing Product or a Competing Product in a country in the Territory [*****].
- 3.6 Allergy Product Development. Acura will not file a Regulatory Approval Application or seek Regulatory Approval of or launch or assist a Third Party in the launch of an Allergy Product containing Acura's Impede® Technology [*****].
- 3.7 Right of First Negotiation Product. As used in this Agreement, "Right of First Negotiation Product" means a product containing the following as its only active pharmaceutical ingredients: [*****]. If Acura [*****] and in each case Acura determines to license, develop, collaborate with respect to or sell such Right of First Negotiation Product, then it will send Bayer written notice of same, before offering such Right of First Negotiation Product to any Third Party. [*****]. This Section 3.7 shall not survive termination or expiration of this Agreement.

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- 3.8 Sublicenses. Bayer shall not grant a sublicense in the United States of the licenses granted to it under Section 3.1, to a Third Party to market or sell the Developed Product without the consent of Acura, such consent not be unreasonably withheld. Bayer may grant sublicenses outside of the United States of the licenses granted to Bayer under Section 3.1, to a Third Party to market or sell the Developed Product (other than sublicenses granted to Third Parties acting as distributors or wholesalers or to Third Parties providing products or non-marketing/selling services to or on behalf of Bayer or its Affiliates), provided, however, [*****].

ARTICLE IV-MILESTONES AND ROYALTIES

- 4.1 Milestone Payments. Bayer shall make the following non-refundable, non-creditable milestone payments (“Milestone Payments”), and provide the following notices, to Acura:
- 4.1.1 Within [*****], Bayer shall pay Acura [*****].
- 4.1.2 Within [*****] Bayer shall pay Acura [*****].
- 4.1.3 Within [*****] Bayer shall pay Acura [*****].
- 4.1.4 Within [*****] Bayer shall pay Acura [*****].
- 4.1.5 The Milestone Payments provided in each of Sections 4.1.2, 4.1.3 and 4.1.4 shall be reduced by [*****] if [*****].
- 4.2 Royalties and Other Payments. The following payments shall be payable by Bayer to Acura for sales made during each calendar quarter and payment will be remitted within [*****] after the end of the quarter to which it relates.
- 4.2.1 Standard Royalty Payment. For each country in the Territory during any period of the Term in which (a) a claim under any Impede® Patent Right is Valid in a country and (b) a Third Party does not sell a Competing Product in such country, Bayer shall pay to Acura a royalty of [*****]. Such royalty shall be payable for sales made during each calendar quarter and payment will be remitted [*****]. The royalty payment under this section 4.2.1 is referred to as the “Standard Royalty Payment.”

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- 4.2.2 Know-How Royalty Payment. For each country during any period of the Term in which (a) Impede® Patent Rights do not exist or are not Valid in a country or (b) a Third Party sells a Competing Product in such country, Bayer shall pay Acura a quarterly royalty payment of [*****]. Bayer shall only be required to make payments under this Section 4.2.2 with respect to a country (determined on a country-by-country basis) until [*****]. Bayer shall provide Acura a detailed written explanation if it makes any Know-How Payments due to a Competing Product within [*****] of reaching such determination. The royalty payment under this Section 4.2.2 is referred to as the “Know-How Royalty Payment.”
- 4.3 Royalty Reports. Bayer shall prepare in respect of each calendar quarter a report (“Royalty Report”) that shows for that calendar quarter the [*****]. The Royalty Report shall be in the form of Exhibit E.
- 4.4 Royalty Stacking. The Royalty Payments with respect to a country will be reduced by [*****], but for any calendar quarter shall not reduce the Royalty Payments payable to Acura with respect to such country to less than [*****].
- 4.5 Minimum Annual Royalty.
- 4.5.1 Notwithstanding the calculation of the Royalty Payments under Section 4.2, commencing [*****], the aggregate Royalty Payments in the Territory payable by Bayer to Acura in any calendar year during the Term of this Agreement shall not be less than [*****] (the “Annual Minimum Royalty Amount”). In the first year in which the minimum Royalty Payments are payable, the minimum royalty shall be pro-rated by dividing (A) the number of days during such calendar year in which such minimum royalty obligations exist by (B) 365 and multiplying the result by the Annual Minimum Royalty Amount. Similarly in the calendar year of expiration, the minimum royalty shall equal (A) the number of days in such calendar year prior to expiration divided by (B) 365 and multiplying the result by the Annual Minimum Royalty Amount. In addition, if a Commercialization Condition exists and Bayer is not commercializing the Developed Product then for such calendar year the minimum royalty shall be reduced (not below zero) by [*****].
- 4.5.2 Within [*****], Bayer shall pay Acura any difference between Annual Minimum Royalty Amount (as the same may be prorated pursuant to section 4.5.1) and the royalties actually paid during the preceding calendar year, if applicable.
- 4.6 Pricing. Bayer shall have sole discretion to determine the price, terms and conditions of sales of Developed Product(s) to Bayer’s customers. Bayer shall not price the Developed Product in any country for any transaction [*****].

