Co-development and co-marketing agreement for linaclotide

AstraZeneca
Ironwood Pharmaceuticals

Oct 23 2012
Co-development and co-marketing agreement for linaclotide

Companies: AstraZeneca  
               Ironwood Pharmaceuticals  
Announcement date: Oct 23 2012  
Deal value, US$m: 150 : sum of upfront and commercial milestone payment

Details

Announcement date: Oct 23 2012  
Start date: Oct 23 2012  
Industry sectors: Bigpharma  
                    Pharmaceutical  
Compound name: Linaclotide  
Exclusivity: Exclusive  
Asset type: Compound  
            Gastrointestinal  
            Gastrointestinal » Irritable bowel syndrome  
            Gastrointestinal » Symptoms » Abdominal pain  
            Gastrointestinal » Symptoms » Bowel movement  
            Gastrointestinal » Symptoms » Constipation  
            Biological compounds  
Therapy areas: Drug delivery » Oral delivery  
Deal components: Co-development  
                    Co-market  
Geographic focus: Asia » China

Financials

Deal value, US$m: 150 : sum of upfront and commercial milestone payment  
Upfront, US$m: 25 : upfront payment  
Milestones, US$m: 125 : commercial milestone payments contingent on achievement of certain sales targets  
Royalty rates, %: 50 : revenue share  
Semi-quant royalties: Revenue share

Termsheet

AstraZeneca and Ironwood Pharmaceuticals announced an agreement to co-develop and co-commercialize Ironwood’s linaclotide in China.

Under the terms of the collaboration, AstraZeneca will make an upfront payment of $25 million to Ironwood and will share the net profits and losses associated with linaclotide in China, with AstraZeneca carrying 55 percent of each until a certain specified milestone is achieved, moving to a 50/50 split thereafter.

Ironwood will also be eligible for $125 million in additional commercial milestone payments contingent on the achievement of certain sales targets.

Press Release
AstraZeneca, Inc. (AZN), Ironwood Pharmaceuticals Ink Pact for Up to $150 Million

10/23/2012 7:18:59 AM

CAMBRIDGE, Mass. & LONDON--(BUSINESS WIRE)--AstraZeneca and Ironwood Pharmaceuticals, Inc. (IRWD) announced today an agreement to co-develop and co-commercialize Ironwood’s linaclotide in China. Linaclotide is the first and only guanylate cyclase-C (GC-C) agonist approved by the US Food and Drug Administration, in August.

In May, Ironwood filed a clinical trial application with the State Food and Drug Administration in China for a Phase III clinical trial to assess the efficacy and safety of linaclotide in adult patients suffering from irritable bowel syndrome with constipation (IBS-C). IBS-C, which is characterized by symptoms of abdominal pain and constipation, is a chronic and prevalent functional gastrointestinal disorder in China and there are currently few treatment options for this condition.

"China is one of the fastest growing prescription medicines markets in the world and linaclotide represents a valuable opportunity to meet the needs of local patients by providing an innovative new treatment option," said Mark Mallon, Regional Vice-President for Asia Pacific and President, AstraZeneca China. "We are pleased to be partnering with Ironwood for linaclotide in China, which capitalizes on our leadership in the gastrointestinal sector in the emerging markets."

Peter Hecht, Ironwood’s Chief Executive Officer, said: "As we continue to advance our efforts to make linaclotide available to patients around the world, we are excited about this opportunity to collaborate in China with AstraZeneca, one of the world’s most successful companies in gastrointestinal medicine."

AstraZeneca and Ironwood are jointly responsible for strategic oversight of the development and commercialization of linaclotide in China. AstraZeneca will have primary responsibility for the local operational execution.

Under the terms of the collaboration, AstraZeneca will make an upfront payment of $25 million to Ironwood and will share the net profits and losses associated with linaclotide in China, with AstraZeneca carrying 55 percent of each until a certain specified milestone is achieved, moving to a 50/50 split thereafter. Ironwood will also be eligible for $125 million in additional commercial milestone payments contingent on the achievement of certain sales targets. In addition, the companies also announced today their agreement that Ironwood’s sales force of approximately 160 experienced clinical sales specialists will promote AstraZeneca’s NEXIUM® (esomeprazole magnesium) in the US. This agreement will augment AstraZeneca’s existing interactions with gastroenterologists and primary care physicians on behalf of NEXIUM and the patients who need it. It will also provide Ironwood with an opportunity to increase its presence with the key gastrointestinal physicians in the US. "A large percentage of adult patients who have IBS-C or who have chronic idiopathic constipation, may also suffer from gastroesophageal reflux disease," said Thomas McCourt, Chief Commercial Officer, Senior Vice President, Marketing and Sales, Ironwood Pharmaceuticals. "This agreement provides our experienced clinical sales specialists with the opportunity to bring two different and effective therapies to physicians for managing their patients who have these prevalent and troublesome gastrointestinal disorders. "About Linaclotide Linaclotide is a guanylate cyclase-C (GC-C) agonist that is provided as an oral capsule intended for once-daily administration. It binds to guanylate cyclase C locally in the intestine, with no measurable blood plasma concentrations, resulting in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevations in intracellular cGMP are believed to stimulate secretion of intestinal fluid and accelerate gastrointestinal transit resulting in increased frequency of bowel movements. Elevations in extracellular cGMP are believed to decrease activity of pain-sensing nerves, which is thought to be responsible for a reduction in intestinal pain, according to non-clinical models. About Ironwood Pharmaceuticals Ironwood Pharmaceuticals (IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Ironwood is located in Cambridge, Mass.

Filing Data

10K abstract - 2013

In October 2012, the Company entered into a collaboration agreement with AstraZeneca (the "AstraZeneca Collaboration Agreement") to co-develop and co-commercialize linaclotide in China, including Hong Kong and Macau (the "License Territory"). The collaboration provides AstraZeneca with an exclusive nontransferable license to exploit the underlying technology in the License Territory. The parties will share responsibility for continued development and commercialization of linaclotide under a joint development plan and a joint commercialization plan, respectively, with AstraZeneca having primary responsibility for the local operational execution.

The parties agreed to an Initial Development Plan ("IDP") which includes the planned development of linaclotide in China, including the lead responsibility for each activity and the related FTE and external costs. The IDP indicates that AstraZeneca is responsible for a multinational Phase 3 clinical trial, Ironwood is responsible for nonclinical development and supplying clinical trial material and both parties are responsible for the regulatory submission process. The IDP indicates that the party specifically designated as being responsible for a particular development activity under the IDP shall implement and conduct such activities. The activities are governed by a Joint Development Committee ("JDC"), with equal representation from each party. The JDC is responsible for approving, by unanimous consent, the joint development plan and development budget, as well as approving protocols for clinical studies, reviewing and commenting on regulatory submissions, and providing an exchange of data information.

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The AstraZeneca Collaboration Agreement will continue until there is no longer a development plan or commercialization plan in place, however, it can be terminated by AstraZeneca at any time upon 180 days' prior written notice. Under certain circumstances, either party may terminate the AstraZeneca Collaboration Agreement in the event of bankruptcy or an uncured material breach of the other party. Upon certain change in control scenarios of AstraZeneca, Ironwood may elect to terminate the AstraZeneca Collaboration Agreement and may re-acquire its product rights in a lump sum payment equal to the fair market value of such product rights.

In connection with the AstraZeneca Collaboration Agreement, the Company and AstraZeneca also executed a co-promotion agreement (the "Co-Promotion Agreement"), pursuant to which Ironwood will utilize its existing sales force to co-promote NEXIUM® (esomeprazole magnesium), one of AstraZeneca's products in the U.S. The Co-Promotion Agreement expires upon the earlier of May 27, 2014 or the date on which a generic version of AstraZeneca's product is first sold in the U.S. The Company may terminate the Co-Promotion Agreement on or after December 31, 2013 upon written notice to AstraZeneca.

There are no refund provisions in the AstraZeneca Collaboration Agreement and the Co-Promotion Agreement (together, the "AstraZeneca Agreements").

Under the terms of the AstraZeneca Collaboration Agreement, the Company received a $25.0 million non-refundable upfront payment upon execution. The Company is also eligible for $125.0 million in additional commercial milestone payments contingent on the achievement of certain sales targets. The parties will also share in the net profits and losses associated with the development and commercialization of linaclotide in the License Territory, with AstraZeneca receiving 55% of the net profits or incurring 55% of the net losses until a certain specified commercial milestone is achieved, at which time profits and losses will be shared equally thereafter.

Activities under the AstraZeneca Agreements were evaluated in accordance with ASC 605-25 to determine if they represented a multiple element revenue arrangement. The Company identified the following deliverables in the AstraZeneca Agreements:

- an exclusive license to develop and commercialize linaclotide in the License Territory (the "License Deliverable"),
- research, development and regulatory services pursuant to the IDP (the "R&D Services"),
- JDC services,
- obligation to supply clinical trial material, and
- co-promotion services for AstraZeneca's product (the "Co-Promotion Deliverable").

The License Deliverable is non-transferable and has certain sublicense restrictions. The Company determined that the License Deliverable had standalone value as a result of AstraZeneca's internal product development and commercialization capabilities, which would enable it to use the License Deliverable for its intended purposes without the involvement of the Company. The remaining deliverables were deemed to have stand-alone value based on their nature and all deliverables met the criteria to be accounted for as separate units of accounting under ASC 605-25. Factors considered in this determination included, among other things, whether any other vendors sell the items separately and if the customer could use the delivered item for its intended purpose without the receipt of the remaining deliverables.

The Company identified the supply of linaclotide drug product for commercial requirements and commercialization services as contingent deliverables because these services are contingent upon the receipt of regulatory approval to commercialize linaclotide in the License Territory, and there were no binding commitments or firm purchase orders pending for commercial supply. As these deliverables are contingent, and are not at an incremental discount, they are not evaluated as deliverables at the inception of the arrangement. These contingent deliverables will be evaluated and accounted for separately as each related contingency is resolved. As of December 31, 2012, no contingent deliverables were provided by the Company under the AstraZeneca Agreements.

The total amount of the non-contingent consideration allocable to the AstraZeneca Agreements of $26.9 million ("Arrangement Consideration") includes the $25.0 million non-refundable upfront payment and 55% of the costs for clinical trial material supply services and research, development and regulatory activities allocated to Ironwood in the IDP, or $1.9 million. The Company allocated the Arrangement Consideration of $26.9 million to the non-contingent deliverables based on management's BESP of each deliverable using the relative selling price method as the Company did not have VSOE or TPE of selling price for such deliverables. The Company estimated the BESP for the License Deliverable using a multi-period excess-earnings method under the income approach which utilized cash flow projections, the key assumptions of which included the following market conditions and entity-specific factors: (a) the specific rights provided under the license to develop and commercialize linaclotide; (b) the potential indications for linaclotide pursuant to the license; (c) the likelihood linaclotide will be developed for more than one indication; (c) the stage of development of linaclotide for IBS-C and CIC and the projected timeline for regulatory approval; (d) the development risk by indication; (f) the market size by indication; (g) the expected product life of linaclotide assuming commercialization; (h) the competitive environment; and (i) the estimated development and commercialization costs of linaclotide in the License Territory. The Company utilized a discount rate of 11.5% in its analysis, representing the weighted average cost of capital derived from returns on equity for comparable companies. The Company determined its BESP for the remaining deliverables based on the nature of the services to be performed and estimates of the associated effort and cost of the services adjusted for a reasonable profit margin such that they represented estimated market rates for similar services sold on a standalone basis.
The Company concluded that a change in key assumptions used to determine BESP for each deliverable would not have a significant effect on the allocation of the Arrangement Consideration, as the estimated selling price of the License Deliverable significantly exceeds the other deliverables.

Of the $26.9 million Arrangement Consideration, $24.7 million was allocated to the License Deliverable, $0.3 million to the R&D Services, $28,000 to the JDC services, $0.1 million to the clinical trial material supply services, and $1.8 million to the Co-Promotion Deliverable in the relative selling price model. The Company recognized all $24.7 million allocated to the License Deliverable as revenue upon the execution of the AstraZeneca Agreements as the associated unit of accounting had been delivered and there is no general right of return. At inception, the remaining $0.3 million of the Arrangement Consideration received, and allocated to the remaining deliverables based on their relative selling prices, was deferred. No additional contingent payments were received through December 31, 2012.

Development costs incurred by Ironwood that pertain to the IDP are recorded as research and development expense as incurred. The Company will perform the R&D Services, JDC services and supply clinical trial materials during the estimated development period of approximately 44 months. All Arrangement Consideration allocated to such services will be recognized as a reduction of research and development costs, using the proportional performance method, by which the amounts are recognized in proportion to the costs incurred.

Because the Company shares development costs with AstraZeneca, payments from AstraZeneca with respect to both research and development and selling, general and administrative costs incurred by Ironwood prior to the commercialization of linaclotide in the License Territory are recorded as a reduction to expense, in accordance with the Company’s policy, which is consistent with the nature of the cost reimbursement. Costs incurred by the parties in 2012 were not material to the consolidated financial statements.

As of December 31, 2012, no clinical trial material has been delivered to AstraZeneca; therefore, no reduction of research and development expense was recorded during the year ended December 31, 2012 related to this deliverable.

The amount allocated to the Co-Promotion Deliverable will be recognized as collaborative arrangements revenue using the proportional performance method, which will approximate recognition on a straight-line basis beginning on the date that Ironwood begins to co-promote AstraZeneca’s product, through December 31, 2013 (the earliest cancellation date).

The Company reassesses the periods of performance for each deliverable at the end of each reporting period.

Milestone payments received from AstraZeneca upon the achievement of sales targets will be recognized as earned.

As of December 31, 2012, approximately $275,000 is included in deferred revenue related to the relative selling price of the R&D Services, JDC Services, clinical trial material supply services and Co-Promotion Deliverable, of which approximately $251,000 is included in the current portion of deferred revenue.

**Contract**

**COLLABORATION AGREEMENT**

by and between

IRONWOOD PHARMACEUTICALS, INC.

and

ASTRAZENECA AB

October 23, 2012

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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COLLABORATION AGREEMENT
THIS COLLABORATION AGREEMENT (the "Agreement") is entered into on this 23rd day of October, 2012 (the "Effective Date"), by and among Ironwood Pharmaceuticals, Inc., a corporation organized under the laws of Delaware ("Ironwood") and AstraZeneca AB, a corporation organized under the laws of Sweden ("AstraZeneca"). Ironwood and AstraZeneca may be referred to in this Agreement individually as a "Party" and collectively as the "Parties.

RECITALS

A. Ironwood is developing the Licensed Compound (defined below) which has uses or potential uses in the treatment and prevention of disease in humans.

B. Ironwood (formerly Microbia, Inc.) has entered into a Collaboration Agreement with Forest Laboratories, Inc. ("Forest"), effective as of September 12, 2007, as amended from time to time prior to the Effective Date or in accordance with this Agreement (the "Forest Agreement"), under which Ironwood exclusively licensed to Forest certain rights to the Licensed Compound in the Forest Territory (defined below) and Ironwood and Forest agreed to collaborate on the development and commercialization of such compound in the Forest Territory.

C. Ironwood has entered into a License Agreement with Almirall S.A. (formerly Laboratorios Almirall, S.A.) ("Almirall") effective as of April 30, 2009, as amended from time to time prior to the Effective Date or in accordance with this Agreement (the "Almirall Agreement"), under which Ironwood exclusively licensed to Almirall certain rights to the Licensed Compound in the Almirall Territory (defined below) and Ironwood and Almirall agreed to collaborate on the development and commercialization of such compound in the Almirall Territory.

D. Ironwood has entered into a License Agreement with Astellas Pharma Inc. ("Astellas") effective as of November 10, 2009, as amended from time to time prior to the Effective Date or in accordance with this Agreement (the "Astellas Agreement"), under which Ironwood exclusively licensed to Astellas certain rights to the Licensed Compound in the Astellas Territory (defined below) and Ironwood and Astellas agreed to collaborate on the development and commercialization of such compound in the Astellas Territory.

E. AstraZeneca is engaged in the research, development, manufacture and commercialization of human pharmaceutical products.

F. Ironwood desires to grant to AstraZeneca and AstraZeneca desires to receive an exclusive license to develop, market, and distribute the Licensed Compound in China on the terms and conditions set forth in this Agreement.

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AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

For purposes of this Agreement, the following terms, when used in this Agreement, have the meanings assigned to them in this Article 1.

1.1 “Accounting Standards” means GAAP or IFRS, as applicable.

1.2 [**]

1.3 “Affiliate" means, with respect to a Person, any Person that controls, is controlled by, or is under common control with such first Person. For purposes of this definition only, "control" means (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, more than 50% of the outstanding voting securities or other ownership interests of such Person.

1.4 “Agreement” is defined in the Introduction.

1.5 “Almirall” is defined in Section C of the Recitals.

1.6 “Almirall Agreement" is defined in Section C of the Recitals.

1.7 “Astellas Territory” means the current and any future member states of the European Union (consisting of the following countries as of the Effective Date: Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom), Albania, Andorra, Georgia, Lichtenstein, Iceland, San Marino, Switzerland, Turkey, Norway and Russia, as well as other countries of the former Yugoslavia and those other countries forming the Commonwealth of Independent States.

1.8 [**]
1.9 “Ancillary Agreements” means the Supply Agreement, the Pharmacovigilance Agreement, and the Quality Assurance Agreement.

1.10 “Anti-Corruption Laws” is defined in Section 5.5.1.

1.11 “Applicable Law” means all applicable statutes, ordinances, regulations, rules, or orders of any kind whatsoever of any governmental authority or Regulatory Authority in the Territory or otherwise having jurisdiction over any portion of the Parties’ activities under this Agreement, as amended from time to time.

1.12 “Arbitrator” is defined in Section 10.1.3(a).

1.13 “Astellas” is defined in Section D of the Recitals.

1.14 “Astellas Agreement” is defined in Section D of the Recitals.

1.15 “Astellas Territory” means Japan, South Korea, Taiwan, Thailand, Philippines, and Indonesia.

1.16 “AstraZeneca” is defined in the Introduction.

1.17 “AstraZeneca Collaboration Patent Rights” is defined in Section 7.4.1.

1.18 “AstraZeneca House Marks” means AstraZeneca’s and its Affiliates’ trade names, corporate names and corporate logos.

1.19 “AstraZeneca Indemnified Party” is defined in Section 9.2.

1.20 “AstraZeneca Know-How” means (a) Know-How that AstraZeneca or its Affiliates Controls as of the Effective Date or that comes into the Control of AstraZeneca or any of its Affiliates during the Term (other than Collaboration Know-How, Joint Know-How and Development Data) that is materially used in connection with or incorporated into the Licensed Compound or Product by or on behalf of AstraZeneca or its Affiliates or Sublicensees, except to the extent that any such Know-How relates to any active ingredient other than a Licensed Compound, and (b) Collaboration Know-How (other than Joint Know-How and Development Data) that is invented, conceived, or developed solely by employees of AstraZeneca or its Affiliates, or Third Parties acting on behalf of AstraZeneca or its Affiliates. Notwithstanding the foregoing, in no event shall AstraZeneca Know-How include any Know-How relating to or arising out of packaging or labeling activities of AstraZeneca.

1.21 “AstraZeneca Patent Right” means any Patent Right that is Controlled by AstraZeneca or any of its Affiliates as of the Effective Date or comes into the Control of AstraZeneca or any of its Affiliates during the Term and, in each case, claims AstraZeneca Know-How.

1.22 “AstraZeneca Related Party” is defined in Section 5.6.

1.23 “AstraZeneca Technology” means AstraZeneca’s interest in (a) the AstraZeneca Know-How, (b) the AstraZeneca Patent Rights and (c) all other intellectual property rights in any of the foregoing.