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- 4.7 Currency. All payments required under this Agreement shall be made in U.S. dollars, regardless of the country(ies) in which sales are made or expenses are incurred, via wire transfer of immediately available funds to an account designated in writing by Acura. Whenever, for the purpose of calculating any sums due under this Agreement, conversion from any foreign currency shall be required, such conversion shall be made as follows: the amounts shall be converted into United States dollars using the average rate of exchange for such currencies for the relevant period, such exchange rate shall be the exchange rate taken from The Wall Street Journal as published on the last day of the relevant period for which payments are due, or such other publication as may be agreed between the Parties from time to time.
- 4.8 Taxes. In the event that a Party is mandated under the laws of a country to withhold any tax to the tax or revenue authorities in such country in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party, provided, however, that the withholding Party shall take reasonable and lawful actions, at the other Party's sole cost, to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the United States Internal Revenue Service related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect. All amounts payable under this Agreement and not paid within [*****] of when due in accordance with the provisions hereof shall bear interest from the due date until paid at the rate equal to [*****]. Unless otherwise stated all dollar amounts in this Agreement are in United States dollars.

ARTICLE V-DEVELOPMENT/REGULATORY

- 5.1 Development. Bayer and Acura shall jointly develop the Developed Product pursuant to the Development Plan attached hereto as Exhibit A. Acura will use Commercially Reasonable Efforts to [*****]. Any activity not specifically assigned to Acura shall be the responsibility of Bayer. Under no circumstances will Acura be responsible for [*****]. Bayer shall be responsible for all costs and expenses (including Acura's FTE Expense), for performing all Developed Product development activities, whether performed by Acura or Bayer. Acura agrees to use Commercially Reasonable Efforts to utilize the Impede® Technology to obtain a formulation meeting the Target Product Profile provided there can be no assurance and Acura makes no representation that the Impede® Technology is sufficient to obtain a formulation meeting the Target Product Profile or that Acura will succeed in the development and Delivery of the Developed Product. Bayer will use Commercially Reasonable Efforts to finalize development and gain Regulatory Approval in the U.S. within [*****].

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

- 5.2 Delivery. Acura shall use commercial reasonable efforts to Deliver a formulation and development scale quantities of a prototype of the Developed Product meeting the Target Product Profile. “Delivery” will occur [*****].
- 5.3 Major Foreign Markets. Bayer shall use Commercially Reasonable Efforts to develop product formulation(s), similar to the Developed Product, for use in the Major Foreign Markets.
- 5.4 Joint Development Committee. The Parties shall coordinate all development activities under a joint development committee (“DC”) which will meet to discuss progress on the Development Plan, Budget and Target Product Profile. The parties shall establish the DC within thirty (30) days after the Effective Date. The DC will consist of equal number of designees from each Party and meet at least quarterly in person or by teleconference during the Term. Either Party may also call a special meeting of the DC (by videoconference or teleconference) by at least seven (7) day’s prior written notice to the other Party, unless the other Party otherwise agrees to shorter notice, in the event such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting. The DC may change its size from time to time by mutual consent of its designees, provided that the DC shall at all times consist of an equal number of designees. Each party may replace its designees at any time upon written notice to the other Party. The DC may invite non-designees to participate in the discussions and meetings of the DC, provided that such participants shall be approved by the other Party and have no voting authority at the DC. A designee may designate a substitute designee if he or she cannot attend a meeting for purpose of that meeting. At each meeting a Secretary will be appointed who shall keep minutes of the meetings, which shall be voted upon at the next meeting. One designee of each Party shall constitute a quorum for the meetings. The DC shall act by unanimous consent, but in no event may it amend any provisions of this Agreement. In the event of a disagreement between the Acura designees and the Bayer designees relating to a matter within the jurisdiction of the DC, either Party may refer the matter to one designated executive of each Party, other than a Chief Executive, for resolution (a “Senior Executive”). If such Senior Executives cannot resolve the matter within ten (10) Business Days, then Bayer shall have final decision making authority for all DC matters other than disputes relating to: (i) any right or obligation under this Agreement, or (ii) amendment of the Budget or the Target Product Profile or the Development Plan that would require Acura to undertake activities not provided in the Development Plan or incur internal or external costs not fully set forth in the Budget (regardless of whether such amounts are funded in whole or in part by Bayer). Any dispute described in clauses (i) through (ii) above that is not resolved by Senior Executives under this Section shall be submitted for resolution by Chief Executives and, if necessary, to binding arbitration pursuant to Section 12.1. This Section is intended to address only disputes that arise within the specifically delineated jurisdiction of the DC and shall not affect the rights of either Party with respect to matters outside the jurisdiction of the DC. The DC shall:

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- A. review all material Developed Product development, manufacturing and regulatory activities, milestones (including expected launch dates) and accomplishments on a calendar quarter basis;
- B. review and upon mutual agreement, approve changes to the Development Plan, Target Product Profile and the Budget;
- C. evaluate the progress of development of the Developed Product inside and outside the United States and the timing of launch in the United States and such other countries following receipt of Regulatory Approval in the United States and such other countries; and
- D. perform such other responsibilities as may be agreed upon by the Parties in writing from time to time such as a joint development of a Right of First Negotiation Product.

5.5 Budget and Expenses.

All expenses of the Parties (including Acura's approved out-of-pocket expenses) with respect to the DC shall be borne by Bayer. The Budget for the development of the Developed Product (exclusive of milestones to Acura) is attached as Exhibit A. Bayer shall be responsible for [****] of any and all costs including without limitation the actual development and regulatory costs associated with the Developed Product. [****]. Notwithstanding the foregoing, nothing in this Agreement shall obligate Acura to continue development of the Developed Product if Acura will expend more than [****] without the express written consent of Acura [****].

5.6 Schedule of Payment.

- 5.6.1 Within sixty (60) days of the Effective Date, Bayer shall pay Acura for all FTE Expenses and approved out-of-pocket expenses listed on Exhibit E and incurred before the Effective Date.

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5.6.2 Bayer shall reimburse Acura for approved out-of-pocket expenses incurred under the Development Plan within sixty (60) days of receipt of invoice for same.

5.6.3 Any FTE Expense or reimbursement for an expense or payment associated with a “Development Event” item set forth below or incurred prior to the date set forth opposite such Development Event item shall be paid within [****] of Bayer’s receipt of such invoice. The Parties acknowledge that payments due relating to a Development Event may exceed the budgeted amounts for same, as contained in the Budget or as previously approved by the DC.

Development Event
[****]
[****]
[****]

5.6.4 Any FTE Expense for a service/event not described above or contained in the Budget or previously approved in the budget by the DC may be invoiced by Acura after incurrence of the FTE Expense and such invoice shall be paid by Bayer within [****] of Bayer’s receipt of such invoice.

5.6.5 Notwithstanding the foregoing, on expiration or termination of the Agreement, in each case in its entirety, Bayer shall pay all outstanding invoices from Acura within [****] of Bayer’s receipt of such invoices and Acura shall invoice Bayer for all unpaid FTE Expenses, unreimbursed expenses and for services performed under the Development Plan but not paid and incurred to date and Bayer shall make payment within [****] of Bayer’s receipt of such invoice.

5.7 Cooperation for Regulatory Filings.

5.7.1 Acura shall make available to Bayer all relevant Impede® Technology, Information and other documentation relating to the Developed Products Controlled by it, including but not limited to Developed Product design history profile, device master records, existing tool and fixture designs, component specifications and test procedures, component supplier information, and any other data necessary or useful to support the regulatory filings to be submitted by Bayer for the Developed Products in the Territory. From time to time during the Term, at the reasonable request of Bayer, Acura shall provide, [****].

5.7.2 Bayer shall be responsible for all required regulatory activities in the Territory. All costs related to the regulatory activities shall be the responsibility of Bayer, except that Acura shall reasonably cooperate with Bayer to accomplish such regulatory tasks, for which [****].

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- 5.8 Regulatory Approvals and Fees. Bayer shall be the sole owner of the Developed Product Regulatory Approvals, registration materials, clinical documentation, and any and all country specific dossiers for [*****]. Bayer shall be responsible for maintaining the Developed Product Regulatory Approvals and pay any and all fees and expenses in connection therewith including, without limitation, any filing fees, establishment fees, annual product fees, active pharmaceutical supplier fees, and any fees associated with the amendment of a Regulatory Approval, any costs and expenses associated with regulatory changes requested by a Regulatory Authority relating to the Developed Product, or the Developed Product Regulatory Approvals.

ARTICLE VI-RECORDS

- 6.1 Records. During the Term and for [*****] thereafter, each Party shall keep all usual and proper records and books of account and all usual and proper entries relating to the Developed Product. Bayer shall maintain (electronically or otherwise) such records and books of account containing all necessary data for the calculation of Royalty Payments and Milestone Payments due under this Agreement.
- 6.2 Audits. At the request and expense of either Party (“Auditing Party”), the other Party (“Audited Party”) shall permit an independent, certified public accountant reasonably acceptable to the Audited Party, upon giving of reasonable prior written notice of no less than [*****] and not more than once per calendar year, to examine such records during normal working hours, as may be necessary for the sole purpose of verifying the calculation and reporting of Net Sales, reimbursements and the accuracy of any Royalty Payment or other payment or reimbursement made under this Agreement for any period within the preceding [*****]. All results of any such examination shall be made available to the Audited Party. In the event that any audit reveals an under-payment in the amount of any payment obligation that should have been paid by the Audited Party to the other, then the underpayment amount shall be paid within [*****] after the Audited Party’s receipt of Auditing Party’s written demand therefore, plus interest thereon if such amount is in excess of [*****] unless such underpayment is disputed by Bayer. Bayer shall have [*****] to dispute in writing such underpayment determination and if Bayer disputes such underpayment determination, an independent, mutually agreed upon arbiter shall be selected by the Parties to resolve the dispute within [*****] of notice of Bayer’s dispute. The cost of such arbiter shall be borne by the Party whose position is overruled by such arbiter. Such interest shall be calculated from the date such amount was due until the date such amount is actually paid, at the rate of [*****]. In addition, if the underpayment is in excess of [*****], then the Audited Party shall reimburse the Auditing Party for the reasonable cost of such audit.