1.24 “Audited Party” is defined in Section 4.3.

1.25 “Auditing Party” is defined in Section 4.3.

1.26 “Authorized Recipient” is defined in Section 5.1.1.

1.27 “Authorized Representative” is defined in Section 5.5.2.

1.28 “Bankruptcy” is defined in Section 8.2.3.

1.29 “Calendar Quarter” means each of the three consecutive month periods ending on March 31, June 30, September 30, and December 31.

1.30 “CC” means chronic constipation.

1.31 “Change of Control” means, with respect to a Person, any of the following: (i) the sale or disposition of all or substantially all of the assets of such Person to a Third Party, (ii) the acquisition by a Third Party, other than an employee benefit plan (or related trust) sponsored or maintained
1.32 “Claim” is defined in Section 10.1.3(a).

1.33 “Clinical Trial Material” means the Licensed Compound in finished dosage form that is used in clinical trials, but not for Commercial sale.

1.34 “Collaboration Know-How” means Know-How that is invented, conceived, or developed by or on behalf of either Party’s or both Parties’ employees or Third Parties acting on such Party’s or Parties’ behalf, in each case in the course of such Party’s or Parties’ performance under this Agreement or any Ancillary Agreement.


1.37 “Combination” is defined in Section 5.6.

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1.38 “Combination Product” means a Product that contains the Licensed Compound in combination with one or more other products or active ingredients, the manufacture, use or sale of which are not covered by a Patent Right Controlled by Ironwood.

1.39 “Commercialization” means any and all activities of importing, marketing, promoting, distributing, offering for sale, or selling a Product in the Territory, including for example pre-First Commercial Sale market development activities conducted in anticipation of Regulatory Approval of Product, seeking pricing reimbursement approvals for Product, if applicable, preparing advertising and promotional materials and sales force training. Commercialization does not include Development or Manufacturing. When used as a verb, “Commercialize” means to engage in Commercialization.

1.40 “Commercialization Budget” means the budget adopted in accordance with Section 3.5.1 for conducting Commercialization activities pursuant to the Commercialization Plan.

1.41 “Commercialization Expenses” means all fully-burdened internal and external costs and expenses (except as otherwise expressly provided in the Commercialization Budget, which provision explicitly acknowledges a deviation from this Section 1.41) (a) associated with Commercialization activities relating to the Commercialization of the Product pursuant to the Commercialization Plan, in each case as set forth in the Commercialization Plan and Commercialization Budget (or constituting a permitted overage thereto under Section 4.2.6), including Selling Expenses, Marketing Expenses, Managed Care Expenses, and all irrevocable, Indirect Taxes and duties, or (b) approved by the JCC as Commercialization Expenses prior to the date on which the Initial Commercialization Plan and the initial Commercialization Budget are approved by the JCC. For clarity, any import duties or non-recoverable VAT incurred due to shipping the Product into the Territory for Commercialization purposes shall be considered a Commercialization Expense. Notwithstanding the foregoing, Commercialization Expenses will not include [**].

1.42 “Commercialization Plan” means the strategic commercialization plan for the Product in the Field in the Territory, as such plan may be amended or updated from time to time in accordance with this Agreement. The Commercialization Plan will include, but is not limited to, (a) a multi-year marketing strategy, (b) a multi-year communications strategy that includes plans for public relations, conferences and exhibitions and other external meetings, internal meetings and communications, publications and symposia, internet activities and core brand package, (c) a high level operating plan for the implementation of such strategies on an annual basis, including information related to product positioning, core messages to be communicated, share of voice requirements and pricing strategies, (d) a multi-year Detailing strategy, including a call plan consisting of a high-level geographic distribution of Details, a targeted range of the aggregate number of Details to be performed in connection with the Commercialization of the Product in the Field in the Territory.

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1.43 “Commercially Reasonable Efforts” means those efforts and resources normally used by [**], taking into account, without limitation, issues of safety and efficacy, product profile, the proprietary position of the product or compound, the regulatory environment and status of the compound, and other relevant scientific factors, market conditions then prevailing, as well as profitability, the extent of market exclusivity, the cost to develop the compound or product, health economic claims, and other similar factors reasonably determined by [**] to be relevant.

“Commercially Reasonable” as used in this Agreement will be interpreted in a corresponding manner.

1.44 “Confidential Information” means, subject to Sections 5.1.2 and 5.1.3, any and all data, results, Know-How (including the Ironwood Know-How and AstraZeneca Know-How) and business information, whether oral or in writing or in any other form, disclosed before, on or after the date of this Agreement by one Party to the other Party under this Agreement or any Ancillary Agreement or prior to the Effective Date. Any information disclosed at a meeting of the JDC, JOC or JCC will constitute Confidential Information unless otherwise specified.

1.45 “Control” or “Controlled” means, with respect to any intellectual property right or Know-How of a Party or any of its Affiliates or, as applicable, Future Acquirer, that the Party or its Affiliates or, as applicable, a Future Acquirer (a) owns, has an interest in, or, other than pursuant to this Agreement, has a license to such intellectual property right or Know-How and (b) has the ability to grant access, a license or a sublicense to such intellectual property right or Know-How to the other Party as provided in this Agreement without violating an agreement with or other rights of any Third Party, provided, however, that (i) any intellectual property right or Know-How of a Party or any of its Affiliates, which intellectual property right or Know-How is acquired after the Effective Date, may be excluded from the scope of the intellectual property rights and Know-How Controlled by such Party by written notice to the other Party if (A) the exercise of such intellectual property or use of such Know-How by the other Party would trigger a royalty or other payment to a Third Party, (B) such intellectual property right or Know-How is not the subject of a license entered into pursuant to Section 7.8 and (C) following notification of the other Party, the other Party [**] and (ii) any intellectual property right or Know-How Controlled by a Future Acquirer of Ironwood will be excluded from intellectual property Controlled by Ironwood for purposes of this Agreement except to the extent that such intellectual property right or Know-How is (A) developed, acquired or otherwise Controlled pursuant to or in connection with a license or other agreement with Ironwood, whether owned by Ironwood or any Future Acquirer for purposes of this Agreement or (b) such intellectual property rights and Know-How, the “Related IP” as of the effective date of the applicable Change of Control of Ironwood, (B) developed or acquired by such Future Acquirer following such Change of Control with the use of the Ironwood Know-How or any Related IP or (C) used in the development, manufacture or commercialization of the Licensed Compound or Product by the Future Acquirer.

1.46 “Counterfeiting” is defined in Section 5.7.

1.47 “CRO” means a qualified clinical research organization.

1.48 [**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

1.49 “Detail” means a face-to-face meeting, in an individual or group practice setting, between one or more physician prescribers and one or more AstraZeneca or Ironwood (if Ironwood exercises its rights under Section 3.5.4) sales representatives during which product information is communicated in a manner consistent with the Commercialization Plan and this Agreement. When used as a verb, “Detail” or “Detailing” will mean to engage in a Detail.

1.50 “Detail Rate” as applicable to both Parties, means the Detail rate set forth in the Commercialization Plan, as amended from time to time. For purposes of applying the Detail Rate, each Detail will be weighted as set forth in the Commercialization Plan. The Commercialization Plan shall specify what costs are intended to be covered by the Detail Rate.

1.51 “Development” means all activities performed by or on behalf of either Party in the performance of the Development Plan. Development will include all activities related to research (including Post-Approval Research), non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, quality assurance/quality control, clinical studies including Phase II, Phase III and pricing studies, medical-scientific affairs, scientific publications, obtaining, maintaining or expanding Regulatory Approval and otherwise handling regulatory affairs, statistical analysis and report writing performed pursuant to the Development Plan with respect to the Product. Development will not include Manufacturing or Commercialization. When used as a verb, “Develop” means to engage in Development.

1.52 “Development Budget” means the budget adopted in accordance with Section 3.1.1 for conducting Development activities pursuant to the Development Plan.

1.53 “Development Data” means any (a) pharmacology, toxicology and other biological data included in the Collaboration Technology that was created to support a Regulatory Submission in the Territory and (b) clinical data included in the Collaboration Technology.

1.54 “Development Expense” means the fully-burdened internal and external costs (except as otherwise expressly provided in the Development Budget, which provision explicitly acknowledges a deviation from this Section 1.54 incurred by a Party in connection with studies or activities performed pursuant to the Development Plan in order to obtain, maintain or expand the relevant Regulatory Approval to Manufacture, use or sell Product in the Field in the Territory to the extent included in the Development Budget. Development Expense will include, in each case to the
extent relating to the Development of the Product and set forth in the Development Plan and Development Budget (or constituting a permitted overage thereto under Section 4.2.6), (a) all out-of-pocket costs and expenses actually incurred by AstraZeneca or Ironwood in conducting such studies or activities including without limitation costs of studies on the toxicological, pharmacological, metabolic or clinical aspects of the Licensed Compound or Product.

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conducted internally or by individual investigators or consultants and necessary for the purpose of obtaining, maintaining or expanding Regulatory Approval of the Product, including Post-Approval Research, process development, process improvement and scale-up costs (including validation, qualification lots, technology transfer and analytical transfer for supply of Licensed Compound or Product to AstraZeneca), (b) the costs of internal personnel engaged in the performance of such studies or activities, including the activities described below in this Section 1.54 (such costs will be included in the Development Budget [**]), (c) all costs of developing data for Regulatory Submissions and all costs associated with making such submissions, (d) all costs related to pharmacovigilance activities (unless included in Commercialization Expenses), (e) all costs of Clinical Trial Materials, (f) all irrevocable, Indirect Taxes and duties, and (g) any other costs that are designated as Development Expenses herein. For clarity, any import duties or non-recoverable VAT incurred due to shipping the Product into the Territory for Development purposes shall be considered a Development Expense. Notwithstanding any other provision of this Agreement to the contrary, [**].

1.55 “Development Plan” means the plan for the development of the Licensed Compound for Regulatory Approval and Post-Approval Research in the Territory, including (a) a multi-year strategy for Phase IV studies and lifecycle management activities, if any, (b) success criteria for any clinical trials included in such Development Plan, (c) a strategy for obtaining, maintaining and, if applicable, expanding Regulatory Approvals for the Product, including an allocation of responsibilities for implementing such strategy and (d) an expected timetable for the completion of such clinical trials, as such plan may be amended or updated from time to time in accordance with this Agreement.

1.56 “Disclosing Party” is defined in Section 5.1.1.

1.57 “Dyspepsia” means functional dyspepsia, postprandial distress syndrome, epigastric pain syndrome, ulcer-like dyspepsia, dysmotility-like dyspepsia and unspecified dyspepsia.

1.58 “Effective Date” is defined in the Introduction.

1.59 [**]

1.60 “Existing Agreements” means the Forest Agreement, the Almirall Agreement and the Astellas Agreement.

1.61 “Fair Market Value” means with respect to a valuation required by any provision of this Agreement, (a) [**], if such valuation must be determined [**], or (b) if clause (a) does not apply, [**]. Fair Market Value will be determined by [**].

1.62 “Field” means all human prophylactic and therapeutic uses of a Product in all Oral Forms for any and all indications, including but not limited to IBS-C, CC, OIC, IBS-A, Dyspepsia and other lower gastrointestinal disorders.

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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

1.63 “First Commercial Sale” means, with respect to the Product, the first sale of such Product under this Agreement for use in the Field to a Third Party in the Territory, after such Product has been granted Regulatory Approval for use in the Field by the competent Regulatory Authorities.

1.64 “Force Majeure” is defined in Section 10.2.

1.65 “Forest” is defined in Section B of the Recitals.

1.66 “Forest Agreement” is defined in Section B of the Recitals.

1.67 “Forest Territory” means the countries of North America, consisting of the United States, Canada, and Mexico, and their respective territories and possessions (including Puerto Rico, irrespective of political status).

1.68 “FTE Rate” means the [**] per employee [**]. The FTE Rates will initially be [**] provided however that such rates may be adjusted from time to time by the JDC, JOC, or JCC, as applicable, and such updated rate will be set forth in the Development Plan or Commercialization Plan, as applicable. The FTE Rate for a full-time equivalent for a Calendar Quarter shall equal 25% of the foregoing annual rate. For purposes of determining the FTE Rate, [**].
1.69 “Future Acquirer” means the Third Party to any Change of Control transaction and such Third Party’s Affiliates immediately prior to the Change of Control.

1.70 “GAAP” means United States generally accepted accounting principles, as in effect from time to time.

1.71 “GC-C Agonist” means a guanylate cyclase C agonist.

1.72 “GI Effect” means all human prophylactic and therapeutic uses for gastrointestinal indications.

1.73 “Good Clinical Practice” or “GCP” means the standards of good clinical practice as are required by governmental agencies in countries in which the Products are intended to be sold under this Agreement.

1.74 “Group” is defined in Section 5.6.

1.75 “IBS-A” means irritable bowel syndrome with alternating bowel habits.

1.76 “IBS-C” means irritable bowel syndrome with the primary manifestation of constipation.

1.77 “ICC” is defined in Section 10.1.3(a).

1.78 “IFRS” means the International Financial Reporting Standards, as in effect from time to time.

1.79 “Impairment” means that (a) it is reasonably anticipated that the entity resulting from a Change of Control of AstraZeneca, Parent or any Local Affiliate will be unable to perform its obligations in accordance with the terms of this Agreement, as reasonably determined based on objective criteria available to both Parties, including the new entity’s financial position and product pipeline, (b) the acquiring entity in such Change of Control or any of its Affiliates (prior to the Change of Control) is actively developing or commercializing a GC-C Agonist indicated for the treatment of IBS-C, CC, or OIC (unless as to any such indication, the JDC has determined not to pursue Development for such indication) or any other indication for which the Product is then being Developed or Commercialized in the Territory pursuant to this Agreement, unless such entity or such Affiliate ceases such activity or [**].

1.80 “Indemnified Party” is defined in Section 9.4.

1.81 “Indemnifying Party” is defined in Section 9.4.

1.82 “Indirect Taxes” means VAT, sales taxes, consumption taxes and other similar taxes required by law to be disclosed on a Tax Invoice.

1.83 “Infringement” is defined in Section 7.6.2.

1.84 “Initial Commercialization Plan” is defined in Section 3.5.1(g).

1.85 “Initial Development Plan” is defined in Section 3.1.2.

1.86 “IPWG” is defined in Section 7.3.

1.87 “Ironwood” is defined in the Introduction.

1.88 “Ironwood House Marks” means Ironwood’s and its Affiliates’ trade names, corporate names and corporate logos.

1.89 “Ironwood Indemnified Party” is defined in Section 9.3.

1.90 “Ironwood Know-How” means (a) Know-How that Ironwood or any of its Affiliates Control as of the Effective Date, including Know-How that has arisen or arises under the Existing Agreements to the extent Controlled by Ironwood or its Affiliates, or that comes into the Control of Ironwood or its Affiliates during the Term (other than Joint Know-How and Development Data) to the extent necessary or useful in the Territory to Develop or Commercialize the Licensed Compound or Product, including without limitation any method of making the Licensed Compound or Product, any composition or formulation of the Licensed Compound or Product, or any method of using or administering the Licensed Compound or Product, except to the extent that any such Know-How relates solely to any active ingredient in a Product other than the Licensed Compound, and (b) Collaboration Know-How (other than Joint Know-How and Development Data) that is invented, conceived or developed by one or more of the following: employees of Ironwood or its Affiliates, or Third Parties acting on behalf of Ironwood or its Affiliates.
1.91 “Ironwood Patent Rights” means (a) any Patent Rights claiming Ironwood Know-How, and (b) any other Patent Rights that Ironwood or any of its Affiliates Control as of the Effective Date, including Patent Rights under the Existing Agreements, or that come into the Control of Ironwood or its Affiliates during the Term (other than Joint Patent Rights) to the extent such rights cover or recite the Licensed Compound or Product, any method of making the Licensed Compound or Product, any composition or formulation of the Licensed Compound or Product in the Territory or any method of using or administering any Licensed Compound or Product, except to the extent that any such Patent Rights relate solely to any active ingredient in a Product other than the Licensed Compound.

1.92 “Ironwood Technology” means Ironwood’s and its Affiliate’s interest in (a) the Ironwood Know-How, (b) the Ironwood Patent Rights, and (c) all other intellectual property rights in any of the foregoing.

1.93 “JCC” is defined in Section 3.5.1(a).

1.94 “JCC Deadlock” is defined in Section 3.5.1(f).

1.95 “JDC” is defined in Section 3.1.1(a).

1.96 “JDC Deadlock” is defined in Section 3.1.1(f).

1.97 “JOC” is defined in Section 3.4.1(a).

1.98 “JOC Deadlock” is defined in Section 3.4.1(f).

1.99 “Joint Know-How” means any Collaboration Know-How, other than Development Data, that is invented, conceived or developed jointly by one or more employees of Ironwood or its Affiliates (or any Third Party or Third Parties acting on any of their behalf) and one or more employees of AstraZeneca or its Affiliates (or any Third Party or Third Parties acting on any of their behalf).

1.100 “Joint Patent Right” means any Patent Right that claims Joint Know-How and names as the inventors one or more employees or agents of Ironwood or its Affiliates together with one or more employees or agents of AstraZeneca or its Affiliates, as determined by U.S. law.


1.102 “Know-How” means all inventions, discoveries, data, information (including scientific, technical or regulatory information), processes, methods, techniques, materials, technology, results, analyses, laboratory, non-clinical and clinical data, or other know-how, whether or not patentable, including without limitation pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies, absorption, distribution, metabolism and excretion studies.

1.103 “Liabilities” is defined in Section 9.1.

1.104 “Licensed Compound” means Ironwood’s proprietary GC-C Agonist generally referred to as “linaclotide” and having the chemical structure set forth on Schedule 1.104 and any salts, metabolites, polymorphs and pro-drugs thereof.

1.105 “Local Affiliate” means any of AstraZeneca’s Affiliates that are responsible for Developing or Commercializing the Product in the Territory.

1.106 “Managed Care Expenses” means the costs and expenses of activities related to obtaining reimbursement from payers, work on managed care accounts and other similar activities directly related to the Commercialization of Products in the Territory.

1.107 “Manufacture,” “Manufactured” or “Manufacturing” means all activities involved in the production, storing, handling, packaging, and labeling of any Licensed Compound or Product to be Developed or Commercialized under this Agreement.

1.108 “Marketing Expenses” means the costs and expenses associated with marketing the Product in the Territory, including costs for preparing and reproducing Detailing aids, Product promotional materials and other promotional materials, costs of professional education, Product-related public relations, relationships with opinion leaders and professional societies, market research, costs of sales and marketing data and other similar activities directly related to the Commercialization of Products in the Territory.

1.109 [**]

1.110 “Milestone Event” is defined in Section 4.2.1.
1.111 "Monetization Transaction" is defined in Section 10.9.

1.112 "Net Loss" means, for a given period, Net Sales in the Territory less Program Expenses incurred in connection with the Development and Commercialization of the Product in the Territory, where the result is a negative number.

1.113 "Net Profit" means, for a given period, Net Sales in the Territory less Program Expenses incurred in connection with the Development and Commercialization of the Product in the Territory, where the result is a positive number.