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ARTICLE VII- CONFIDENTIALITY AND LIMITATIONS ON USE

7.1 Confidential Information. During the term of this Agreement and for a period of five (5) years thereafter, Bayer and Acura shall keep, and each shall cause its respective Affiliates, officers, directors, employees and agents to keep, confidential all Confidential Information. The receiving Party will not disclose the Confidential Information to any third party. The receiving Party will hold the Confidential Information secret and in confidence, and take such steps as it normally takes to protect its own confidential and proprietary information, but in any event no less than reasonable steps, to preserve the confidentiality of the Confidential Information. The receiving Party will use the Confidential Information solely for the Purpose of this Agreement. The receiving Party will not use the Confidential Information for its own benefit or for the benefit of any third party. "Confidential Information" means information that the disclosing Party considers confidential and discloses to the receiving Party for the purpose of this Agreement. Confidential Information must be marked or otherwise identified as confidential or proprietary or, under the circumstances surrounding the disclosure, ought in good faith to be treated as confidential or proprietary. Confidential Information may be conveyed in written, graphical, physical or oral form. Confidential Information may include, without limitation, information concerning the study, discovery, design, research, development, manufacture, formulation, extraction, compounding, mixing, processing, testing, control, preservation, storage, finishing, packing, packaging, use, administration, distribution, sale, reimbursement and/or marketing of pharmaceutical products or compounds and potential products or compounds, data from and methodology of pre-clinical and clinical studies, the contents of any submissions to the U.S. Food and Drug Administration (together with any successor agency), marketing plans or computer hardware and software systems and designs and plans for same. Confidential Information may include confidential or proprietary information of a third party that is in the possession of a disclosing Party. Confidential Information does not include information that: (a) is or hereafter becomes generally available to the public other than by reason of any default with respect to confidentiality under this Agreement, (b) is hereafter disclosed to such Party by a Third Party rightfully in possession of the Confidential Information and without restriction as to confidentiality or use (and such disclosure can be properly demonstrated by the receiving Party), (c) was previously or is hereafter developed by or on behalf of such Party, without reliance on confidential information acquired prior to the date hereof (and such can be properly demonstrated by the receiving Party), (d) the receiving Party obtains from a third party, but only for such time that the receiving Party reasonably believes in good faith that such information was not obtained by said third party, directly or indirectly, from the Disclosing Party under an obligation of confidentiality; or (e) is developed by or for the receiving Party independently of the information provided by the Disclosing Party, as evidenced by the receiving Party's corporate records. Confidential Information shall not be deemed to be in, or have come into, the public domain merely because any part of such Confidential Information is embodied in general disclosures or because individual features, components or combinations thereof are or become publicly known. Nothing in this Agreement shall prohibit a Party from disclosing Confidential Information under confidentiality provisions similar to those in this Agreement, to Third Parties for insurance, consulting, accounting, legal, lending and borrowing, acquisition, investment, divestment or sale and similar purposes, or to any permitted assignee of this Agreement, to the extent considered reasonably necessary to facilitate the assignment. Nothing in this Agreement shall prohibit either Party from disclosing Confidential Information complying with applicable legal or regulatory requirements or a validly issued subpoena, order of a court of competent jurisdiction or other request for information from a governmental agency, seeking disclosure of any Confidential Information, provided that such Party provides prompt notice thereof to the other Party (unless legally prohibited) so that such other Party may seek a protective order or other appropriate remedy. Such Party shall thereafter be entitled to comply with such legal or regulatory requirements, subpoena, court order or other request for information. The Confidential Information that is disclosed pursuant to the prior two sentences section shall remain Confidential Information for all other purposes of this Agreement. Each of Bayer and Acura recognizes that any violation of this confidentiality provision would cause the other irreparable harm and agrees that the other Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction without the posting of any bond or other security, enjoining the disclosing Party, its Affiliates and their respective officers, directors, employees and agents from any violation or potential violation of this Section 7.1. The terms of this Section 7.1 shall survive any termination or expiration of this Agreement for five (5) years, except the obligations with respect to trade secrets shall survive indefinitely. Confidential Information disclosed by an Affiliate of a Party to the other Party shall be deemed to have been disclosed by the Party whose Affiliate disclosed such information.

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- 7.2 Limitations on Use. Bayer and Acura agree that they will not use the Confidential Information of the other Party for any purpose, other than as set forth in this Agreement and carrying out their respective obligations set forth in this Agreement, including, without limitation, publication of any kind, without the prior written consent of such other Party.
- 7.3 Prior Confidentiality Agreement. Nothing herein shall relieve any Party of any breach of that certain Confidentiality Agreement, dated as of January 21, 2014, by and between the Parties with respect to the information disclosed between the Parties prior to the date hereof, provided any information disclosed under such agreement shall also be deemed disclosed under this Agreement and such agreement shall not apply to any information disclosed after the date hereof, which disclosure shall be governed by this Agreement.

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- 7.4 Publicity. A Party may originate any publicity, news release and/or other public announcement, written or oral, relating to the existence or terms of this Agreement or referencing the other party's name, trademarks, trade name or logos (a "Public Disclosure") that is required by Applicable Law, stock exchange and/or regulatory authority (a "Required Public Disclosure"). In the event of any Required Public Disclosure, the disclosing party shall endeavor, on a reasonable basis under the circumstances, to provide a meaningful opportunity for the other party to review and comment upon such Required Public Disclosure before disclosure to the public and shall give reasonable consideration to all reasonable additions, deletions or changes suggested thereto including whether the disclosure is in fact a Required Disclosure. The review and/or comment by a Party on any Required Public Disclosure to be made by the other Party shall not constitute or be deemed confirmation by the reviewing Party of the accuracy of such disclosure, and the originating Party shall solely be responsible for its contents. Mutual consent of the Parties shall be discussed and obtained prior to a Party originating any Public Disclosure that is not a Required Public Disclosure. The contents of any Required Public Disclosure, or Public Disclosure mutually consented to by the Parties, previously released pursuant to this Section 7.4 can be subsequently verbally disclosed only by either Party without the other Party's approval, provided that each Party shall keep the other Party reasonably informed about their plans for such verbal disclosure.
- 7.5 Contacts and Statements. Contacts with the applicable governmental agency with respect to this Agreement shall be coordinated between Acura and Bayer. The Parties shall mutually agree to the responsible Party for initiating such contact. All public statements regarding Bayer trademarks will be the responsibility solely of Bayer. Where practical, all such statements will be provided to Acura for content review prior to release.

ARTICLE XIII- LIABILITY AND INDEMNIFICATION

- 8.1 Maximum Liability. Other than a Party's indemnification obligations (except for [*****) or breach of the confidentiality provisions, each Party's maximum liability to the other Party for any claim arising from this Agreement for any reason whatsoever (excluding monetary consideration for this Agreement, such as such as Milestone Payments, Royalty Payments, reimbursements for FTE Expenses and out-of-pocket costs and expenses) will not exceed [*****)

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- 8.2 Consequential Damages. Except for breaches of the confidentiality provisions, under no circumstances whatsoever will either Party be liable to the other in contract, tort, negligence, breach of statutory duty, or otherwise for (i) any (direct or indirect) loss of profits, of production, of anticipated savings, of business, or goodwill or (ii) for any other liability, damage, costs, or expense of any kind incurred by the other Party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.
- 8.3 Indemnification by Acura. Acura shall indemnify, defend and hold Bayer, its officers, employees and its Affiliates harmless from and against all liabilities, claims, demands, damages, costs, expenses or money judgments (including reasonable attorneys' fees) incurred by or rendered against Bayer, its officers and employees or its Affiliates for personal injury, sickness, disease or death or other damages which arise out of (a) Acura's development of the Developed Product pursuant to the Development Plan (limited to those subjects included in the clinical studies conducted by Acura); (b) Acura's breach of any of its obligations under this Agreement; (c) the gross negligence or intentional misconduct of Acura; or (d) Acura's breach of any representation or warranty made or given in this Agreement.
- 8.4 Indemnification by Bayer. Bayer shall indemnify, defend and hold Acura, its officers, employees and its Affiliates harmless from and against all liabilities, claims, demands, damages, costs, expenses or money judgments (including reasonable attorneys' fees) incurred by or rendered against Acura, its officers and employees or its Affiliates for personal injury, sickness, disease or death or other damages which arise out of: (a) Bayer's breach of any of its obligations under this Agreement; (b) any claims arising out of the development (exclusive of the claims described in Section 8.3(b) above), manufacturing, or commercialization of the Developed Product; (c) the gross negligence or intentional misconduct of Bayer; (d) Bayer's breach of any representation or warranty made or given by Bayer in this Agreement; or (e) any actual or alleged infringement of any Third Party patent, copyright, trademark or trade dress rights arising from materials, labeling, marketing or advertising of the Developed Product.

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8.5 Procedure; Defense.

8.5.1 Each party claiming indemnification must promptly notify the other Party in writing, providing reasonable detail, of any claim upon receipt of notice thereof; provided, however, that failure to give such notice shall not affect the indemnification provided under this Agreement except to the extent the indemnifying Party shall have been actually prejudiced as a result of such failure.