1.114 "Net Sales" means, with respect to any period, the gross amounts invoiced by AstraZeneca, its Affiliates or Sublicensees, as applicable, to Third Parties for sales of the Product in the Field in the Territory, less the following deductions to the extent included in the gross invoiced sales price for the Product or otherwise directly paid or incurred by AstraZeneca, its Affiliates or Sublicensees, with respect to the sale of the Product in the Territory: (i) trade, quantity or cash discounts credits, adjustments or allowances, including those granted on account of price adjustments, billing errors, rejected goods, or damaged goods; (ii) rebates and chargebacks allowed, given or accrued (including, but not limited to, cash, governmental and managed care rebates, hospital or other buying group chargebacks, and governmental taxes in the nature of a rebate based on usage levels or sales of the Product); (iii) sales, excise, turnover, inventory, and similar taxes (not offset or refunded, except in the case of value added taxes) assessed on the sale of the Product; (iv) bad debts reserved for on the basis utilized by AstraZeneca in its branded pharmaceutical business generally or, if greater, bad debts actually written off, in each case which are attributable to sales of Product; (v) administrative fees paid to group purchasing organization, managed care entities or other similar types of organizations or networks participating in the distribution and/or sales of the Product; (vi) amounts paid or credited to customers for inventory management services; (vii) any other similar and customary deductions that are consistent with GAAP or IFRS, if applicable; and (viii) an allowance for transportation costs, distribution expenses, special packaging and related insurance charges, freight and insurance charges, taken in accordance with AstraZeneca’s standard practices applicable to other of AstraZeneca’s products, which allowance will in no event exceed [%] of the amount arrived at after application of items (i) to (vii) above. Net Sales will be determined in accordance with applicable Accounting Standards. Without limiting the generality of the foregoing, sales, transfers, or dispositions of Product for charitable, promotional (including samples), non-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of Product among a Party and its Affiliates or Sublicensees.

Net Sales of Combination Products will be calculated by first determining Net Sales of such Combination Product (in its entirety) pursuant to the foregoing and then multiplying the Net Sales of the Combination Product by the fraction A/(A+B), where A is the gross invoice price of the Licensed Compound if sold separately as a single agent Product in the Territory and B is the gross invoice price of the other active ingredient(s) sold as single agent product(s) included in the Combination Product if sold separately in the Territory. In the event no such separate sales are made by AstraZeneca, its Affiliates or Sublicensees, in the Territory, Net Sales of the Combination Product will be calculated by multiplying such Net Sales by a fraction fairly and reasonably reflecting the relative value contributed by the Licensed Compound or Product to the total value of the Combination Product as determined by the Parties in good faith.

1.115 "New Drug Application" or "NDA" means a new drug application filed with a Regulatory Authority (not including pricing and reimbursement approval), that is analogous to the new drug application with the United States Food and Drug Administration described in 21 C.F.R. § 314.

1.116 "Official" is defined in Section 5.5.2.

1.117 "OIC" means opioid induced constipation.

1.118 "Oral Form" means a finished dosage form that is delivered to the gastrointestinal tract after delivery through the mouth, in any dosage strength or form. Specifically, an Oral Form includes forms that dissolve in the mouth but not forms that are delivered by injection or inhalation.

1.119 "Order" is defined in Section 5.1.3.

1.120 [%]

1.121 “Other Out-of-Pocket Costs” means the (a) costs incurred in connection with [%], (b) costs incurred in [%], (c) costs incurred in [%], and (d) such other costs as are designated as Other Out-of-Pocket Costs herein or otherwise mutually agreed upon by the Parties. All costs included in the foregoing will be fully burdened internal and external costs except as otherwise agreed by the Parties in writing.

1.122 "Parent" is defined in Section 8.4.2.
1.123 “Party” and “Parties” is defined in the Introduction.

1.124 “Patent Rights” means any and all (a) U.S. or foreign patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (b) all U.S. or foreign patents, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, and (c) any other form of government-issued right substantially similar to any of the foregoing.

1.125 “Payments” is defined in Section 4.4.1.

1.126 “Person” means any individual, corporation, company, limited liability company, partnership, limited liability partnership, trust, estate, proprietorship, joint venture, association, organization, or entity.

1.127 “Pharmacovigilance Agreement” is defined in Section 3.2.4.

1.128 “Phase II” in reference to a clinical trial means a trial defined in 21 C.F.R. 312.21(b), as may be amended from time to time, or any foreign equivalent thereto.

1.129 “Phase III” in reference to a clinical trial means a trial defined in 21 C.F.R. 312.21(c), as may be amended from time to time, or any foreign equivalent thereto.

1.130 “Phase IV” in reference to a clinical trial means a trial conducted for purposes of further characterizing and supporting the Product for marketing but not for purposes of seeking Regulatory Approval or otherwise fulfilling a requirement of a Regulatory Authority.

1.131 “Post-Approval Research” means ongoing research and development of a Product after such Product has received Regulatory Approval in the Territory, including Phase IV clinical studies and clinical studies in support of indications within the Field or labeling changes for such Product within the Field in the Territory during the Term.

1.132 “Procurement Costs” means any costs or expenses of AstraZeneca or its Affiliates incurred in its capacity as purchaser of Product for sale in the Territory under the Supply Agreement that are not reimbursed under the Supply Agreement, including any [**], but excluding (a) [**] and (b) [**].

1.133 “Product” means any pharmaceutical product in finished form that contains the Licensed Compound either as the sole active ingredient or in a Combination Product, in any present or future Oral Forms. For the avoidance of doubt, “Product” excludes non-Oral Forms, including intravenous and inhalable forms.

1.134 “Product Domain Name” is defined in Section 7.5.1.

1.135 “Product Liability Claims” is defined in Section 9.1.

1.136 “Product Trademarks” is defined in Section 7.5.1.

1.137 “Program Expenses” means the Development Expenses, Commercialization Expenses, Supply Costs, Procurement Costs, and Other Out-of-Pocket Costs. Any category of Program Expenses is intended to include those costs and expenses incurred by either a Party or its Affiliates in accordance with this Agreement.

1.138 “Prohibited Payment” is defined in Section 5.5.2.

1.139 “Quality Assurance Agreement” is defined in Section 3.4.2.

1.140 “Receiving Party” is defined in Section 5.1.1.

1.141 “Reconciliation Report” is defined in Section 4.2.5.

1.142 “Referenced Regulatory Filings” means all Regulatory Submissions Controlled by Ironwood or any of its Affiliates on the Effective Date and during the Term, including Regulatory Submissions to which Ironwood receives a transferable Right of Reference from other licensees of the Licensed Compound or Product, that are necessary or useful to Manufacture the Licensed Compound or Product anywhere in the world or Develop or Commercialize the Licensed Compound or Product in the Field in the Territory.

1.143 “Regulatory Approval” means the approval and authorization of a Regulatory Authority in a country necessary to develop, manufacture, distribute, sell, or market a Product in that country, including pricing and reimbursement approval.

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
1.144 “Regulatory Authority” means any government regulatory authority involved in granting approvals for the development, manufacturing, distribution, marketing, reimbursement or pricing of a Product.

1.145 “Regulatory Submission” means any application for Regulatory Approval, notification, and other submission made to or with a Regulatory Authority that is necessary or reasonably desirable to develop, manufacture, distribute or commercialize the Product in the Field in a particular country, whether obtained before or after a Regulatory Approval in the country. Regulatory Submissions include, without limitation, investigational new drug applications, clinical trial applications and NDAs or imported drug license (IDL) applications, and amendments, renewals and supplements to any of the foregoing and their foreign counterparts, applications for pricing and reimbursement approvals, and all proposed labels, labeling, package inserts, monographs, and packaging for the Product.

1.146 “Reimbursement Drug List” means the Medicine Catalog for the National Basic Medical Insurance, Industrial Injury Insurance and Maternity Insurance issued by the Ministry of Human Resource and Social Security, and any revisions or reissuances thereof from time to time, in China.

1.147 “Responsible Party” means, with respect to any activity to be performed by a Party in connection with the obtaining, maintaining or expanding of a Regulatory Approval in the Territory, the Party identified in the Development Plan or designated by the JDC as the Party responsible for conducting such activity. In the absence of such a designation, [**] is considered the Responsible Party.

1.148 “Revenue Buyer” is defined in Section 10.9.

1.149 “Right of Reference” is defined in Section 2.4.

1.150 “Safety Panel” means a panel of [**]. In the event the Parties are required to select a Safety Panel, each Party will [**]. Each Party will [**]. The decision of [**] will be deemed the decision of the Safety Panel. The Parties will instruct the Safety Panel to reach its decision as promptly as practicable, but within [**]. The costs of any Safety Panel will be [**].


1.152 “Selling Expenses” means for Detailing, the applicable Detail Rate multiplied by the number of Details weighted in accordance with the Commercialization Plan and other selling costs and expenses not included in the Detail Rate, including [**].

1.153 “Shared Liability Claims” is defined in Section 9.1.

1.154 “Subject Technology” is defined in Section 7.6.5.

1.155 “Sublicense” means an agreement or arrangement pursuant to which a sublicense or distribution right has been granted.

1.156 “Sublicensee” means a Third Party that is granted a license, sublicense, covenant not to sue, or other grant of rights under this Agreement pursuant to the terms of this Agreement.

1.157 “Sued Party” is defined in Section 7.7.2.

1.158 “Summary Statement” is defined in Section 4.2.3.

1.159 “Supply Agreement” means the Manufacturing and Supply Agreement to be entered into pursuant to Section 3.3.1.

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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

1.160 “Supply Costs” means, for a given period, (a) the sum of (i) the quantity of Product sold by AstraZeneca or its Affiliates in the Territory in such period and (ii) the quantity of Product written off by AstraZeneca or its Affiliates in accordance with Accounting Standards (e.g., expired Product or Product otherwise rendered unusable), in each case ((i) and (ii)), multiplied by [**].

1.161 “Supply Price” will have the meaning set forth in the Supply Agreement (see Exhibit B).

1.162 “Tax” or “Taxation” means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority.
1.163 “Tax Authority” or “Tax Authorities” means any government, state or municipality, or any local, state, federal or other fiscal, revenue, customs, or excise authority, body or official anywhere in the world, authorized to levy tax.

1.164 “Tax Invoice” means an invoice including such particulars as are required by any law imposing Tax and such other information as required to claim any credit allowed under a law imposing Tax.


1.166 “Term” is defined in Section 8.1.

1.167 “Territory” the People's Republic of China, including Hong Kong and Macau, but excluding Taiwan.

1.168 “Third Party” means any Person other than Ironwood, AstraZeneca and their respective Affiliates.

1.169 “Third Party Claims” is defined in Section 9.1.

1.170 “Trademark” means all trademarks, service marks, trade names, brand names, sub-brand names, trade dress rights, product configuration rights, certification marks, collective marks, logos, taglines, slogans, designs or business symbols and all words, names, symbols, colors, shapes, designations or any combination thereof that function as an identifier of source or origin or quality, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.171 “Trigger Year” means the first Year in which [**].

1.172 “U.S. Bankruptcy Code” means Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States.

1.173 “United States” or “U.S.” means the United States of America, its territories and possessions (including Puerto Rico, irrespective of political status).

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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

1.174 “Valuation Panel” means a panel of [**]. In the event the Parties are required to select a Valuation Panel, each Party will [**]. Each Party will [**]. The decision of [**] will be deemed the decision of the Valuation Panel. The Parties will instruct the Valuation Panel to reach its decision as promptly as practicable, but within [**]. The costs of this Valuation Panel will be [**].

1.175 “Year” means each 12 month period ending December 31st.

2. LICENSE GRANT

2.1. License to AstraZeneca. Subject to the terms and conditions of this Agreement, Ironwood hereby grants to AstraZeneca, a perpetual (except as otherwise provided in Section 8), exclusive, nontransferable (except as set forth in Section 10.9) license, with the right to grant sublicenses as described in Section 2.6 and, subject only to the rights reserved to Ironwood to the extent necessary to perform its obligations or exercise its rights hereunder under the Ironwood Technology and Ironwood's interest in the Joint Technology and Development Data to Develop the Licensed Compound and Products pursuant to the Development Plans and to Commercialize Products pursuant to the Commercialization Plans in each case, in the Field in the Territory and, subject to Section 3.3, to make or have made the Licensed Compound or Products anywhere in the world for Development or Commercialization in the Field in the Territory. Notwithstanding the foregoing, Ironwood reserves the right under the Ironwood Technology and Ironwood’s interest in the Joint Technology and the Development Data to (a) subject to Section 3.2.5(c), develop and manufacture the Licensed Compound and Products inside or outside of the Territory in support of development or commercialization of the Licensed Compound and Products outside of the Territory, (b) Develop and Manufacture the Licensed Compound and Products in the Territory and Commercialize the Products in the Territory in the Field pursuant to Section 3.5.4 upon exercise of Ironwood’s rights thereunder, (c) develop and commercialize the Licensed Compound and Products in the Territory outside of the Field, and (d) commercialize the Licensed Compound and Products outside of the Territory, in each case ((a) through (d)) in accordance with any applicable terms of this Agreement. Unless and until specified in Section 5.3, [**]. The Parties acknowledge that the Development Plan currently contemplates and may in the future contemplate certain Development activities for the Territory that may occur outside the Territory and agree that such Development activities for such purpose shall be considered in the Territory for purposes of this Agreement.

2.2. License to Ironwood. Subject to the terms and conditions of this Agreement, AstraZeneca hereby grants to Ironwood (a) a perpetual, royalty-free, exclusive, nontransferable (except as set forth in Section 10.9) license, with the right to sublicense to any Third Party to the extent that corresponding rights are granted to Ironwood by its Sublicensee and sublicensed to AstraZeneca hereunder, under the AstraZeneca Technology to develop, manufacture and commercialize the Licensed Compound or Products outside of the Territory and to develop and manufacture the Licensed Compound or Products in the Territory for purposes of commercialization
outside of the Territory or commercialization in the Territory outside of the Field, (b) a perpetual, royalty-free, exclusive, nontransferable (except as set forth in Section 10.9) license, with the right to sublicense to any Third Party to the extent that corresponding rights are granted to Ironwood by its Sublicensee and sublicensed to AstraZeneca hereunder, under AstraZeneca’s interest in the Joint Technology and Development Data to develop, manufacture and commercialize the Licensed Compound or Products or any other GC-C Agonist outside of the Territory and to develop and manufacture the Licensed Compound or Products or any other GC-C Agonist in the Territory for purposes of commercialization outside of the Territory or commercialization in the Territory outside of the Field and (c) a perpetual, royalty-free, non-exclusive, nontransferable (except as set forth in Section 2.6 and Section 10.9) license under the AstraZeneca Technology and AstraZeneca’s interest in the Joint Technology and Development Data to Develop and Manufacture the Licensed Compound or Products in the Territory, to Commercialize the Products in the Territory in the Field pursuant to Section 3.5.4 upon exercise of Ironwood’s rights thereunder and to perform its obligations under this Agreement, all in accordance with any applicable terms of this Agreement.

2.3. Joint Technology and Development Data. Subject to the terms and conditions of this Agreement, each Party hereby grants the other Party a world-wide, non-exclusive, perpetual, royalty-free, fully paid up, freely sublicensable right and license under its interest in the Joint Technology and the Development Data (a) to exploit compounds that are not GC-C Agonists and products containing compounds that are not GC-C Agonists anywhere in the world, and (b) without compensating or accounting to the other Party.

2.4. Rights of Reference. Ironwood hereby grants to AstraZeneca a “Right of Reference,” as that term is defined in 21 C.F.R. § 314.3(b) and any foreign counterpart to such regulation, to the Referenced Regulatory Filings and the Development Data to the extent necessary or useful to Develop, Manufacture or Commercialize the Licensed Compound or Product in the Field in the Territory, in each case, pursuant to the Development Plan or Commercialization Plan and otherwise subject to the terms and conditions of this Agreement. AstraZeneca hereby grants to Ironwood (and any current or future licensee by Ironwood of the Licensed Compound) such a Right of Reference to the Development Data to the extent necessary or useful to (a) subject to Section 3.2.5(c), develop and manufacture the Licensed Compound and Products inside or outside of the Territory in support of development or commercialization of the Licensed Compound and Products outside of the Territory, (b) Develop and Manufacture the Licensed Compound and Products in the Territory and Commercialize Products in the Territory in the Field pursuant to Section 3.5.4 upon exercise of Ironwood’s rights thereunder, (c) develop and commercialize the Licensed Compound and Products in the Territory outside of the Field or manufacture the Licensed Compound and Products in the Territory for use outside of the Field and (d) commercialize the Licensed Compound and Products outside of the Territory, in each case (a) through (d) in accordance with any applicable terms and conditions of this Agreement. Each Party will provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R.

2.5. Use of Third Party Contractors. Subject to Section 3.2.5(a) and Section 3.5.5, the Supply Agreement and the Quality Assurance Agreement, (a) AstraZeneca may grant a Sublicense of its rights under this Agreement to [**], provided that [**], provided further, that if [**], then [**], and (b) Ironwood may grant a Sublicense of its rights under this Agreement to [**], provided, that, [**].

2.6. Sublicensing. Each Party may only sublicense the rights granted to such Party under this Agreement as provided in Section 2.2, Section 2.3, Section 2.5 and Section 8.5 and in accordance with the provisions of Section 3.2.5(a) and Section 3.5.5. Any Sublicenses granted by either Party pursuant to such Sections will be consistent with the terms of this Agreement. In addition, each Party will require any licensee with respect to the Licensed Compound or Product or Sublicensee, whether within or outside the Territory, to cross-license or otherwise transfer or convey back to the granting Party all Technology which such licensee or Sublicensee may develop or acquire in connection with its activities with respect to the Licensed Compound and Products that would constitute Ironwood Technology or AstraZeneca Technology if arising under Ironwood’s or AstraZeneca’s (or their respective Affiliates’) activities, respectively, so that any such Technology will be Controlled by the granting Party for purposes and to the extent of the licenses to the other Party provided by Sections 2.1, 2.2 and 2.3 above. Notwithstanding the foregoing, [**].

2.7. Section 365(n). All rights and licenses granted under or pursuant to this Agreement by AstraZeneca or Ironwood are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code, the Party hereto that is not a party to such proceeding will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property and any such intellectual property and all embodiments of such intellectual说起。
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Meetings of the JDC will be effective only if at least one representative of each Party is in attendance or participating in the meeting. JDC members may participate in and vote at meetings by telephone. Each Party will be responsible for expenses incurred by its employees and its members of the JDC in attending or otherwise participating in JDC meetings. Such expenses shall not constitute Program Expenses. Each Party will use reasonable efforts to cause its representatives to attend the meetings of the JDC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate with equivalent experience and authority as such representative to attend such meeting in place of the absent representative.

(e) Minutes. The minutes of each JDC meeting will provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JDC.

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Minutes of each JDC meeting will be approved or disapproved, and revised as necessary, at the next meeting.

(f) Elevation and Dispute Resolution. Each Party’s representatives on the JDC will collectively have one vote on all matters that are within the responsibility of the JDC. The members of the JDC will use reasonable efforts to reach consensus on all decisions. In the event that the members of a JDC are unable to agree on a particular issue after endeavoring to reach consensus for a period of 30 days (a “JDC Deadlock”), at the request of either Party, such JDC Deadlock will be submitted to AstraZeneca’s VP CVGI gMED and Ironwood’s Chief Scientific Officer or, in each case, his or her designees. Such executives or their designees will meet (in person or by teleconference) to attempt in good faith to resolve such JDC Deadlock through discussions promptly following submission thereof, and in any event within 15 days thereafter, unless otherwise mutually agreed upon by the executives or their designees. In the event such individuals are unable to resolve such issue within 15 days, such issue will be referred to the Chief Executive Officer of Ironwood and the EVP of Global Medicines Development of AstraZeneca or, in each case, his or her designee for resolution. Such executives or their designees will meet (in person or by teleconference) to attempt in good faith to resolve such JDC Deadlock through discussions promptly following submission thereof, and in any event within 15 days thereafter, unless otherwise mutually agreed upon by the executives or their designees. If a matter for which consensus cannot be reached following escalation in accordance with this Section 3.1.1(f) is addressed by the Development Plan, then [**].

3.1.2. Development Plan. The initial Development Plan is set forth in Exhibit A (the “Initial Development Plan”). The JDC will direct, coordinate, and manage the Development of the Product in the Field, according to the Development Plan. The Development Plan will include, among other things, the indications in the Field for which the Product is to be Developed and other exploratory indications in the Field for which the Product may be developed, critical activities to be undertaken, certain timelines, go/no go decision points and relevant decision criteria and certain allocations of responsibilities between the Parties for the various activities to be undertaken under the Development Plan. During the Term, the JDC will review the Development Plan and Development Budget at least once per Year and will amend such Development Plan and Development Budget on an ongoing basis as necessary. The then-current Development Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the Initial Development Plan.

3.1.3. Development Responsibility.

(a) Except as specifically set forth in the Development Plan, using the efforts set forth in Section 3.1.4, AstraZeneca will implement and conduct

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all clinical Development activities set forth in the Development Plan in accordance with the Development Plan, Applicable Law and GCP.

(b) Except as otherwise provided in the Development Plan, Ironwood will implement and conduct any non-clinical Development activities set forth in the Development Plan using the efforts set forth in Section 3.1.4 in accordance with such Development Plan and Applicable Law and AstraZeneca will not conduct any such non-clinical Development activities. If Ironwood is assigned any Development activities under this Agreement, Ironwood will conduct such activities in accordance with the Development Plan, Applicable Law and GCP.

3.1.4. Diligence. Each Party will use Commercially Reasonable Efforts to conduct the Development activities assigned to it in the Development Plan and all activities reasonably necessary to achieve the goals of such assigned activities.

3.1.5. Future Development Activities. The JDC will make recommendations regarding whether to Develop a Product for new indications or new formulations. Any such recommendations that are approved by the JDC will become part of the Development Plan.

3.1.6. Reports of Development Activities. Each Party will report on Development activities undertaken by it in accordance with the Development Plan in connection with meetings of the JDC, including by providing a reasonably detailed summary of all results, data, and material Collaboration Know-How generated from such activities. In addition, each Party will, at its own expense, make appropriate scientific and regulatory personnel available to the other Party, either by telephone or in person as the Parties may mutually agree, as reasonably required to
3.2. Regulatory Matters.

3.2.1. Responsibility For Regulatory Interactions. Regulatory strategy for the Products in the Territory and all decision-making with respect thereto will be determined by the JDC. Subject to the other Party's conduct of activities allocated to such other Party under the Development Plan, the Responsible Party will use Commercially Reasonable Efforts to obtain in a timely manner Regulatory Approvals for Products in the Territory.

3.2.2. Regulatory Cooperation. Each Party will keep the other Party reasonably informed regarding the status and progress of its Development activities relating to the obtaining, maintaining or expanding of any Regulatory Approval in accordance with the provisions set forth on Exhibit D. Subject to the Development Budget and Section 4.2.6, all costs and expenses incurred by a Party in carrying out its allocated regulatory activities pursuant to this Agreement [**].

3.2.3. Clinical Trial Data. [**] will be responsible, at its own expense, for maintaining a database of clinical trial data being developed under this Agreement [**]. Also at its expense, [**] will provide [**] with copies of any such clinical trial data that is necessary or useful in connection with any Regulatory Submission made by [**] in the Territory.

3.2.4. Adverse Events. The Parties will use good faith efforts to enter into a pharmacovigilance agreement within 30 days after the Effective Date, or earlier if required by Applicable Law and will be incorporated into this Agreement by reference (the 'Pharmacovigilance Agreement'). The Parties will comply and cause their respective Affiliates to comply with the provisions of such agreement. All costs and expenses incurred by the Parties or their respective Affiliates in performing their respective obligations under the Pharmacovigilance Agreement [**].

3.2.5. Clinical Trials.

(a) Any clinical trials conducted in accordance with the Development Plan by [**] will be conducted [**]. In the event that [**] engages [**] to undertake any such clinical trial (or any portion of any clinical trial or other clinical trial task), [**] will be qualified in such country and capable of producing data acceptable to the Regulatory Authorities in such country. [**] will [**]. Except as set forth in the Development Plan, any studies conducted in the Territory will be conducted only at hospitals that are, to the extent applicable, accredited by the Regulatory Authorities for the country in which such studies are conducted. Any studies will be conducted in accordance with GCP and involve investigators of recognized competence. If so requested by Ironwood, to enable Ironwood to use study data from the Territory in support of its Regulatory Submissions outside of the Territory, AstraZeneca will permit, and will use reasonable efforts to require any clinical trial sites to permit, Regulatory Authorities from outside of the Territory to validate any such clinical trial data through on-site inspections to the extent any such on-site inspections do not materially interfere with AstraZeneca's or such clinical trial sites', as applicable, day-to-day operations; provided that Ironwood provides reasonable advance notice of such inspection, and such inspections do not occur more than once in any given year for a given site, unless required by applicable law.

(b) The Parties acknowledge that [**] is required to [**] and (i) with respect to any clinical studies that are reasonably necessary to obtain, maintain or expand Regulatory Approval for the Product in the Territory, [**] and (ii) with respect to any pre-clinical or clinical studies of the Product, including Phase IV studies, that are not required for registration or imposed by a Regulatory Authority in the Territory, [**]. For the avoidance of doubt, any such studies that are not required for registration or imposed by a Regulatory Authority in the Territory will constitute Post-Approval Research under the Development Plan. The foregoing rights of Forest apply to the extent and for so long as Forest has such

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3.3. Supply of Products.

3.3.1. General. The Parties shall negotiate and enter into the Supply Agreement no later than [**], on the terms set forth in Exhibit B. Subject to the Supply Agreement, (a) Ironwood will be the exclusive supplier of Clinical Trial Material and Product, in each case, for use in the Field in the Territory (which shall be supplied in fully packaged and labeled form and, if applicable, in such other forms as determined in accordance with the Supply Agreement), and (b) AstraZeneca will order its requirements for Clinical Trial Material and such Product from Ironwood, which exclusivity and requirement commitments will be subject to the failure to supply and other provisions under the Supply Agreement. For the avoidance of doubt, the supply by Ironwood of Product is outside the scope of this collaboration and governed separately by the Supply Agreement. Ironwood represents and warrants that [**] and in particular that [**] and that [**].

3.3.2. Recall. To the extent not constituting Third Party Claims covered by Section 9.1, 9.2 or 9.3, the costs and expenses of any recall or product withdrawal of a Product in the Territory for Product sold during the Term (even if incurred after the Term) [**].

3.4. Operations.

3.4.1. Joint Operations Committee.

(a) General. Within [**] days after the Effective Date, the Parties will establish a joint operations committee ("JOC"). The JOC will oversee the supply to AstraZeneca of Clinical Trial Material and Products for Development and Commercialization in the Field in the Territory. The JOC will coordinate supply efforts under the Supply Agreement for the Territory and will serve as a forum regarding the foregoing in the Field in the Territory. The Parties anticipate that the JOC will perform the functions ascribed to it in this Section 3.4.1; provided, however, that the functions and operations of the JOC may be altered from time to time during the Term by the mutual written agreement of the Parties to appropriately address ongoing requirements with respect to the supply of Clinical Trial Material and Products for Development and Commercialization in the Territory.

(b) Membership. The JOC will consist of three senior representatives of appropriate seniority and geographical responsibility from each Party. Ironwood and AstraZeneca will each designate a co-chair for the JOC. The co-chairs of the JOC will be responsible for calling meetings of the JOC and setting the agenda for such meetings (which will include a list of all participants expected at such meeting) and circulating such agenda at least ten days, or such other period as agreed by the co-chairs, prior to each meeting and distributing minutes of each meeting within 30 days following such meeting (which minutes will be in the English language), but will not otherwise have any greater power or authority than any other member of the applicable JOC. JOC members must have such expertise as appropriate to the activities of the applicable JOC. From time to time, the JOC may invite personnel of the Parties having development, manufacturing, financial and other expertise to participate in discussions of the JOC as appropriate to assist in its activities.

(c) Responsibilities. Subject to Section 3.4.1(a) and the terms of the Supply Agreement, the JOC will be responsible for overseeing supply matters, including future capacity plans, sourcing strategies, technology transfers, and other related issues, in each case, relating to the Territory, and for those matters specified in the Supply Agreement. Notwithstanding anything to the contrary herein, the JOC, rather than the JDC, shall be responsible for oversight of scale-up of the Product, provided that any budget therefor shall be by consensus and subject to clause (i)(C) below.

3.4.2. Meetings. The first meeting of the JOC will take place within 120 days after the Effective Date at a location outside the United States. Thereafter, the JOC will meet at such frequency as will be established by the Parties (but not less frequently than once per Calendar Quarter). Meetings of the JOC will be held [**] and alternate between a location selected by AstraZeneca and a location selected by Ironwood, unless otherwise agreed upon by the members of the JOC, or may be held telephonically or by video conference. Meetings of the JOC will be held only if at least one representative of each Party is in attendance or participating in the meeting. JOC members will have the right to participate in and vote at meetings by telephone. Each Party will be responsible for expenses incurred by its employees and its members of the JOC in attending or otherwise participating in JOC meetings. Such expenses shall not constitute Program Expenses. If a representative of a Party is attending or otherwise participating in JOC meetings. Such expenses shall not constitute Program Expenses. If a representative of a Party is
and selecting the Product Trademarks and Product Domain Names in the Territory; (viii) preparing and providing the JOC with a forecast of
promotion, brand integrity, sales, and launch sequence); (iv) establishing [**]; (v) reviewing the annual marketing plans for Product(s) in the Field
Officer of Ironwood and the EVP of Operations of AstraZeneca, or, in each case, his or her designee for resolution. Such executives or their
cannot resolve such JOC Deadlock within 15 days, at the request of either Party, such JOC Deadlock will be submitted to the Chief Executive
following such meeting (which minutes will be in the English language), but will not otherwise have any greater power or authority than any other
Commercialization is established pursuant to Section 3.5.1(g)); (iii) establishing the Commercialization strategy for the Territory, which
Commercialization Budget is established pursuant to Section 3.5.1(g)); (ii) reviewing and approving the Commercialization Budget no less than once per
3.4.2. Quality Assurance Agreement. The Parties will use good faith efforts to enter into one or more agreement(s) governing the quality
standards required under this Agreement or by any Third Party vendors or subcontractors of either Party (the “Quality Assurance Agreement”) within 45 days after execution of the Supply Agreement, or earlier if required by Applicable Law.

3.5. Commercialization in the Territory.
3.5.1. Joint Commercialization Committee.
(a) General. Within [**] days after the Effective Date, the Parties will establish a joint commercialization committee ("JCC"). The JCC will oversee the Commercialization of the Product in the Field in the Territory. The JCC will coordinate selling and marketing efforts under the Commercialization Plan and will serve as a forum regarding Product Commercialization in the Field in the Territory. The Parties anticipate that the JCC will perform the functions ascribed to it in this Section 3.5.1; provided, however, that the functions and operations of the JCC may be altered from time to time during the Term by the mutual written agreement of the Parties to appropriately address ongoing requirements with respect to the Commercialization of the Product in the Territory.
(b) Membership. The JCC will consist of three senior representatives of appropriate seniority and geographical responsibility from each Party. Ironwood and AstraZeneca will each designate a co-chair for the JCC. The co-chairs of the JCC will be responsible for calling meetings of the JCC and setting the agenda for such meetings (which will include a list of all participants expected at such meeting) and circulating such agenda at least ten days, or such other period as agreed by the co-chairs, prior to each meeting and distributing minutes of each meeting within 30 days following such meeting (which minutes will be in the English language), but will not otherwise have any greater power or authority than any other member of the applicable JCC. JCC members must have such expertise as appropriate to the activities of the applicable JCC. From time to time, the JCC may invite personnel of the Parties having development, manufacturing, financial and other expertise to participate in discussions of the JCC as appropriate to assist in its activities.
(c) Responsibilities. Subject to Section 3.5.1(a), the JCC will be responsible for: (i) reviewing and approving the Commercialization Plan

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foregoing, 

(d) Meetings. The first meeting of the JCC will take place within 120 days after the Effective Date at a location outside the United States. Thereafter, the JCC will meet at such frequency as will be established by the Parties (but not less frequently than once per Calendar Quarter). Meetings of the JCC will be held [**] and alternate between a location selected by AstraZeneca and a location selected by Ironwood, unless otherwise agreed upon by the members of the JCC, or may be held telephonically or by video conference. Meetings of the JCC will be effective only if at least one representative of each Party is in attendance or participating in the meeting. JCC members will have the right to participate in and vote at meetings by telephone. Each Party will be responsible for expenses incurred by its employees and its members of the JCC in attending or otherwise participating in JCC meetings. Such expenses shall not constitute Program Expenses. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate with equivalent experience and authority as such representative to attend such meeting in place of the absent representative.

(e) Minutes and Agendas. The minutes of each JCC meeting will provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JCC. Minutes of each JCC meeting will be approved or disapproved, and revised as necessary, at the next meeting.

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(f) Elevation and Dispute Resolution. Each Party’s representatives on the JCC will collectively have one vote on all matters that are within the responsibility of such committee. The members of the JCC will use reasonable efforts to reach consensus on all decisions. In the event that the members of the JCC are unable to agree on a particular issue within its authority, after endeavoring to reach consensus for a period of 30 days (a “JCC Deadlock”), at the request of either Party, such JCC Deadlock will be submitted to the Chief Commercial Officer of Ironwood and the Senior Vice President of GRA & KA of AstraZeneca’s Chinese Affiliate responsible for Commercializing the Product in the Territory or, in each case, his or her designee for resolution. Such executives or their designees will meet (in person or by telephone) to attempt in good faith to resolve such JCC Deadlock through discussions promptly following submission thereof, and in any event within 15 days thereafter, unless otherwise mutually agreed upon by the executives or their designees. In the event such individuals are unable to resolve such JCC Deadlock within 15 days, at the request of either Party, such JCC Deadlock will be submitted to the Chief Executive Officer of Ironwood and the Chief Operating Officer of AstraZeneca’s Chinese Affiliate responsible for Commercializing the Product in the Territory, as applicable, or, in each case, his or her designee for resolution. Such executives or their designees will meet (in person or by telephone) to attempt in good faith to resolve such JCC Deadlock through discussions promptly following submission thereof, and in any event within 15 days thereafter, unless otherwise mutually agreed upon by the executives or their designees. If such individuals are unable to resolve such JCC Deadlock within 15 days following submission thereof, if such JCC Deadlock is addressed by the then-current Commercialization Plan, then [**]. Notwithstanding the foregoing, [**].

(g) Commercialization Plan. The JCC will use good faith efforts to approve an initial Commercialization Plan (the “Initial Commercialization Plan”) and a corresponding Commercialization Budget in accordance with this Section 3.5.1(g) no later than the date that is [**] months prior to the date on which the JCC anticipates that the First Commercial Sale will occur in the Territory. After the adoption of the initial Commercialization Plan, for the remainder of the Term, the JCC will review the Commercialization Plan and Commercialization Budget at least once per Year and will amend such Commercialization Plan on an ongoing basis as necessary. The then-current Commercialization Plan will at all times contain at least that level of detail and cover at least the same matters (to the extent applicable) as the Initial Commercialization Plan. The Commercialization Plan will be binding for the first Year that is the subject thereof and will cover an additional period that is consistent with the period covered by commercialization plans of AstraZeneca (or its applicable Affiliate) for other similar products in the Territory.

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3.5.2. Responsibility. Subject to Ironwood’s co-promotion rights under Section 3.5.4, AstraZeneca will be responsible for, and will control, the implementation of the Commercialization Plan, and will book (directly itself or indirectly through any of its Affiliates and Sublicensees) all sales of Products and will have the sole responsibility for the sale, invoicing, promotion, and distribution of the Product in the Territory. AstraZeneca will be responsible for operating the Product Domain Names, including the content thereof, subject to the Commercialization Plan and Commercialization Budget. Ironwood will use Commercially Reasonable Efforts to assist AstraZeneca in enabling AstraZeneca to have its corporate name and logo on the Product packaging in the Territory.

3.5.3. Diligence. Each Party will use Commercially Reasonable Efforts to conduct the Commercialization activities assigned to it in the Commercialization Plan, including the performance of Detailing in accordance therewith, and all activities reasonably necessary to achieve the goals of such assigned activities. AstraZeneca will use Commercially Reasonable Efforts to achieve the First Commercial Sale of the Product in
3.5.4. Co-Promotion. At any time after the latest of (a) [*] days following [*], (b) [*] days following [*], and (c) the [*], Ironwood may elect to exercise its co-promotion rights under this Section 3.5.4, provided that at the time of the commencement of such co-promotion, [*]. Within [*] after receipt of notice of an election by Ironwood, the Parties will negotiate in good faith for a period of [*] (or less if an agreement is reached earlier) a co-promotion agreement under which Ironwood may provide no more than [*] of the Detailing for the Product in the Territory, unless otherwise agreed by the Parties at the time. In the event that the Parties are unable to reach an agreement on the terms of any such co-promotion despite good faith efforts within such [*] period, then Ironwood will have no further rights to co-promote the Product in the Territory under this Agreement. In the event Ironwood exercises its co-promotion rights under this Section 3.5.4, AstraZeneca will assist Ironwood in training sales representatives in all standards applicable to AstraZeneca’s promotion efforts pursuant to Section 5.5 (and notwithstanding anything to the contrary herein, the costs of such assistance [*]). Any co-promotion by the Parties will be structured so that [*]. Neither Party will make any claims or statements with respect to the Product that are not in compliance with Applicable Law and the sales and marketing materials approved for use pursuant to the Commercialization Plan.

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3.5.5. Commercial Sales Organization. If AstraZeneca or Ironwood (if Ironwood exercises its co-promotion rights pursuant to Section 3.5.4) desires to utilize a Third Party sales force to Detail the Product in the Territory, then [*]. Any such sales force will be required to agree in writing to meet the quality, ethical and compliance standards undertaken by AstraZeneca or Ironwood (as the case may be, including, but not limited to, all of AstraZeneca’s policies regarding engagement of health care professionals and all standards applicable to AstraZeneca’s promotion efforts pursuant to Section 5.5) or applicable to such Party’s Detailing activities hereunder, and will not have been found to have committed a material violation of any rule or regulation of any Regulatory Authority in any country where such Detailing will take place.

3.6. Other Committee Matters.

3.6.1. Joint Responsibilities of the JDC, JOC and JCC. In addition to the independent JDC, JOC and JCC meetings, the JDC, JOC and JCC will coordinate to hold joint meetings as appropriate to discuss issues which are relevant to Development, supply and Commercialization, including, in order to: (a) discuss [*] for the Product (including [*] given the competitive environment, and any other [*] for the Product), (b) discuss development of the Product for [*], (c) discuss development of [*] of the Products throughout the Territory and (d) discuss matters relating to the Development, supply and Commercialization of the Product in the entire Territory. Such joint meetings may be held by videoconference, teleconference, or in person and any decisions required to be taken will be submitted to the JDC, JOC or JCC, whichever is responsible for resolution in accordance with the terms hereof; provided that any in person meetings will be held [*]. Each Party will be responsible for expenses incurred by its employees and its committee members in attending or otherwise participating in joint meetings of the JDC, JOC and JCC and such expenses shall not constitute Program Expenses.

3.6.2. Other Committees. The Parties may establish other committees or sub-committees as the Parties deem appropriate.

3.6.3. Safe Harbor. If Ironwood approves a Development Plan or Commercialization Plan (or, as applicable, an update or amendment thereto) in the JDC, JOC or JCC, either at a meeting of any such committee or through any of its officers to which a deadlock arising out of any such committee has been referred, or otherwise in writing (or, as applicable, an update or amendment thereto), [*].