8.5.2 The following provisions shall apply to any Third Party claim for which a Party is entitled to indemnification from the other Party under this Article 8. If the indemnifying Party elects to defend or, if local procedural rules or laws do not permit the same, elects to control the defense of a Third Party claim, it shall be entitled to do so provided it gives notice to the indemnified Party of its intention to do so within [*****] after the receipt of the written notice from the indemnified Party of the potentially indemnifiable Third Party Claim (the "Litigation Condition"). Subject to compliance with the Litigation Condition, the indemnifying Party shall retain counsel reasonably acceptable to the indemnified Party (such acceptance not to be unreasonably withheld or delayed) to represent the indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the indemnified Party. The indemnified Party shall not settle any claim for which it is seeking indemnification without the prior consent of the indemnifying Party which consent shall not be unreasonably withheld, conditioned or delayed. The indemnified Party shall, if requested by the indemnifying Party, cooperate in all reasonable respects in the defense of such claim that is being managed and/or controlled by the indemnifying Party, at the indemnifying Party's cost and expense. The indemnifying Party shall not, without the written consent of the indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed), effect any settlement of any pending or threatened proceeding in which the indemnified Party is, or based on the same set of facts could have been, a party and indemnity could have been sought hereunder by the indemnified Party, unless such settlement includes an unconditional release of the indemnified Party from all liability on claims that are the subject matter of such proceeding and will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the indemnified Party in any manner. Notwithstanding the foregoing, a Party's consent (which shall not be unreasonably withheld, delayed or conditioned) shall be required for any settlement that entails any license, covenant not to sue relating to, admission of invalidity or unenforceability or abandonment of any of its intellectual property. If the Litigation Condition is not met, then the indemnified Party shall have the right to control the defense of such Third Party Claim, for which the indemnifying Party shall pay the reasonable fees and costs incurred by the indemnified Party, and the Parties shall cooperate in and be consulted on the material aspects of such defense at the indemnifying Party's expense.

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ARTICLE IX– NOTICES

9.1 Notices. Any notice or request to be given or furnished under this Agreement by any Party to the other shall be in writing and shall be delivered personally or registered or certified mail, postage prepaid, or by overnight delivery service to the following:

TO ACURA: Acura Pharmaceuticals, Inc.
616 N. North Court
Palatine, IL 60067
Attn: Robert B. Jones
Telephone No. [*****]

Copy To: LeClairRyan
1037 Raymond Blvd.
Newark, NJ 07102
Attn: John P. Reilly, Esq.
Telephone No. [*****]

With a copy to the Attention of the Legal Department at the same address.

TO BAYER: Bayer HealthCare LLC
100 Bayer Blvd.
Whippany, NJ 07981
Attention: Business Development Department
Telephone No.: [*****]

With a copy to the Attention of the Legal Department at the same address.

9.2 Receipt of Notice. All notices and other communications given to any Party in accordance with the provisions of this Agreement shall be deemed to have been given on the date of receipt if delivered by hand or overnight courier services or sent by telecopy, or on the date five (5) business days after dispatch by certified or registered mail (postage prepaid) if mailed, in each case delivered, sent or mailed (properly addressed) to such Party as provided in this Article IX, or in accordance with the latest unrevoked direction from such Party given in accordance with this Article IX.

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ARTICLE X- PATENT PROSECUTION, INFRINGEMENT

- 10.1 Ownership of Intellectual Property Rights. Except as otherwise provided in Section 5.8, Acura shall own [*****]. Bayer owns [*****]. Acura hereby licenses to Bayer, on a non-exclusive basis, the use of the mark Impede® in the Field and Territory solely for the commercialization of the Developed Product during the Term.
- 10.2 Patent Prosecution and Maintenance. Acura is responsible for the prosecution and maintenance of the Impede® Patent Rights in its sole discretion and at its own cost and expense. Acura shall provide Bayer a reasonable opportunity to review and comment on such prosecution and maintenance efforts regarding Impede® Patent Rights in the Territory that may claim the Developed Product, or the making or the use thereof. Acura shall provide Bayer with a copy of material communications from any patent authority in the Territory regarding such Impede® Patent Rights within a reasonable time after receipt of such communications and shall provide drafts of any material filings or responses to be made to such patent authorities in a reasonable amount of time in advance of submitting such filings or responses for Bayer's review and comment. Acura shall reasonably consider such comments by Bayer in connection with the prosecution and maintenance of the Impede® Patent Rights. If Acura decides to cease the prosecution or maintenance of any Impede® Patent Rights that claim the Developed Product, after it has commenced prosecution of such Impede Patent Rights in the Territory, Acura shall notify Bayer in writing at least sixty (60) days prior to any relevant deadline so that Bayer may, at its discretion, assume the responsibility for the prosecution or maintenance of such Impede® Patent Rights in the Territory. Bayer shall have forty (40) days to decide whether or not to assume these costs, during which time Acura shall make Commercially Reasonable Efforts to prepare, prosecute, and maintain any such Impede® Patent Rights. In the event Bayer chooses to maintain such preparation and prosecution or pay such maintenance fees (to the extent it is not already required to pay such fees), Acura agrees to cooperate with Bayer to execute all lawful papers and instruments reasonably necessary to transfer and assign such Impede® Patent Rights to Bayer, at Bayer's sole expense, provided Bayer shall grant Acura an exclusive, perpetual, sub licensable, royalty free license to such Impede Patent Rights other than with respect to the Developed Product.
- 10.3 Infringement of Impede® Patent Rights. Each of Bayer and Acura will notify the other Party within [*****] upon learning of any possible infringement by a Third Party of the Impede® Patent Rights, which infringement may reasonably be expected to affect the commercialization of the Developed Product. [*****][two pages redacted].