3.7. Executive Meetings. The Parties anticipate that the Chief Executive Officer of Ironwood and AstraZeneca’s Regional Vice President of Asia Pacific will meet periodically as necessary or appropriate during the Term (and in any event such executives will meet at least once per Year in person) in order to review significant issues and developments in the Development, Manufacture and Commercialization of Products in the Territory.

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[*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

3.8. Publication.

3.8.1. Prior Review. Ironwood and Forest will be afforded the opportunity to review and approve any scientific paper or presentation with respect to any Product proposed for publication, presentation, or distribution by AstraZeneca or its Affiliates and will have no more than 30 days to complete such review and approval or such shorter period as may reasonably be required by applicable publication deadlines promptly communicated to such Party. Neither Party will unreasonably reject comments furnished by the other Party, will comply with the other Party’s request to delete references to its Confidential Information in any such publication or presentation and will delay publication for such reasonable period requested by the reviewing Party in order to permit the filing of patent applications concerning any Ironwood Technology or AstraZeneca
Technology that would be disclosed in such publication or presentation.

3.8.2. Clinical Study Results. Subject to the [**], the Parties, [**], will coordinate the disclosure of the initiation and results of clinical studies performed pursuant to the Development Plan or clinical studies performed by either Party’s approved licensees or Sublicensees with respect to any Licensed Compound or Product, whether within or outside of the Territory, to the extent required by applicable law or AstraZeneca’s internal policies applicable to other of AstraZeneca’s products; provided that all proposed disclosures and publications will be submitted for expeditious review by the JDC and [**] and due regard will be given to the comments of each Party; the maintenance of confidentiality of Confidential Information of each Party and allowing time for intellectual property registrations as described in Section 3.8.1. Nothing set forth in this Agreement will be deemed to limit or restrict either Party from disclosing the results of clinical trials (whether performed by the Parties or by Third Parties) to the extent required by applicable law; provided, however, that AstraZeneca will not disclose any results of clinical trials prior to the time such disclosure is required by applicable law.

3.8.3. Publication by AstraZeneca Sublicensees. No Sublicensee of AstraZeneca will be permitted to publish or present materials regarding any Product, and any Sublicense hereunder will contain a provision prohibiting such activities.

3.8.4. [**] 3.9. Compliance. AstraZeneca and Ironwood will at all times during the Term, including during the Commercialization of the Product in the Territory, implement and adhere to quality and compliance standards consistent with Applicable Law, industry best practices and reasonably acceptable to the other Party in connection with the performance of its obligations or exercise of its rights under this Agreement. If either Party fails to comply with its obligations under this Section 3.9 in the Territory in a manner that has a material adverse effect on the other Party's or ability to Develop or Commercialize the Product, as contemplated by this Agreement, in the Territory, such breach will be deemed a “material breach” hereunder and the non-breaching Party may terminate this Agreement pursuant to Section 8.2.1 (including the provisions relating to notice and opportunity to cure therein). Notwithstanding the foregoing, with respect to a breach of this Section 3.9 by Ironwood, in lieu of such termination, AstraZeneca may elect (a) to terminate Ironwood’s right to co-promote the Product(s) under Section 3.5.1(f) and (b) to make all final decisions with respect to all JCC Deadlocks for which consensus cannot be reached by the JCC, except for those JCC Deadlocks relating to the review and approval of the Commercialization Budget, which will continue to be subject to Section 3.5.1(f).

4. CONSIDERATION

4.1. Upfront Payment. Within 10 business days after the Effective Date, AstraZeneca will pay to Ironwood $25,000,000 as an upfront, non-creditable, non-refundable fee.

4.2. Other Consideration.

4.2.1. Milestones. As additional consideration for the rights granted to AstraZeneca pursuant to Section 2.1, AstraZeneca will pay to Ironwood the following one-time milestone payments within [**] after the first occurrence of each of the following events (each, a “Milestone Event”):

<table>
<thead>
<tr>
<th>Milestone Event</th>
<th>Milestone Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) First Year in which the aggregate annual Net Sales of all Products in the</td>
<td>[**]</td>
</tr>
<tr>
<td>Territory exceed [**]</td>
<td></td>
</tr>
<tr>
<td>(b) First Year in which the aggregate annual Net Sales of all Products in the</td>
<td>[**]</td>
</tr>
<tr>
<td>Territory exceed [**]</td>
<td></td>
</tr>
</tbody>
</table>

Once AstraZeneca has made any particular milestone payment under this Section 4.2.1, AstraZeneca will not be obligated to make any payment with respect to the re-occurrence of the same Milestone Event. If the Milestone Events in both (a) and (b) above occur in the same Year, both applicable milestone payments will be due to Ironwood.

4.2.2. Allocation of Net Profit and Net Loss. Net Profits and Net Loss during the Term will be shared by the Parties as follows:

(a) Until and during the Trigger Year, for each Calendar Quarter during such period:

(i) AstraZeneca will be allocated 55% of the Net Profit or 55% of the Net Loss, as applicable; and
with Third Parties in a manner designed to benefit countries outside the Territory over those within the Territory.

accrual of specific Program Expenses.

adding interest as provided in Section 4.8 compounded monthly from the date such additional amount should have first been paid; provided,

Commercialization hereunder shall be negotiated on an arm's length basis. In no event may Ironwood structure its contractual arrangements

payment is made after the date specified in the preceding sentence, the paying Party will increase the amount otherwise due and payable by

costs incurred prior to the Effective Date. All Third Party contracts executed by a Party for purposes of Development, supply or

Reconciliation Report is complete and the receiving Party will pay such invoice within 

its Program Expenses any amounts that constitute an inter-company mark-up or profit to an Affiliate of such Party, nor may a Party include any

procedures. The Parties' respective Summary Statements will serve as the basis of the Reconciliation Reports prepared by AstraZeneca

deduction under Net Sales and as a reimbursable expense under this Agreement (i.e., no double counting). In no event may a Party include in

estimated and actual costs and expenses may be delayed by a Calendar Quarter as reasonably necessary in light of a Party's internal reporting

accordance with Section 4.2.2 (the report setting forth the foregoing reconciliation being the "Reconciliation Report"). Based on the

Profits and Net Losses (determined based on such Program Expenses), to be allocated to each of the Parties for such Calendar Quarter in

control and in no event is this Section 4.2.4 intended to expand or modify the manner in which Supply Price is calculated. For clarity, a Party may

Statement during such Calendar Quarter pursuant to Section 4.2.3 and the share of the Parties' aggregate Program Expenses and their Net

expenses will be 

and Commercialization of the Product in the Territory consistent with the

Quarter, each Party will submit to the other a written report reflecting the accrual of Program Expenses and, with respect to AstraZeneca, Net

Sales during the just-ended calendar month. Within three business days after the end of each Calendar Quarter, each Party will submit to the other a written report reflecting the accrual of Program Expenses and, with respect to AstraZeneca, Net

reasonable supporting documents and calculations sufficient to support each Party's financial reporting obligations, independent auditor

requirements and obligations under the Sarbanes-Oxley Act, which reconciles the amounts accrued and reported in each Party's Summary

Statement during such Calendar Quarter pursuant to Section 4.2.3 and the share of the Parties' aggregate Program Expenses and their Net

Profits and Net Losses (determined based on such Program Expenses), to be allocated to each of the Parties for such Calendar Quarter in

agreement of the Parties for purposes of Developing or Commercializing the Product in the Territory or under the Supply Agreement for such

after the end of each calendar month, each Party will submit to the other a non-binding, good faith estimate of the Program Expenses accrued,

and with respect to AstraZeneca, Net Sales during the just-ended calendar month. Within three business days after the end of each Calendar

for the last month of such Calendar Quarter shall be a good faith estimate and not actual amounts (each a "Summary Statement"). Each Summary Statement (after the initial Summary Statement) shall reflect an adjustment for the actual amount of the previous Calendar Quarter as needed. Any reporting and reconciliation of variances between estimated and actual costs and expenses may be delayed by a Calendar Quarter as reasonably necessary in light of a Party's internal reporting procedures. The Parties' respective Summary Statements will serve as the basis of the Reconciliation Reports prepared by AstraZeneca pursuant to Section 4.2.5. Upon the request of either Party from time to time, the Parties' respective finance departments, coordinated by the JDC, the JOC or JCC as appropriate, will discuss any questions or issues arising from the Summary Statements, including the basis for the accrual of specific Program Expenses.

4.2.4. Expense Limitations. Additionally, the Parties hereby agree that efforts of the employees of a Party or its Affiliates in performing its activities hereunder related to Development, supply or Commercialization of the Product in the Territory will be accrued and reported at the applicable FTE Rate then in effect; provided, however, that only those efforts that relate to the Development or Commercialization of the Product and are contemplated by the Development Plan or Commercialization Plan, or are activities approved hereunder by the JOC or by mutual agreement of the Parties for purposes of Developing or Commercializing the Product in the Territory or under the Supply Agreement for such purposes, will be so accrued and reported. All payments made by a Party (or its Affiliates) to a Third Party in connection with the Development and Commercialization of the Product in the Territory consistent with the

Reconciliation. As soon as practicable after the receipt by AstraZeneca of Ironwood’s Summary Statement, but in any event within [**] days after the end of each Calendar Quarter, AstraZeneca will prepare a reconciliation report in accordance with Exhibit C, accompanied by reasonable supporting documents and calculations sufficient to support each Party’s financial reporting obligations, independent auditor requirements and obligations under the Sarbanes-Oxley Act, which reconciles the amounts accrued and reported in each Party’s Summary Statement during such Calendar Quarter pursuant to Section 4.2.3 and the share of the Parties’ aggregate Program Expenses and their Net Profits and Net Losses (determined based on such Program Expenses), to be allocated to each of the Parties for such Calendar Quarter in accordance with Section 4.2.2 (the report setting forth the foregoing reconciliation being the "Reconciliation Report"). Based on the Reconciliation Report, the applicable Party will invoice the other Party the amount due under the Reconciliation Report within [**] days after such Reconciliation Report is complete and the receiving Party will pay such invoice within [**] days of receipt of such invoice. In the event any payment is made after the date specified in the preceding sentence, the paying Party will increase the amount otherwise due and payable by adding interest as provided in Section 4.8 compounded monthly from the date such additional amount should have first been paid; provided,
however, no Party will be charged interest hereunder to the extent it is late in making payment as a result of the other Party’s delay in
reporting its Program Expenses or other information required to prepare such reconciliation. In the event a Party fails to make payment as
required pursuant to this Section 4.2.5, amounts due may be offset against any which are payable to such Party hereunder; provided, however,
amounts being contested in good faith pursuant to appropriate proceedings hereunder will not be subject to offset.

4.2.6. Cost Overruns. If a Party’s aggregate Development Expenses and Commercialization Expenses in any Year are likely to exceed or
exceed those set forth in the Development Budget or Commercialization Budget for all of its activities under the Development Plan or
Commercialization Plan in such Year by up to [**], such Party shall provide to the other Party an explanation for such excess costs and
expenses, and such excess costs and expenses shall be included in Program Expenses. Such Party will be solely responsible for any amounts
spent in excess of the Development Budget or Commercialization Budget that are not included in Program Expenses pursuant to this Section
4.2.6. For the avoidance of doubt, to the extent a Party’s aggregate Development Expenses or Commercialization Expenses exceed those set
forth in the Development Budget or Commercialization Budget by more than [**], such Development Expenses or Commercialization Expenses
will not be included in Program Expenses.

4.3. Records and Audits. During the Term, each Party and its Affiliates will keep and maintain accurate and complete records showing Net Sales
made and expenses incurred by it in performing its activities under the Development Plan and the Commercialization Plan during the three
preceding Years, which books and records will be sufficiently detailed such that Program Expenses, Net Profits and Net Losses can accurately
be determined and each Party’s financial reporting obligations, independent auditor requirements and obligations under the Sarbanes-Oxley Act
can be satisfied. Upon 15 days’ prior written notice from a Party (the “Auditing Party”), the other Party (the “Audited Party”) will permit an
independent certified public accounting firm of internationally recognized standing, selected by the Auditing Party and reasonably acceptable to
the Audited Party, to examine the relevant books and records of the Audited Party and its Affiliates as may be reasonably necessary to verify
any Summary Statement submitted by the Audited Party in accordance with Section 4.2.3 and the accuracy of the Reconciliation Report
prepared in accordance with Section 4.2.5. An examination by a Party under this Section 4.3 will occur not more than once in any Year and will
be limited to the pertinent books and records for any Year ending not more than 36 months before the date of the request. The accounting firm
will be provided access to such books and records at the Audited Party’s facility where such books and records are normally kept and such
examination will be conducted during the Audited Party’s normal business hours. The Audited Party may require the accounting firm to sign a
standard non-disclosure agreement before providing the accounting firm access to the Audited Party’s facilities or records. Upon completion of
the audit, the accounting firm will provide both Ironwood and AstraZeneca a written report disclosing whether the reports submitted by the
Audited Party are correct or incorrect and the specific details concerning any discrepancies. No other information will be provided to the Auditing

4.4. Taxes and Withholding.

4.4.1. Taxes. The royalties, milestones and other amounts payable by AstraZeneca to Ironwood pursuant to this Agreement (“Payments”) shall
not be reduced on account of any Taxes unless required by Applicable Law. Ironwood alone shall be responsible for paying any and all Taxes
(other than withholding taxes required by Applicable Law to be paid by AstraZeneca) levied on account of, or measured in whole or in part by
reference to, any Payments it receives.

4.4.2. Withholding. AstraZeneca shall deduct or withhold from the Payments any Taxes that it is required by Applicable Law to deduct or
withhold. Notwithstanding the foregoing, if Ironwood is entitled under any applicable treaty to a reduction of rate of, or the elimination of,
applicable withholding tax, it may deliver to AstraZeneca or the appropriate governmental authority (with the assistance of AstraZeneca to the
extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of
withholding or to relieve AstraZeneca of its obligation to withhold Tax, and AstraZeneca shall apply the reduced rate of withholding, or dispense
with withholding, as the case may be, provided that AstraZeneca has received evidence, in a form satisfactory to AstraZeneca, of Ironwood’s
delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least 15 days prior to the time that the
Payments are due. If, in accordance with the foregoing, AstraZeneca withholds any amount, it shall pay to Ironwood the balance when due,
make timely payment to the proper Tax Authority of the withheld amount, and send to Ironwood proof of such payment within 60 days following that payment. For purposes of this Agreement, the stated amount of the Payments payable by AstraZeneca shall include any Indirect Tax that Ironwood may be required to collect.

4.4.3. Indirect Taxes. All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, the paying Party shall pay such Indirect Taxes at the applicable rate in respect of such Payments.

4.7. Confidentiality. All financial information of a Party which is subject to review under this Article 4 will be deemed to be Confidential Information subject to the provisions of Section 5.1, and such Confidential Information will not be disclosed to any Third Party or used for any purpose other than verifying payments to be made by one Party to the other hereunder; provided, however, that such Confidential Information may be disclosed to Third Parties only to the extent necessary to enforce a Party's rights under this Agreement.

4.8. Interest. Any payment under this Article 4 that is more than 30 days past due will be subject to interest at an annual percentage rate of 1% (as published in the “Money Rates” table of the Eastern Edition of The Wall Street Journal during the period such amount is overdue) if a Party does not make payment within 30 days of its receipt of notice that such amount is past due. Likewise, any overpayment that is not refunded within 30 days of the date such overpayment was made will thereafter be subject to interest at an annual percentage rate of 1% (as published in the “Money Rates” table of the Eastern Edition of The Wall Street Journal during period such amount is overdue) if a Party contests any amounts due hereunder to the other Party in good faith and promptly notifies the paying Party within 45 days of receipt.

4.9. [**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

5. COVENANTS

5.1. Confidentiality.

5.1.1. Confidential Information. Except to the extent expressly permitted by this Agreement and subject to the provisions of Sections 5.1.2 and 5.1.3, at all times during the Term and for [**] years following the expiration or termination of this Agreement, each Party (a “Receiving Party”) (a) will keep completely confidential and will not publish or otherwise disclose any Confidential Information furnished to it by the other Party (a “Disclosing Party”), except to those of the Receiving Party’s employees, Affiliates, consultants or representatives who have a need to know such information (collectively, “Authorized Recipients”) to perform such Party’s obligations hereunder or to potential Sublicensees under an obligation of confidentiality no less protective than the terms hereof, and (b) will not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than verifying payments to be made by one Party to the other hereunder; provided, however, that such Confidential Information may be disclosed to Third Parties only to the extent necessary to enforce a Party’s rights under this Agreement.

5.1.2. Authorized Recipients. Authorized Recipients of Confidential Information will be restricted to those of the Receiving Party’s employees, Affiliates, consultants or representatives who have a need to know such information and will agree in writing to keep the Confidential Information confidential and to use the Confidential Information solely for the purposes permitted under Section 5.1.1. Authorized Recipients who are employees of the Receiving Party will be subject to a continuing duty of confidentiality to the Disclosing Party.

5.1.3. Third Party. Authorized Recipients of Confidential Information will not disclose Confidential Information to any Third Party or use Confidential Information in any manner other than verifying payments to be made by one Party to the other hereunder; provided, however, that such Confidential Information may be disclosed to Third Parties only to the extent necessary to enforce a Party’s rights under this Agreement.
5.1.2. Exceptions to Confidentiality. The Receiving Party’s obligations set forth in this Agreement will not extend to any Confidential Information of the Disclosing Party:

(a) that is or hereafter becomes part of the public domain through no wrongful act, fault or negligence on the part of a Receiving Party or its Authorized Recipients;

(b) that is received from a Third Party without restriction and without breach of any agreement or fiduciary duty between such Third Party and the Disclosing Party;

(c) that the Receiving Party can demonstrate by competent evidence was already in its possession without any limitation or restriction on use or disclosure prior to its receipt from the Disclosing Party;

(d) that is generally made available to Third Parties by the Disclosing Party without any restriction imposed by the Disclosing Party on disclosure, whether such restriction is by contract, fiduciary duty or by operation of law; or

(e) that the Receiving Party can demonstrate by competent evidence was independently developed by the Receiving Party without any reference to Confidential Information.

5.1.3. Authorized Disclosure.

(a) Each Party and its Authorized Recipients may disclose Confidential Information received from the other Party to the extent that such disclosure is:

(i) made in response to a valid order, governmental inquiry, or request (each an “Order”) of a court of competent jurisdiction or other agency, as applicable; provided, however, that the Receiving Party must first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such Order or to obtain a protective order requiring that the Confidential Information or documents that are the subject of such Order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the Order was issued; and provided further that if an Order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such Order will be limited to that information that is legally required to be disclosed in such response to such Order;

(ii) made by a Party or its Affiliates, or Sublicensees to a Regulatory Authority as may be necessary or useful in connection with any filing, application or request for a Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

(iii) made by a Party to a patent authority as may be necessary or useful for purposes of obtaining or enforcing a Patent Right (consistent with the terms and conditions of Article 7); provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

(iv) otherwise required by law; provided, however, that if either Party is required to disclose Confidential Information of the other Party, the Party required to make the disclosure shall (A) provide to the other Party reasonable advance notice of and an opportunity to comment on any such required disclosure, (B) if requested by the other Party, seek confidential treatment with respect to any such disclosure to the extent available, and (C) use good faith efforts to incorporate the comments of the other Party in any such disclosure or request for confidential treatment; or

(v) made by either Party to Third Parties under confidentiality obligations no less protective than the obligations set forth herein as may be necessary or useful in connection with the Development, Commercialization, or Manufacture of the Licensed Compound or Products as contemplated by this Agreement, including subcontracting or sublicensing transactions in connection therewith.

(b) Notwithstanding the provisions of this Section 5.1, Ironwood may disclose AstraZeneca’s Confidential Information to (i) Forest, Almirall, Astellas and any future licensees of the Licensed Compound or Product in connection with the development, manufacture and commercialization of the Licensed Compound or Product outside of the Territory or outside of the Field in the Territory to the extent required under agreements with such parties and provide such Third Parties with copies of all Regulatory Submissions in the Territory, and (ii) a Revenue Buyer or bona fide
5.1.6. Use of Name and Disclosure of Terms. Except as permitted under Section 10.14, each Party will and will cause its Affiliates to (a) keep the existence of, the terms of, and the transactions covered by this Agreement confidential and (b) not disclose such information to any other Third Party through a press release or otherwise, and, except as otherwise permitted hereunder, will not mention or otherwise use the name, insignia, symbol, trademark, trade name, or logotype of the other Party or its Affiliates in any manner without the prior written consent of the other Party in each instance (which will not be unreasonably withheld, conditioned or delayed). The restrictions imposed by this Section 5.1.6 will not prohibit either Party or its Affiliates from making any disclosure that is required by Applicable Law, rule, or regulation or the requirements of a national securities exchange or another similar regulatory body including disclosing such information in any clinical trial database maintained by or on behalf of a Party. In addition, in connection with a specific transaction or proposed transaction, including, with respect to Ironwood, a Monetization Transaction, either Party may disclose the terms of this Agreement to the counter party to such transaction if such counter party is a bona fide potential investor, underwriter, lender or Revenue Buyer; provided that (i) such disclosure shall be under provisions of confidentiality which contain, incorporate, or are derived from such Confidential Information as well as any information or materials that contain, incorporate, or are derived from such Confidential Information.

5.1.7. Remedies. The Parties acknowledge and agree that the restrictions set forth in this Section 5.1 are reasonable and necessary to protect the legitimate interests of the Parties and that neither Party would have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of this Section 5.1 will result in irreparable injury to the other Party for which there will be no adequate remedy at law. Notwithstanding the dispute resolution mechanism agreed to by the Parties in Section 10.1, in the event of a breach or threatened breach of any provision of Section 5.1 by a Party, the other Party will be authorized and entitled to obtain from any court of competent jurisdiction, applying the laws of that court, injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights will be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. The breaching Party agrees to waive any requirement that the non-breaching Party (a) post a bond or other security as a condition for obtaining any such relief and (b) show irreparable harm, balancing of harms, consideration of the

5.1.8. Waiver. Any waiver or modification of any provision of this Agreement must be in writing and signed by the Party to which it is directed. No failure or delay by a Party in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof.

5.1.9. Enforceability. Each Party to this Agreement represents and warrants to the other Party that all of its exhibits hereto are for the purpose of indicating confidential information, and that all information in any such exhibits is treated as such and no right or privilege is hereby conferred to either Party with respect thereto in good faith, provided that the Party subject to such requirement shall have final decision-making authority with respect to the contents of such redacted version of this Agreement.

5.1.10. Severability. If any provision of this Agreement is rendered invalid, ineffective, or unenforceable by the laws of any jurisdiction, such invalidity, ineffectiveness, or unenforceability will not affect the validity, effectiveness, or enforceability of the remaining provisions of this Agreement, and the Parties agree to substitute therefor such provisions as, in the judgment of such court, would be valid, effective, and enforceable in order to achieve the intent of the Parties with respect to the fullest extent permitted by law.

5.1.11. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York. The Parties irrevocably consent to the exclusive jurisdiction of the courts of the State of New York in any action or proceeding arising out of or relating to this Agreement.

5.1.12. Construction. The Parties agree that this Agreement has been negotiated between them with the benefit of expert legal advice and that no party is to be construed as having drafted this Agreement. The Parties further agree that each provision of this Agreement has been the subject of negotiation by the Parties and that they have not relied upon any representation, warranty, agreement or understanding other than those expressed in this Agreement.

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 5.1.7 is intended, or will be construed, to limit the
Parties’ rights to equitable relief or any other remedy for a breach of any provision of this Agreement.

5.2. Restrictions.

5.2.1. On AstraZeneca. During the period commencing [**], neither AstraZeneca nor any of its Affiliates [**].

5.2.2. Reciprocal Non-Compete Provisions.

(a) [**], neither Party, nor any of their respective Affiliates will [**].

(b) Without limitation of Section 5.2.2(a), during the period [**], neither Party nor any of their respective Affiliates will [**].

(c) Notwithstanding the provisions of Sections 5.2.2(a) and 5.2.2(b), if a Party or any of its Affiliates [**].

5.3. [**].

5.4. Compliance with Law. Each Party hereby covenants to comply with all Applicable Law and industry professional standards applicable to its
activities connected with the Development, Manufacture, and Commercialization (as applicable) of Products. Without limiting the generality of the
foregoing:

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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed
separately with the Commission.

5.4.1. Patient Information. Each Party agrees to abide by all laws, rules, regulations, and orders of all applicable supranational, national, federal,
state, provincial, and local governmental entities concerning the confidentiality or protection of patient identifiable information or patients’
protected health information, as defined by any other applicable legislation in the course of their performance under this Agreement.

5.4.2. Debarment. Each Party will not use in any capacity, in connection with the activities to be performed under this Agreement, any person
who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or analogous law, or who is the
subject of a conviction described in such section or a corresponding section of any analogous law. Each Party will inform the other Party in
writing immediately if it or any person who is performing or has performed activities hereunder or is conducting or has conducted any
development of the Licensed Compound or Product is debarred or is the subject of a conviction described in Section 306 or a corresponding
section of any analogous law, or if any action, suit, claim, investigation or legal or administrative proceeding is pending relating to the debarment
or conviction of such Party or any person performing services hereunder.

5.5. Business Ethics.

5.5.1. Each Party will conduct its business in accordance with Applicable Law. By signing this Agreement, each Party agrees to conduct its
activities under this Agreement in a manner that is consistent with Applicable Law, including the U.S. Foreign Corrupt Practices Act, the UK
Bribery Act 2010, and the relevant provisions of the People’s Republic of China Criminal Law and People’s Republic of China Anti-Unfair
Competition Law, each as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, or money
laundering (collectively, “Anti-Corruption Laws”).

5.5.2. Each Party will not, directly or indirectly, pay, offer or promise to pay, or authorize the payment of any money, or give, offer or promise to
give, or authorize the giving of anything of value (collectively, a “Prohibited Payment”) to any government or political party officials, officials of
international public organizations, candidates for public office or representatives of other businesses or persons acting on behalf of any of the
foregoing (collectively, “Officials”) where such Prohibited Payment would constitute a violation of any Anti-Corruption Law. In addition, regardless
of legality, each Party will make no Prohibited Payment, directly or indirectly, to any Official if such Prohibited Payment is for the purpose of
influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the other Party’s business. Each
Party acknowledges and agrees that none of it, or any of its Affiliates or its or their respective officers, directors, employees, agents and
representatives (collectively, “Authorized

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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed
separately with the Commission.

Representatives”) is authorized to waive compliance with the provisions of this Section 5.5 and that each Party will be solely responsible for its
compliance with the provisions of this Section 5.5 and the Anti-Corruption Laws irrespective of any act or omission of the other Party or any of its
Affiliates, Sublicensees or its or their respective Authorized Representatives. Each Party’s failure to abide by the provisions of this Section 5.5
shall be deemed a material breach of this Agreement and without prejudice to any other rights or remedies that may be available to the
non-breaching Party under this Agreement or in law or equity, then the consequences in Section 3.9 will apply.

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5.6. Standstill Agreement. [*] Neither AstraZeneca nor any of its controlled Affiliates or its Affiliates under common control (collectively the “AstraZeneca Related Parties”) will, in any manner, directly or indirectly, do the following unless requested by Ironwood, except in connection with the transactions contemplated by this Agreement:

(a) make, effect, initiate, directly participate in or cause

(i) any acquisition of beneficial ownership of any voting securities of Ironwood, if, after such acquisition, the AstraZeneca Related Parties would beneficially own more than ten percent of the outstanding common stock of Ironwood provided that the AstraZeneca Related Parties may own an amount in excess of such percentage to the extent resulting exclusively from actions taken by Ironwood or its Affiliates;

(ii) any acquisition of all or substantially all of the assets of Ironwood; provided this subsection (ii) will not apply to the acquisition by the AstraZeneca Related Parties of a license or other rights to Ironwood assets or technology under terms negotiated by the Parties;

(iii) any tender offer, exchange offer, merger, business combination, recapitalization, restructuring, liquidation, dissolution or extraordinary transaction involving Ironwood, or involving any voting securities or material portion of the assets of Ironwood (except as otherwise permitted hereunder); provided that this subsection (iii) will not apply to such a transaction by the AstraZeneca Related Parties involving a license or other rights to Ironwood assets or technology under terms negotiated by the Parties; or

(iv) any “solicitation” of “proxies” (as those terms are used in the proxy rules of the Securities and Exchange Commission) or consents with respect to any voting securities of Ironwood;

(b) form, join or participate in a Group with respect to the beneficial ownership of any voting securities of Ironwood;

(c) act, alone or in concert with others, to seek to control the management, board of directors or policies (except as they related to the activities under this Agreement) of Ironwood;

(d) take any action that might require Ironwood to make a public announcement regarding any of the types of matters set forth in Section 5.6(a)(i);

(e) enter into any agreement with any other person relating to any of the foregoing; or

(f) publicly request or propose that Ironwood amend, waive or consider the amendment or waiver of any provision set forth in this Section 5.6.

Notwithstanding the foregoing, the provisions of this Section 5.6 will not apply to (i) the exercise by any of the AstraZeneca Related Parties of any rights available to shareholders generally pursuant to any transaction described in Section 5.6(a) above, provided that such AstraZeneca Related Party has not then either directly or as a member of a Group made, effected, initiated or caused such transaction to occur, (ii) the acquisition of, or offering to acquire, directly or indirectly, any, company or business unit (other than Ironwood) that beneficially owns Ironwood voting securities so long as such company or business unit’s acquisition of Ironwood’s securities was not made on AstraZeneca’s behalf, provided that although the AstraZeneca Related Parties shall not be required to divest the holdings of Ironwood’s securities by such company or business unit upon acquisition thereof, such holdings when aggregated with the then-existing holdings of Ironwood securities of the AstraZeneca Related Parties may prevent the AstraZeneca Related Parties, pursuant to the terms of Section 5.6(a)(i), from acquiring additional Ironwood securities, (iii) the making of any non-public proposal, or entering into any commercial transaction with respect to, or otherwise consummating, any commercial transaction in the ordinary course of the business or the Parties’ ongoing business relationships or (iv) any activity by any of the AstraZeneca Related Parties after (1) Ironwood has made any public announcement of its intent to solicit or engage in any transaction of the type which if consummated would constitute a Combination, (2) Ironwood enters into an agreement or an agreement in principle providing for a Combination or Ironwood redeems any rights under or modifies or agrees to modify a shareholder rights plan to facilitate any specific Combination, or (3) a tender or exchange offer which if consummated would constitute a Combination is made and the Board of Directors of Ironwood either accepts such offer or fails to recommend that its stockholders reject such offer within ten business days from the date of commencement of such offer, provided, however, that, the provisions of this Section 5.6 will again be applicable, in each case, (y) if Ironwood terminates such transaction (if entered into previously) or announces its intent to terminate such transaction (if only an announcement has then been made), withdraws such recommendation or rejects such offer, each as applicable, and (z) (A) such AstraZeneca Related Party has not previously made any public announcement of its intent to solicit or engaged in any transaction of the type referred to in Section 5.6(a) above, or (B) in the event that such public announcement has been made by any of the AstraZeneca Related Parties, such AstraZeneca Related Party has terminated or

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announced its intent to terminate such transaction.

“Group” means two or more Persons acting as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding or disposing of securities of Ironwood. A “Combination” means a transaction in which (1) a Person or Group acquires, directly or indirectly, securities representing 50% or more of the voting power of the outstanding securities of Ironwood or properties or assets constituting 50% or more of the consolidated assets of Ironwood and its subsidiaries or (2) in any case not covered by (1), (x) Ironwood issues securities representing 50% or more of its total voting power, including the case of (1) and (2) by way of a merger or other business combination with Ironwood or any of its subsidiaries or (y) ironwood engages in a merger or other business combination such that the holders of voting securities of Ironwood immediately prior to the transaction do not own more than 50% of the voting power of securities of the resulting entity.

Ironwood [**].

Nothing in this Section 5.6 shall preclude discussions or communications of any kind between AstraZeneca and its Affiliates.

5.7. Enforcement of Infringing or Counterfeit Goods. AstraZeneca will use Commercially Reasonable Efforts to (a) monitor commercial markets in the Territory for incidences of sales of counterfeit goods or uses of Trademarks, including trade dress, that infringe the Product Trademarks or Product Domain Names, including Product trade dress that may cover, compete with, or damage sales of the Product and other similar offenses (collectively, “Counterfeiting”) in accordance with the procedures established by the IPWG and (b) stop all such Counterfeiting using all Commercially Reasonable measures available under Applicable Law. AstraZeneca will promptly notify Ironwood of any incidence of Counterfeiting in the Territory of which it becomes aware and will coordinate with and keep Ironwood apprised of any efforts to stop such Counterfeiting. Ironwood will cooperate with AstraZeneca as reasonably requested by AstraZeneca with respect to the foregoing matters and will use Commercially Reasonable Efforts to enforce any analogous provisions in the Existing Agreements to the extent likely to impact the Territory.

Costs incurred under this Section 5.7 [**].

5.8. Development Data. AstraZeneca will not use any Development Data in connection with the development, manufacture or commercialization of any GC-C Agonist anywhere in the world other than the Licensed Compound and Products in

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In accordance with this Agreement, unless (a) AstraZeneca is exercising (sub)licensed rights to the Development Data under an Existing License Agreement (or other separate license agreement under which Ironwood grants rights to use the Development Data in the applicable jurisdiction), or (b) such Development Data becomes part of the public domain though no wrongful act, fault or negligence on the part of AstraZeneca, its Affiliates or Sublicensees.

5.9. Export Restrictions. AstraZeneca will not knowingly sell, export, or distribute, directly or indirectly, any Product to any location outside of the Territory or take any action that AstraZeneca reasonably believes will result in such export. Ironwood will not knowingly sell, export, or distribute, or permit any Third Party to do any of the foregoing, directly or indirectly (including through Forest), any Product or the Licensed Compound to any location within the Territory that is intended to be the final location for sale, export or distribution of such Product or Licensed Compound or take any action that Ironwood reasonably believes would result in any of the foregoing (except for the supply of Licensed Compound and Product to AstraZeneca pursuant to the terms and conditions of this Agreement and the Supply Agreement).

5.10. Existing Agreements. Ironwood covenants the following relating to the Existing Agreements, except as would not materially adversely affect any of AstraZeneca’s rights or obligations under this Agreement: (a) Ironwood will not and will cause its Affiliates to not make any amendments or modifications with respect to, or provide any consents or waivers or enter into any side letter relating to any of the Existing Agreements without AstraZeneca’s prior written consent; (b) Ironwood will use Commercially Reasonable Efforts to ensure (i) the performance of any acts contemplated in this Agreement to be undertaken by Forest, Astellas, or Almirall and (ii) compliance by Forest, Astellas, and Almirall with any corresponding obligations of Forest, Astellas, or Almirall under the Forest Agreement, Astellas Agreement, and Almirall Agreement, as applicable; and (c) Ironwood will not breach (i) any material provisions of any agreements with Third Parties relating to the Ironwood Patent Rights or Ironwood Know-How or (ii) any of the Existing Agreements.

5.11. Other Linaclotide Partners. [**]

5.12. [**]

6. REPRESENTATIONS AND WARRANTIES

6.1. Representations and Warranties of Each Party. As of the Effective Date, each of AstraZeneca and Ironwood hereby represents and warrants to the other Party hereto as follows:

(a) it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of its incorporation or formation;
b) the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

(d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions do not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any agreement to which it or its Affiliates is a party, (ii) the provisions of its charter or operative documents or bylaws or (iii) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(e) it has the full right, power and authority to grant all of the right, title and interest in the licenses granted to the other Party under this Agreement;

(f) it and its Affiliates have not violated in any manner that is reasonably likely to affect the rights of the other Party hereunder or adversely affect the Development, or Commercialization of any Product hereunder, any laws, rules, regulations, or any order of any applicable supranational, national, federal, state, provincial, and local governmental entities, in each case, concerning the confidentiality or protection of patient identifiable information or patients’ protected health information, as defined by any applicable legislation.

6.2. Additional Representations, Warranties and Covenants of Ironwood. Ironwood hereby represents, warrants and covenants to AstraZeneca that as of the Effective Date:

(a) Ironwood has with respect to any Patent Right that has reached the nationalization stage as of the Effective Date and will have at the time of nationalization of any other Patent Right, in each case, in the Territory, the sole and exclusive right in the Territory in and to the Ironwood Patent Rights listed in Schedule 6.2(a) attached hereto and the ownership of such Ironwood Patent Rights is as set forth on such Schedule 6.2(a).

Ironwood has the sole and exclusive rights in the Territory with respect to all Ironwood Know-How that it purports to grant to AstraZeneca hereunder, in each case free of any encumbrance, lien, or claim of ownership by any Third Party.

(b) Ironwood is not subject to any agreement with a Third Party that includes a royalty or similar payment obligation to, or other restriction or limitation in favor of, such Third Party (including, for this purpose, to current or former officers, directors, employees, consultants or personnel of Ironwood or any predecessor) with respect to (i) its rights to practice the Ironwood Technology in the Territory or (ii) the Development or Commercialization of the Licensed Compound or any Product in the Territory.

(c) To Ironwood’s and its Affiliates’ knowledge [**], no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate the Ironwood Patent Rights or the Ironwood Know-How.

(d) To Ironwood’s and its Affiliates’ knowledge, the conception, development, and reduction to practice of the Ironwood Patent Rights and Ironwood Know-How existing as of the Effective Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person.

(e) No Ironwood Patent Rights are subject to, or were developed pursuant to any funding agreement with any government or government agency.

(f) Ironwood is not in material breach of any provisions of any agreements with Third Parties relating to the Ironwood Patent Rights or Ironwood Know-How and is not in material breach of any of the Existing Agreements, in each case, in a manner that is reasonably likely to affect the rights of the other Party hereunder or adversely affect the Development, or Commercialization of any Product hereunder.

(g) Ironwood has not received any written or oral claim of ownership, inventorship or patent infringement from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Ironwood or any predecessor) with respect to the Ironwood Technology, and Ironwood is not aware of any reasonable basis for any such claim.

(h) Except [**], no claim or litigation has been brought or threatened by any Person alleging, and Ironwood is not aware, that any of the Ironwood Patent Rights or the Ironwood Know-How are invalid or unenforceable.

(i) To Ironwood’s and its Affiliates’ knowledge, the manufacture, use or sale of the Product in the Territory for the indications set forth in the Initial Development Plans will not infringe any issued claim of an issued patent right of any Third Party, other than Patent Rights that Ironwood Controls.
(j) Ironwood has made available to AstraZeneca all material Regulatory Approvals and Regulatory Submissions, including the Referenced Regulatory Filings and Ironwood Know-How, in each case, in its Control regarding or related to any Licensed Compound or Product.