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10.7 Allegations of Infringement by Third Parties. [*****][one page redacted].

10.8 Settlement of Allegations of Infringement. [*****].

ARTICLE XI-WARRANTIES

11.1 Mutual Representations, Warranties and Covenants. Each Party represents and warrants that (i) it has the full right, power and authority to enter into this Agreement; (ii) that entering into and performing its obligations set forth in this Agreement does not conflict with any other agreement to which it is a party; and (iii) as at the Effective Date, there are no claims, judgments, litigations, suits, actions, disputes, arbitration, judicial or legal, administrative or other proceedings or governmental investigations pending or, to such Party's knowledge, threatened against such Party or any of its Affiliates, and neither such Party nor its Affiliates is a party to any settlement agreement, which would be reasonably expected to materially affect or restrict the ability of such Party to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement.

11.2 Acura Representations, Warranties and Covenants. Acura represents and warrants that: [*****].

11.3 Bayer's Representations Warranties and Covenants. Bayer represents, warrants and covenants that (i) it shall develop, manufacture, commercialize the Developed Product in accordance with Applicable Law; and (ii) it believes the amounts in the Budget (other than those to be paid to Acura) are reasonable amounts to complete development and receipt of U.S. Regulatory Approval of the Developed Product. [*****].

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ARTICLE XII- MISCELLANEOUS

- 12.1 Dispute Resolution. Bayer and Acura agree to use good faith efforts to resolve any and all disputes arising out of or relating to this Agreement. If after [*****], the Parties are unable to resolve the dispute, then the matter shall be fully and finally resolved by arbitration. A Party that desires to arbitrate a dispute shall serve a written notice upon another requesting arbitration of a dispute pursuant to this Section 12.1. Any such arbitration shall be submitted to final and binding arbitration under the then current commercial arbitration rules of the American Arbitration Association (the "AAA") in accordance with this Section 12.1. The place of arbitration of any dispute shall be New York, New York. Such arbitration shall be conducted by one (1) arbitrator mutually agreed by the Parties but if such agreement cannot be reached within [*****] of the commencement of the arbitration, then an arbitrator appointed by the AAA. The arbitrator shall be a person with relevant experience in the pharmaceutical industry. The arbitration proceeding shall be held as soon as practicable but in any event within [*****] of appointment of the arbitrator. Any award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. The arbitrator shall render a formal, binding, non-appealable resolution and award as expeditiously as possible, but not more than [*****] after the hearing. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrator shall be equally shared between the Parties unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party (including reasonable attorneys' fees) against the other Party. A Party may make application to the Arbitrator for the award and recovery of its fees and expenses (including reasonable attorneys' fees). This Section 12.1, shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by any other Party which would cause irreparable harm to the first Party.
- 12.2 Waivers; Amendment. The failure of either Party to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Agreement or to exercise any right hereunder, shall not be construed as a waiver or relinquishment of the future performance of any such term, covenant or conditions or the future exercise of such right, and the obligation of the other Party with respect to such future performance shall continue in full force and effect. No item or provision of this Agreement may be altered, amended or waived except by a writing signed by both Parties.
- 12.3 Assignment and Sub-License. Neither Party shall sub-license any of its rights or obligations under this Agreement, in whole or in part to any person, firm, partnership, or other entity, except to an Affiliate, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, a Party may assign this Agreement in connection with (i) the transfer of all or substantially all of its assets or its Impede Technology assets (by merger, sale of assets or otherwise) to the transferee thereof or (ii) the sale of its line of business to which this Agreement relates, provided however, that Acura will cause the acquirer to confirm with Bayer prior to closing such transaction that Bayer has such licenses to and a non-compete with respect to the Developed Product as are provided herein. Notwithstanding the foregoing, nothing shall prevent Bayer from offering to acquire the Developed Product intellectual property from Acura on terms negotiated between the parties.