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including to its and its Affiliates’ knowledge, all of the foregoing, in each case, that are necessary to allow Ironwood and AstraZeneca to file for initial Regulatory Approvals in the Field in the Territory as contemplated hereunder, other than those activities contemplated by the Development Plans and Commercialization Plans, Ironwood has made available to AstraZeneca all Regulatory Approvals and Regulatory Submissions, including the Referenced Regulatory Filings and Ironwood Know-How in its Control regarding or related to any Licensed Compound or Product and all such Regulatory Approvals, Regulatory Submissions, Referenced Regulatory Filings and Ironwood Know-How are true and complete. As of the Effective Date, Ironwood has prepared, maintained and retained all Regulatory Approvals and Regulatory Submissions pursuant to and in accordance with GCP and good laboratory practices, as applicable, and Applicable Law and all such information is and will be true and complete.

(k) Material trade secrets comprising the Ironwood Know-How have been kept confidential or have been disclosed to Third Parties only under terms of confidentiality. To Ironwood’s and its Affiliates’ knowledge, no breach of such confidentiality with respect to such Know-How has been committed by any Third Party.

(l) Ironwood Controls, as of the Effective Date, and will maintain Control of, such Know-How, and Patent Rights that have arisen or may arise under the Existing Agreements as are required to the extent necessary for AstraZeneca to perform its obligations and exercise its rights under this Agreement, including to conduct the Development activities with respect to the Licensed Compound and Product(s) in the Field in the Territory contemplated in the Initial Development Plan.

(m) To Ironwood’s and its Affiliates’ knowledge, it has conducted any Development and Commercialization activities in accordance with good laboratory and clinical practice and Applicable Law.

(n) To Ironwood’s and its Affiliates’ knowledge, neither Ironwood nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to any Regulatory Authority with respect to the Development of the Licensed Compound or the Products, failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Development of the Licensed Compound or the Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Licensed Compound or the Products that could reasonably be expected to provide a basis for the United States Food and Drug Administration to invoke its policy respecting “Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities”, set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.

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(o) Neither Ironwood nor any of its Affiliates has been debarred or is subject to debarment and neither Ironwood nor any of its Affiliates has used in any capacity, in connection with the Ironwood Technology, the Licensed Compound or the Products, any Person who has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act, or who is the subject of a conviction described in such section.

(p) The countries comprising Astellas’ territory under the Astellas Agreement are the same as those existing as of the effective date of the Astellas Agreement[**].

(q) To Ironwood’s and its Affiliates’ knowledge, it and its Affiliates have not violated any material Anti-Corruption Laws with respect to the Territory except for such matters as has been disclosed to AstraZeneca prior to the Effective Date.

(r) Ironwood has made available to AstraZeneca for review in due diligence all material (i) clinical and pre-clinical data relating to the Product(s) existing as of the Effective Date that is contained in Regulatory Submissions for such Product(s) in the Field in the Territory in its or any of its Affiliates’ possession, and (ii) Ironwood Know-How that has been requested of Ironwood by AstraZeneca or, to Ironwood’s or its Affiliates’ knowledge, is material to the Development or Commercialization of the Product(s) hereunder. To Ironwood’s or its Affiliates’ knowledge, all Ironwood Know-How that has been disclosed by Ironwood or its Affiliates to AstraZeneca under this Agreement or in connection with such due diligence or the negotiation of this Agreement is or will be true and correct in all material aspects. All adverse information with respect to the safety and efficacy of the Products known to Ironwood or its Affiliates as of the Effective Date has been disclosed by Ironwood to AstraZeneca.

8.3. Additional Representations and Warranties of AstraZeneca. AstraZeneca hereby represents, warrants and covenants to Ironwood that as of the Effective Date:
AstraZeneca has no products [**].

To AstraZeneca’s knowledge, AstraZeneca and its Affiliates have not materially violated any Anti-Corruption Laws with respect to the Territory except for such matters as has been disclosed to Ironwood prior to the Effective Date.

6.4. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

6.5. No Inconsistent Agreements. Neither Party has in effect and after the Effective Date neither Party may enter into any oral or written agreement or arrangement that would be inconsistent with its obligations under this Agreement or limit the ability of either Party to grant the licenses set forth in Article 2 of this Agreement.

6.6. Disclaimer. THE FOREGOING WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF NONINFRINGEMENT, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

7. INTELLECTUAL PROPERTY

7.1. Disclosure. During the Term, the Parties will promptly disclose to one another all Collaboration Know-How (whether patentable or not).

7.2. Ownership.

7.2.1. Ownership of Technology. Except as set forth in Section 7.2.2, determinations as to which Party has invented any Patent Right or Know-How will be made in accordance with the standards of inventorship under U.S. patent law. Subject to the license grants under Article 2, as between the Parties, Ironwood will own all Ironwood Technology (including any Collaboration Know-How (other than Joint Know-How and Development Data) that is invented, conceived or developed solely by employees of Ironwood or its Affiliates, or Third Parties acting on behalf of Ironwood or its Affiliates, and any Patent Rights claiming such Collaboration Know-How) and AstraZeneca will own all AstraZeneca Technology (including Collaboration Know-How (other than Joint Know-How and Development Data) that is invented, conceived, or developed solely by employees of AstraZeneca or its Affiliates, or Third Parties acting on behalf of AstraZeneca or its Affiliates, and any Patent Rights claiming such Collaboration Know-How). Each Party will own an undivided one-half interest in and to the Joint Technology. In the event inventorship and ownership of any Collaboration Technology cannot be resolved by the Parties with advice of their respective intellectual property counsel, such dispute will be resolved through arbitration pursuant to Section 10.1.3, provided such arbitration panel will include at least a single arbitrator who is a specialist in U.S. chemical and pharmaceutical patent law

7.2.2. Development Data. Each Party will own an undivided one-half interest in and to all Development Data. Subject to the license grants to the other Party under this Agreement and the other terms of this Agreement, each Party has the right to exploit its interest in the Joint Technology without consent of and without accounting to the other Party except, neither Party may assign its right, title, or interest in the Joint Technology to any Person, except (a) in connection with a permitted transaction under Section 10.9, or (b) to an Affiliate.

7.2.3. Employee Assignment. Each Party shall procure from each of its employees and permitted assignees and subcontractors who are conducting work under this Agreement, rights to any and all Ironwood Technology, AstraZeneca Technology, Development Data or Joint Technology, as applicable, such that each Party shall receive from the other Party, without payments beyond those contemplated by this Agreement, the rights granted to such Party to use such Ironwood Technology (in the case of Ironwood), AstraZeneca Technology (in the case of AstraZeneca), Development Data or Joint Technology, as applicable, pursuant to this Agreement. In the event such rights have not been
7.3. Intellectual Property Working Group. The Parties will promptly establish an intellectual property working group ("IPWG") comprised of at least one senior patent attorney and, as needed, one trademark attorney, from each Party, together with research and development personnel and such other representatives of the Parties as the Parties may determine to be appropriate from time to time, to manage and review the patent strategy for Collaboration Know-How to the extent such Collaboration Patent Rights are necessary or useful in the Territory to Develop, Manufacture or Commercialize the Licensed Compound or Product and perform such other activities as may be delegated to the IPWG pursuant to this Agreement or by the Parties from time to time during the Term by mutual written agreement. All decisions of the IPWG will be made by consensus, with each Party's representatives on the IPWG having collectively one vote on all matters that are within the responsibility of the IPWG. In the event that the IPWG adopts a patent strategy, the Parties shall comply with such strategy in connection with the exercise of their rights under this Article 7. If there is no such strategy, then the Party with the primary responsibility for an activity under this Article 7 will be responsible for developing and implementing the applicable strategy.


7.4.1. Patent Prosecution and Maintenance. Ironwood will be responsible for the preparation, filing, prosecution and maintenance of the Ironwood Patent Rights, and AstraZeneca will have the first right, but not the obligation, to prepare, file, prosecute and maintain the Collaboration Patent Rights included in the AstraZeneca Patent Rights (the "AstraZeneca Collaboration Patent Rights") worldwide, each at their own expense except [**], and in each case, provided that: in the case of the Ironwood Patent Rights and the AstraZeneca Collaboration Patent Rights, each Party will provide the other with (a) advance copies of, and a reasonable opportunity to comment upon, proposed patent filings in the Territory (in the case of the Ironwood Patent Rights) and worldwide (in the case of the AstraZeneca Collaboration Patent Rights) and prosecution strategies and proposed correspondence with patent offices in the applicable jurisdiction undertaken pursuant to any such filings, and will consider comments received in good faith and will not unreasonably reject such comments, except that Ironwood will not be obligated to provide AstraZeneca with advance copies of proposed patent filings, related prosecution strategies or proposed correspondence for any Patent Rights that are included in the rights granted by Forest, Astellas or Almirall, as applicable, to Ironwood pursuant to any of the Existing Agreements, unless it is permitted to do so thereunder; and (b) correspondence or other communications or actions which relate to the validity of Collaboration Patent Rights, to the extent such Collaboration Patent Rights are necessary or useful in the Territory to Develop, Manufacture or Commercialize a Licensed Compound or Product in the Territory, which correspondence or other communications or actions that are to be made during the course of an action before a national or regional patent office in the Territory or national court in the Territory will require the mutual approval of both Parties. A Party providing comments in accordance with this Section 7.4.1 will provide such comments, if any, expeditiously and in any event in reasonably sufficient time to meet any filing deadline communicated to it by the other Party. The Party receiving any such patent application and correspondence will maintain such information in confidence, except for patent applications that have been published and official correspondence that is publicly available.

7.4.2. Joint Patent Rights. Ironwood will have the first right, but not the obligation for the preparation, filing, prosecution and maintenance of the Joint Patent Rights. Except as otherwise agreed by the Parties in writing, costs incurred under this Section 7.4.2 for Joint Patent Rights [**].

7.4.3. Second Rights. If a Party decides not to file, prosecute or maintain a Patent Right covering, as applicable, Ironwood Technology, Collaboration Technology included in the AstraZeneca Technology or Joint Technology, to the extent such Technology covers the Development, Manufacture or Commercialization of the Licensed Compound or Product, with respect to Ironwood Technology within the Territory and with respect to such

7.4.4. Patent Term Extensions. Regardless of which Party is filing, prosecuting and maintaining any Patent Right pursuant to this Article 7, the Parties shall attempt to make all decisions by mutual consent regarding all patent term extensions for (a) the Ironwood Patent Rights in the Territory, (b) the AstraZeneca Collaboration Patent Rights in the Territory and (c) the Joint Patent Rights worldwide, including, if applicable, in

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the United States with respect to extensions pursuant to 35 U.S.C. § 156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for such Patent Rights. If, with respect to a Product and a country, the Parties cannot agree on which of such Patent Rights(s) as to which the term is to be extended in such country, then (i) with respect to such Patent Rights in the Territory, the Parties shall mutually agree on a Third Party patent lawyer (whose costs [*]*) and shall give such lawyer instructions to resolve such disagreement in a manner designed to maximize the period of exclusivity for the applicable Product, and the decision of such lawyer shall be binding on the Parties and (ii) Ironwood will have the right to make such decision outside the Territory for the Joint Patent Rights. Upon request by a Party controlling a decision under this Section 7.4.4, the other Party shall reasonably cooperate in the implementation of such decision.

7.5. Trademarks and Domain Names.

7.5.1. Product Trademark. Until such time as the Parties determine that the launch by a Third Party of a generic equivalent of the Product is imminent in the Territory (provided that discussion shall not be required if the JCC no longer has jurisdiction with respect to the Territory, for example in the case of Section 3.9) (based upon objective evidence shared and discussed by both Parties), all Products are to be Commercialized in the Territory under those Trademarks and using those domain names selected by the JCC, after good faith consultation with the Parties’ intellectual property counsel (each such

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Trademark, other than AstraZeneca House Marks or Ironwood House Marks, a “Product Trademark” and each such domain name, other than those containing a AstraZeneca House Mark or Ironwood House Mark, a “Product Domain Name”). After such time, AstraZeneca may select any Trademark or domain name of its choosing for the Commercialization of the Products in the Territory. The Parties acknowledge and agree that any Trademarks or domain names developed or used in connection with the Existing Agreements may not be used by the Parties in the Territory unless agreed to by Ironwood and Forest, Ironwood and Almirall, or Ironwood and Astellas, as applicable, in writing. Ironwood shall notify AstraZeneca of such restricted Trademarks and domain names so that AstraZeneca is able to comply with this requirement.

7.5.2. Ownership. Ironwood will own all Product Trademarks and Product Domain Names, subject to the license granted to AstraZeneca herein, and is responsible for the filing, prosecution, registration and maintenance of such Product Trademarks and the registration and maintenance of such Product Domain Names. If Ironwood decides not to file or continue to prosecute, register or maintain a Product Trademark or obtain or maintain a Product Domain Name in the Territory, it will give AstraZeneca reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Product Trademark or Product Domain Name in the Territory to permit AstraZeneca to carry out such activity. After such notice, AstraZeneca may undertake such activity on behalf of and in the name of Ironwood. The expenses of the selection, filing, prosecution and maintenance of the Product Trademarks and obtaining and maintaining the Product Domain Name [*]). Each Party will keep the other Party regularly apprised of the status of its activities under this Section 7.5.2 and will consult with such other Party (through the IPWG) in good faith prior to taking any material action with respect to any such Product Trademark or Product Domain Name.

7.5.3. Trademark and Domain Name Use. The manner of use of the Product Trademarks and the Product Domain Names will be subject to periodic review by the JCC. Neither Party will use the Product Trademarks in a way that is inconsistent with the trademark usage guidelines and the usage instructions approved by the JCC, and neither Party will use a Trademark confusingly similar to any of the Product Trademarks with any of its other products in the Territory or, except as otherwise provided herein, use the Product Trademarks in combination with its other Trademarks in the Territory in a manner which would create a composite or combination marks. The Parties will utilize the Product Trademarks and the Product Domain Names within the Territory only in accordance with this Agreement and for no other product in the Territory. Either Party may utilize the Product Trademarks and the Product Domain Names outside of the Territory, provided that such use is not reasonably likely to cause confusion or devalue the Product Trademark or Product Domain Name, as applicable, in the Territory.

7.5.4. Party Name on Product Promotional Material. Subject to Applicable Law, all Product promotional material in the Territory will include those Ironwood House Marks as may be requested by Ironwood in a manner that has equal prominence with AstraZeneca House Marks.

7.5.5. Trademark and Domain Name License. To effectuate the purposes of this Agreement, Ironwood hereby grants to AstraZeneca a royalty free license, to use and display the Product Trademarks and to use the Product Domain Names in connection with the Commercialization of the Products in accordance with this Section 7.5 and to use the Ironwood House Marks in connection with the Commercialization of a Product in the Field in the Territory, all in accordance with this Agreement. All goodwill arising from the use of such Product Trademarks, Product Domain Names and Ironwood House Marks will inure to the benefit of Ironwood.

7.6.1. Monitoring. The IPWG will develop procedures for monitoring Third Party patent submissions in the Territory. AstraZeneca will be responsible for executing such procedures and promptly reporting any relevant discovered activities or information to Ironwood. The costs of such execution [*].

7.6.2. Notice. If Ironwood or AstraZeneca becomes aware that any Ironwood Technology, AstraZeneca Technology, Collaboration Technology (including Joint Technology), Development Data, Product Trademark, or Product Domain Name is infringed or misappropriated by a Third Party in the Territory in the Field, or Collaboration Technology that is included in AstraZeneca Technology is infringed or misappropriated by a Third Party outside the Territory, or is subject to an invalidation action (including any administrative or judicial action, whether initiated at the State Intellectual Property Office of China or otherwise), or a declaratory judgment action arising from such infringement (any of the foregoing, being an "Infringement"), Ironwood or AstraZeneca, as the case may be, will promptly notify the other Party of such Infringement.

7.6.3. Enforcement and Defense of Product Trademarks and Domain Names. Subject to Section 5.7, AstraZeneca has the first right (but not the obligation) to enforce or defend any Product Trademark or Product Domain Name, against an Infringement in the Territory. If AstraZeneca exercises its right to enforce (and so defend) any Product Trademark or Product Domain Name pursuant to this Section 7.6.3, Ironwood will reasonably cooperate with AstraZeneca with respect to such enforcement or defense, including by joining any lawsuit or proceeding as a party where such joinder is required under Applicable Law to enforce or so defend the Product Trademark or Product Domain Name. In the event that AstraZeneca declines to enforce or so defend the Product Trademark or Product Domain Name against an Infringement within 90 days (or such shorter period as may be required to comply with legal or regulatory deadlines which relate to such Infringement) of becoming aware thereof, Ironwood will have the right to so enforce or so defend [*]

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

such Product Trademark or Product Domain Name. Irrespective of which Party controls an action pursuant to this Section 7.6.3, the Parties will collaborate with respect to such action and the comments of the other Party will not be unreasonably rejected with respect to strategic decisions and their implementation with respect to such action. In furtherance of the foregoing, the Party responsible for any such action will keep the other Party reasonably informed, in person or by telephone, regarding the status and costs of such action or proceeding prior to and during any such enforcement or defense. Neither Party will settle any such action without the written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Neither Party will incur any liability to the other as a consequence of such litigation or any unfavorable decision resulting therefrom, but for clarity, this sentence is without limitation of a Party’s other obligations hereunder, including Sections 9.2 and 9.3.

7.6.4. Costs and Recoveries for Product Trademarks and Domain Names. Irrespective of which Party prosecutes the action, the costs of any prosecution or defense of any Infringement of Product Trademarks or Product Domain Names in the Territory [*] and the proceeds of any awards, judgments or settlements obtained in connection with an Infringement in the Territory [*].

7.6.5. Enforcement and Defense of Patent Rights. Subject to the terms of any applicable license as a result of which Ironwood Controls any Patent Rights included in the Ironwood Technology (i.e., the Existing Agreements or other Third Party agreements), AstraZeneca has the first right (but not the obligation) to enforce or defend in connection with any such enforcement activity any Ironwood Technology in the Territory, AstraZeneca Technology worldwide (provided that it has the sole right, but not the obligation, with respect to AstraZeneca Technology that is not Collaboration Technology), and Collaboration Technology that is not included in AstraZeneca Technology (including Joint Technology and Development Data) in the Territory, to the extent either Party has the legal power to enforce or defend such Technology ("Subject Technology"), against an Infringement in the Territory, provided that AstraZeneca may not admit the invalidity or unenforceability of any Ironwood Technology or Joint Technology without first consulting with Ironwood and obtaining Ironwood’s prior written consent to such admission. If AstraZeneca exercises its right to enforce (and so defend) any Subject Technology pursuant to this Section 7.6.5, Ironwood will reasonably cooperate with AstraZeneca with respect to such enforcement or defense, including by joining any lawsuit or proceeding as a party where such joinder is required under Applicable Law to enforce or so defend the Subject Technology. In the event that AstraZeneca declines to enforce or so defend the Subject Technology (other than AstraZeneca Technology that is not Collaboration Technology) against an Infringement within 90 days (or such shorter period as may be required to comply with legal or regulatory deadlines which relate to such Infringement) of becoming aware thereof, Ironwood will have the right to so enforce or so defend such Subject Technology against such Infringement. Ironwood has the first right (but not the obligation) to enforce and defend any Joint Technology against an Infringement outside the Territory, provided that [*]

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Ironwood may not admit the invalidity or unenforceability of such Technology without first consulting with AstraZeneca and obtaining AstraZeneca’s prior written consent to such admission. In the event that Ironwood declines to enforce or so defend such Technology against an Infringement within 90 days (or such shorter period as may be required to comply with legal or regulatory deadlines which relate to such Infringement) of becoming aware thereof, AstraZeneca will have the right to so enforce or defend such Technology. Irrespective of which Party controls an action pursuant to this Section 7.6.5, the Parties will collaborate with respect to such action and the comments of the other Party will

(a) In the Territory. The Parties agree that, irrespective of which Party prosecutes the action, the costs of any prosecution or defense of any Infringement in the Territory [*] and the proceeds of any awards, judgments or settlements obtained in connection with an Infringement in the Territory [*].