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- 12.4 Other Terms and Conditions. Other terms and conditions not inconsistent with terms and conditions in this Agreement covering Developed Product(s) to be supplied under this Agreement will be provided in purchase orders and releases issued by Bayer and in order acknowledgments and invoices issued by Acura. In the event of any conflict of terms in these documents, Bayer and Acura agree to negotiate in good faith to resolve such differences, unless such terms conflict with the terms of this Agreement, in which case the terms of this Agreement shall control.
- 12.5 Covenant of Further Assurances. Bayer and Acura covenant and agree that subsequent to the execution and delivery of this Agreement and without any additional consideration, each of Bayer and Acura shall execute and deliver any further legal instruments and perform such acts which are or may become necessary to effectuate the purposes of this Agreement.
- 12.6 Headings. The heading of the Articles and Sections used in this Agreement are included for convenience only and are not to be used in construing or interpreting this Agreement.
- 12.7 Governing Law. Unless any competent governmental entity or any other applicable laws and regulations require otherwise, this Agreement shall be governed by and construed under the laws of the State of New Jersey as applied to agreements executed and performed solely in New Jersey, without regard to choice-of-law principles thereof.
- 12.8 Subcontracting. Acura shall not subcontract its obligations hereunder to subcontractors (other than Affiliates) without the prior written consent of Bayer, which shall not be unreasonably withheld, provided however that without such consent Acura may use third party contract research organizations and other service and material providers, as long as Acura actively oversees the project.
- 12.9 Relationship. Acura is an independent contractor engaged by Bayer for the provision of the Developed Product(s). Nothing in this Agreement shall constitute either Party as an employee, agent or general representative of the other, nor shall either Bayer or Acura have the right or authority to assume, create or incur any liability or any obligation of any kind, express or implied, against, or in the name of or on behalf of, the other.

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- 12.10 Severability. The provisions of this Agreement shall be deemed separate. Accordingly, the invalidity or unenforceability of any particular provision of this Agreement shall not affect the other provisions, and this Agreement shall be construed in all respects as if such invalid or unenforceable provision were omitted, except in cases where such unenforceable provision is a basic prerequisite of any Party or both Parties to enter into this Agreement. The Parties shall in such an instance use their best efforts to replace the unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- 12.11 Entire Agreement. This Agreement including all Exhibits and Schedules attached hereto constitutes the entire Agreement between Bayer and Acura with respect to the subject matter addressed herein and this Agreement supersedes all prior understandings and agreements, whether oral or written, between the Bayer and Acura with respect thereto. Any amendment to any provisions set forth in the Agreement must be in writing, signed by both Bayer and Acura and specifically state that it is an amendment.
- 12.12 Counterparts; Facsimile Signatures. This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original and of equal force and effect, but all of which taken together shall constitute one and the same instrument. A facsimile, digital, PDF, e-mail or other electronic copy hereof shall suffice as an original Agreement.
- 12.13 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

IN WITNESS WHEREOF, Bayer and Acura have caused this Agreement to be executed by their duly authorized officers as of the day and year first above written.

ACURA PHARMACEUTICALS, INC.

By: /s/ Robert B. Jones
Name: Robert B. Jones
Title: President & CEO
Date: June 15, 2015

BAYER HEALTHCARE LLC

By: /s/ Mike DiBiasi
Name: Mike DiBiasi
Title: V.P. Allergy
Date: June 5, 2015

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT A

Development Plan

[*****][table redacted]

*****Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.

Exhibit B

BAYER budget and timeline for Delivery of the Prototype [*****].

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

[*****] – Budget

[*****][1.1 pages redacted]	
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*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Exhibit C
Impede® Patent Rights
ISSUED OR NOTICE OF ALLOWANCE

[*****][1.25 pages redacted]

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

EXHIBIT D

Target Product Profile
Including Success Criteria for
Pilot Bioequivalence Study

The following constitutes the Target Product Profile [*****]

Pilot Bioequivalence Study Requirements:

[*****]

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

Exhibit E

Form of Royalty Report.

ROYALTY REPORT

Contract Year Ended _____

Quarter Reported _____

Licensee Name:

Property:

Territory:

Address:

Contact:

Phone Number:

Fax Number:

[*****][1.1 pages redacted]

*****Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.

Exhibit F

Pre-Effective Date Amounts to be Reimbursed to Acura

Item	Quantity	Amount
[*****]	[*****]	[*****]
[*****]	[*****]	[*****]
Total		[*****]

*******Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission; omitted portions have been separately filed with the Commission.**

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert B. Jones, the President & Chief Executive Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this amendment to the quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

February 16, 2016

/s/ Robert B. Jones

Robert B. Jones
President & Chief Executive Officer

CERTIFICATION OF PERIODIC REPORT PURSUANT TO RULES 13a-14 AND 15d-14
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Peter A. Clemens, the Chief Financial Officer of Acura Pharmaceuticals, Inc., certify that:

1. I have reviewed this amendment to the quarterly report on Form 10-Q of Acura Pharmaceuticals, Inc.; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

February 16, 2016

/s/ Peter A. Clemens
Peter A. Clemens
Chief Financial Officer