(b) Outside the Territory. Costs of any prosecution or defense of any Infringement relating to Subject Technology outside the Territory [*] and the proceeds of any awards, judgments, or settlements obtained in connection with any prosecution or defense against any such Infringement [*].

7.7. Third Party Claims.

7.7.1. Third Party Claims - Course of Action. If the Development, Commercialization or Manufacture of a Product or the use of any Product Trademark or Product Domain Name, in each case, under this Agreement is alleged by a Third Party to infringe a Third Party’s Patent Right(s) or Trademark rights or misappropriates said Third Party’s trade secret, the Party becoming aware of such allegation will promptly notify the other Party thereof, in writing, reasonably detailing the claim.

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7.7.2. Third Party Suit. If a Third Party sues a Party (the “Sued Party”) alleging that the Sued Party’s or the Sued Party’s Affiliates’ or Sublicenses’, Development, Manufacture or Commercialization of the Product or use of the Product Trademark or Product Domain Name infringes or will infringe said Third Party’s Patent Right(s) or Trademark rights or misappropriates said Third Party’s trade secret, then upon the Sued Party’s request and in connection with the Sued Party’s defense of any such Third Party suit, the other Party will provide reasonable assistance to the Sued Party for such defense and will join such suit if deemed a necessary party; provided that for suits relating to any Product Trademark or Product Domain Name, subject to Section 5.7, AstraZeneca will have the first right (but not the obligation) and Ironwood will have the second right (but not the obligation) to assume the defense of any such suit; provided further that, with respect to any suit AstraZeneca elects to defend, Ironwood may select separate counsel of its own choosing at Ironwood’s expense. The Sued Party (or the controlling Party in the case of suits relating to any Product Trademark or Product Domain Name) will keep the other Party, if such other Party has not joined in such suit, reasonably informed with respect to the status of such suit on a quarterly basis, in person or by telephone, prior to and during the pendency of any such suit. The Sued Party or the controlling Party, as applicable, will not admit the invalidity of any Patent Right within the Ironwood Patent Rights, the AstraZeneca Patent Rights, or Joint Patent Rights, nor settle any such suit, without written consent of the other Party, such consent not to be unreasonably withheld (and Ironwood’s consent will not be required with respect to AstraZeneca Collaboration Patent Rights), and in the case of the Product Trademarks and Product Domain Names, the other Party will submit any argument or take any position in such Third Party suit which may in any way lessen, impair or undermine the Product Trademarks, or settle any such suit, without written consent of the other Party, such consent not to be unreasonably withheld. Subject to the Parties’ respective indemnity obligations pursuant to Sections 9.2 and 9.3, all litigation costs and expenses incurred with respect to a Third Party suit, including settlement costs, royalties paid in settlement of any such suit, and the payment of any damages to the Third Party, under this Section 7.7.2 [*] and the proceeds of any awards, judgments or settlements obtained in connection with any such suit [*].

7.8. Third Party Licenses. If, either Party in good faith believes that, in order to avoid infringing or misappropriating any Third Party’s Patent Right, Know-How, Trademark or domain name, that is necessary to Develop, Manufacture or Commercialize the Licensed Compound or Products in the Territory, it is necessary to obtain a license to such Patent Right, Know-How, Trademark or domain name, from such Third Party, then such Party will deliver notice thereof to the other Party setting forth the basis for such belief. With respect to (a) licenses relating to any such Patent or Trademark or domain name, AstraZeneca will have the first right (but not the obligation) and (b) licenses relating to any such Patent Rights or Know-How, Ironwood will have the first right (but not the obligation), in each case, through counsel of its choosing, to negotiate and obtain a license from such Third Party. The costs of any such license under clause (a) or (b) [*]. If the Party with the first right [*]

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[*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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7.9. Patent Marking. Each Party agrees to mark and have its Affiliates and all Sublicensees mark all Products (or their containers or labels) sold pursuant to this Agreement in accordance with the applicable statutes or regulations in the country or countries of manufacture and sale thereof.

7.10. Patent Certifications. Each Party will immediately give written notice to the other of any certification of which it becomes aware has been filed pursuant to any foreign equivalent to 21 U.S.C. § 355(b)(2)(A) or § 355(j)(2)(A)(vii) (or any amendment or successor statute thereto) claiming that the Ironwood Patent Rights, AstraZeneca Patent Rights, or Collaboration Patent Rights, in each case, in the Territory covering the Product are invalid or that infringement will not arise from the manufacture, use or sale in the Territory of such Third Party product by a Third Party. Any response to such certification shall be governed by Section 7.6.5, provided that if AstraZeneca decides not to respond to such certification, including by bringing infringement proceedings against such Third Party, AstraZeneca will give notice to Ironwood of its decision not to bring suit within ten business days after receipt of notice of such certification (or, if the time period permitted by law is less than 20 business days, within half of the time period permitted by law for AstraZeneca to commence such action) and Ironwood may then, but will not be obligated to, bring suit against the Third Party that filed the certification in accordance with its second rights as described in Section 7.6.5. Each Party shall cooperate with the other Party, including joining any action, as described in Section 7.6.5. The costs and recoveries of the Parties under this Section 7.10 [*]. In the event of a conflict between this Section 7.10 and Section 7.6.5, this Section 7.10 will control.

7.11. No Implied Licenses. Except as expressly set forth in this Agreement, no right or license under any Ironwood Technology or AstraZeneca Technology is granted or will be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or will be granted only as expressly provided in this Agreement.

7.12. Privileged Communications. In furtherance of this Agreement, it is expected that AstraZeneca and Ironwood will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they will remain confidential, they will not be deemed to waive any applicable attorney-client privilege and that they are made in connection with the shared community of legal interests existing between Ironwood and AstraZeneca, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Ironwood Patent Rights, AstraZeneca Patent Rights and Joint Patent Rights.

64 [*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

7.13. Registration and Submission of the Agreement. In the event that AstraZeneca or its Affiliate or Sublicensee is required, upon advice of counsel, to disclose or register this Agreement (or any portion of this Agreement), or one or more confirmatory patent or trademark license agreements to a government authority in the Territory, including in China, the Ministry of Commerce or the State Intellectual Property Office (or any agency or bureau thereof), AstraZeneca will, and will cause its Affiliates and Sublicensees to, provide prior written notice to Ironwood of such disclosure requirement and cooperate in good faith to prepare and execute an abbreviated license agreement, in form and substance reasonably acceptable to Ironwood, solely for purposes of such disclosure, with the understanding that the terms and conditions of this Agreement will control in the event of any dispute regarding the interpretation, applicability or enforcement of the abbreviated license agreement, and disclose or register such abbreviated license agreement.

8. TERM AND TERMINATION

8.1. Term. The term of this Agreement will commence on the Effective Date and will continue in full force and effect until there is no longer a Development Plan or Commercialization Plan contemplating Development or Commercialization of a Product in the Territory, unless earlier terminated as provided in this Article 8 (the “Term”).

8.2. Termination for Cause.

8.2.1. Termination for Material Breach. This Agreement may be terminated effective immediately by written notice by either Party at any time during the Term if the other Party materially breaches this Agreement, which breach remains uncured for [**] days measured from the date written notice of such breach is given to the breaching Party by the non-breaching Party, which notice will specify the nature of the breach and demand its cure; provided, however, that if such breach is not capable of being cured within the stated period and the breaching Party uses Commercially Reasonable Efforts to cure such breach during such period and presents a mutually agreeable remediation plan for such breach, this Agreement will not terminate and the cure period will be extended for such period provided in the remediation plan as long as the breaching party continues to use Commercially Reasonable Efforts to cure such breach and cure the breach. Further, in the case of a dispute during the cure period with respect to whether a material breach has occurred, the non-breaching Party shall not have the right to terminate this Agreement until it complies with the applicable dispute resolution procedures hereunder, including those set forth in Section 10.1.2, and the dispute has been resolved pursuant to such procedures and breach remains uncured [**] days after the final resolution of the dispute through such dispute resolution procedures. Notwithstanding anything to the contrary set forth in this Agreement but subject to the limitations set forth in Section 9.6, termination will not be deemed to relieve a defaulting party from any liability arising from such default.

65 [**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
8.2.2. Termination for Safety Reasons. In the event that AstraZeneca determines in good faith in accordance with its internal procedures that there is a material safety issue associated with the Product, which safety issue was not disclosed to AstraZeneca prior to the Effective Date, then AstraZeneca shall discuss the matter with Ironwood as promptly as practicable. Provided that AstraZeneca does not modify its decision following such discussion, AstraZeneca may terminate this Agreement effective upon written notice thereof to Ironwood.

8.2.3. Bankruptcy. If the other Party or a Local Affiliate files in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within [**] days after the filing thereof, or if the other Party proposes or is a Party to any dissolution or liquidation, or if the other Party makes an assignment for the benefit of its creditors (each, a “Bankruptcy”), this agreement may be terminated, provided that in the case of a Local Affiliate’s Bankruptcy, if AstraZeneca notifies Ironwood within [**] days following such Bankruptcy that it will make reasonable arrangements to perform the Development or Commercialization activities assigned to such Local Affiliate in light of such Bankruptcy and then does so within [**] days following such Bankruptcy, Ironwood may not terminate this Agreement due to such Bankruptcy.

8.3. Termination for Convenience. Prior to its expiration, this Agreement may be terminated at any time by AstraZeneca effective upon at least [**] days’ prior written notice to Ironwood for any reason.

8.4. Change of Control.

8.4.1. Change of Control Notice. Each Party will notify the other in writing, referencing this Section 8.4.1, immediately upon any Change of Control, and will provide such notice where permitted at least [**] days prior to the Change of Control.

8.4.2. Consequences of a Change of Control of AstraZeneca. In the event that AstraZeneca, AstraZeneca PLC (“Parent”) or [**] is subject to a Change of Control which could reasonably be expected to lead to an Impairment, Ironwood may elect, in its sole discretion, to (a) continue this Agreement in accordance with its terms or (b) terminate this Agreement effective upon [**] days’ written notice of termination (or any sooner date specified in such written notice), such notice to be delivered within [**] days after the Fair Market Value is determined pursuant to this Section 8.4.2. Within [**] days following the Change of Control, Ironwood may provide notice to AstraZeneca requesting a determination of the Fair Market Value of the Product rights subject to

8.4.3. Consequences of a Change of Control of Ironwood. In the event Ironwood is subject to a Change of Control, AstraZeneca may elect, in its sole discretion to (a) continue this Agreement in accordance with its terms or (b) limit the role of the JCC such that the JCC’s sole role will be to review and approve the Commercialization Budget. Furthermore, in the event Ironwood is subject to a Change of Control, Ironwood’s right to elect to co-promote the Product under Section 3.5.4 will terminate.

8.5. Effects of Termination and Expiration.

8.5.1. Effects of Termination by Ironwood or by AstraZeneca for Convenience. If this Agreement is terminated by Ironwood under Section 8.2.1, 8.2.3, or 8.4.2, or by AstraZeneca under Section 8.3, then the following provisions will be effective upon such termination:

(a) All licenses granted by Ironwood to AstraZeneca hereunder will automatically terminate, except to the extent required for AstraZeneca to perform its surviving obligations hereunder and correspondingly the sublicense rights granted to AstraZeneca will remain in effect solely to allow AstraZeneca to sublicense under such rights and licenses solely for the aforesaid purpose;

(b) All licenses granted by AstraZeneca to Ironwood herein will become fully paid up, fully sublicensable, irrevocable, perpetual, royalty-free licenses and will be expanded to grant Ironwood corresponding rights in the Territory to the extent such rights are not already granted hereunder;

(c) AstraZeneca will assign to Ironwood all right, title, and interest in and to (i) all Regulatory Submissions and Regulatory Approvals pertaining to the Licensed Compound or Product Controlled by AstraZeneca (excluding Regulatory Submissions and Regulatory Approvals to the extent pertaining to AstraZeneca’s proprietary compounds or products that are not or do not contain the Licensed Compound as the sole active ingredient), (ii) all of AstraZeneca’s rights, title and interest in and to any Product Trademark (including, without limitation, the goodwill symbolized by such Product Trademark) used to brand the Product (excluding, for clarity, any AstraZeneca House Marks)
and any Product Domain Names, and (iii) all of AstraZeneca’s interest in any copyrights to the extent necessary or useful to enable Ironwood to continue to conduct Development as contemplated in the then current Development Plan and to use the current versions of promotional materials and sales training materials for the Products in the Territory (excluding, for clarity, any AstraZeneca House Marks) for a period of [**] months or shorter if required after the date of termination of this Agreement to comply with Applicable Law;

(d) AstraZeneca will furnish Ironwood with reasonable cooperation (i) to assure a smooth transition of any clinical or other studies in progress related to the Licensed Compound or Product(s) which Ironwood determines to continue in compliance with Applicable Law and ethical guidelines applicable to the transfer or termination of any such studies, and (ii) as reasonably necessary for Ironwood to assume the Commercialization activities of the Product(s) in the Territory. In addition, AstraZeneca will return all Ironwood Confidential Information to Ironwood as set forth in Section 5.1.5. Ironwood will return all AstraZeneca Confidential Information to AstraZeneca as set forth in Section 5.1.5; provided however, that Ironwood may retain any such Confidential Information that is reasonably necessary or useful for Ironwood to develop, manufacture and commercialize the Licensed Compound or Products or exercise its rights hereunder after the effective date of such termination (but such right of retention shall not be construed to expand the scope of the rights granted to Ironwood hereunder);

(e) Until termination is effective, AstraZeneca will continue to use Commercially Reasonable Efforts to perform its obligations under the Development Plan and the Commercialization Plan then in effect, except with respect to activities that Ironwood elects to discontinue; and

(f) Sections 8.5.1(a) will be effective upon any such termination, and Sections 8.5.1(b), 8.5.1(c), 8.5.1(d), and 8.5.1(e) will be effective upon such termination or, in the case of termination by AstraZeneca pursuant to Section 8.3 or by Ironwood pursuant to Section 8.4, upon Ironwood’s earlier election following a notice of termination. All activities performed by AstraZeneca on behalf of Ironwood in this Section 8.5.1 will be at AstraZeneca’s cost and expense. At the election of AstraZeneca at the time of termination, the Parties will negotiate in good faith a transition agreement in order to effect the provisions of this Section 8.5.1, provided, however, that the inability of the Parties to agree on the terms of such agreement shall not relieve AstraZeneca of its obligations under this Section 8.5.1.

8.5.2. Effects of Termination by AstraZeneca for Ironwood Material Breach or Insolvency. If AstraZeneca terminates this Agreement pursuant to Section 8.2.1 or 8.2.3, all licenses granted by (a) Ironwood to AstraZeneca to Ironwood hereunder, will terminate, and (b) AstraZeneca to Ironwood hereunder will become fully paid up, fully sublicensable, irrevocable, perpetual, royalty-free licenses and will be expanded to grant Ironwood corresponding rights in the Territory to the extent such rights are not already granted hereunder, and neither Party will have any further contractual obligations to the other hereunder, except with respect to any provisions which survive the termination of this Agreement by their respective terms or as set forth in Section 8.6, and obligations accrued but remaining outstanding as of the effectiveness of termination. Ironwood will return all of AstraZeneca’s Confidential Information to AstraZeneca as set forth in Section 5.1.5; provided however, that Ironwood may retain any such Confidential Information that is reasonably necessary for Ironwood to develop, manufacture and commercialize the Licensed Compound or Products or exercise its rights hereunder after the effective date of such termination or perform its obligations under this Agreement in the Territory (but such right of retention shall not be construed to expand the scope of the rights granted to Ironwood hereunder). Notwithstanding the foregoing, in lieu of such termination, AstraZeneca may elect (i) [**] and (ii) to [**]. Furthermore, if AstraZeneca is entitled to terminate this Agreement due to Ironwood’s material breach of its regulatory obligations as provided in Section 3.2, in lieu of terminating this Agreement, AstraZeneca may elect to perform such activities on behalf of and in the name of Ironwood in accordance with the Development Plan, in which case Ironwood will provide any assistance reasonably requested by AstraZeneca in transitioning and performing such activities, including the execution of any power of attorney or similar document necessary for AstraZeneca to perform such activity.

8.5.3. Effects of Termination for Safety Reasons. If AstraZeneca terminates this Agreement for safety reasons pursuant to Section 8.2.2, then the following provisions will be effective upon such termination:

(a) All licenses granted by Ironwood to AstraZeneca hereunder will automatically terminate, except to the extent required for AstraZeneca to perform its surviving obligations hereunder, and correspondingly the sublicense rights granted to AstraZeneca will remain in effect solely to allow AstraZeneca to sublicense under such rights and licenses solely for the aforesaid purpose;

(b) Notwithstanding the survival provisions of Section 8.6, all licenses granted by AstraZeneca to Ironwood hereunder will automatically terminate with respect to any Technology that is the cause of the safety issue underlying such termination, and all other licenses granted by AstraZeneca to Ironwood hereunder will survive such termination;

(c) AstraZeneca will return all Ironwood Confidential Information to Ironwood and Ironwood will return all AstraZeneca Confidential Information to AstraZeneca, each as set forth in Section 5.1.5; provided however, that Ironwood may retain any such Confidential Information that
9. PRODUCT LIABILITY, INDEMNIFICATION, AND INSURANCE

9.1. Sharing of Liability Expenses. The Parties will share all losses, damages, liabilities, settlements, penalties, fines and expenses (including reasonable attorneys’ fees and expenses) arising from claims against the Parties or their respective Affiliates or any of their respective employees, officers, directors, agents or permitted Sublicensees by Third Parties (collectively, “Liabilities” and such claims, “Third Party Claims”) to the extent such Liabilities relate to the Development or Manufacturing of the Licensed Compound or Product for the Territory under this Agreement or the Commercialization of the Product in the Territory, including any (a) the death or bodily injury of any person (or similar claims) (“Product Liability Claims”) in the Territory on account of the use of any Product sold in the Territory during the Term, (b) any recall or withdrawal of Product sold in the Territory during the Term, or (c) any infringement claims brought by any Third Parties in the Territory, which are the subject of Section 7.7 (collectively, “Shared Liability Claims”), as if such Liabilities were Program Expenses at the time such Liabilities were incurred by the applicable Party, except to the extent that one of the Parties would be responsible for such Liabilities (assuming they were incurred by the other Party) under Section 9.2 or 9.3.

9.2. Indemnification by Ironwood. Ironwood shall indemnify, defend and hold harmless AstraZeneca, its Affiliates, and each of its and their respective employees, officers, directors and permitted Sublicensees (each, a “AstraZeneca Indemnified Party”) from and against any and all Liabilities arising out of Third Party Claims to the extent resulting from or arising out of:

(a) any intentional misconduct or negligence on the part of Ironwood or any of its Affiliates or Sublicensees in performing any activity contemplated by this Agreement or any Ancillary Agreement;

(b) any Ironwood representation or warranty set forth in this Agreement or any Ancillary Agreement being untrue;

(c) any loss, damage, or liability arising from a material safety issue under Section 8.2.2; and

(d) for a material safety issue under Section 8.2.2; and

(e) if, within [*] years after the effective date of a termination of this Agreement pursuant to Section 8.2.2, either (i) Ironwood receives express authorization from a Regulatory Authority to recommence or continue the development and commercialization of the Product or (ii) a Safety Panel determines that it is reasonable for Ironwood to continue the development and commercialization of the Product, taking into account all safety issues with the Product, then Ironwood shall be afforded the more expanded reversion rights with respect to the Product as to which it would have been entitled had AstraZeneca terminated this Agreement pursuant to Section 8.3; provided, however, that Ironwood’s indemnification obligations with respect to the Product shall remain in effect and AstraZeneca shall no longer have any indemnification obligation to Ironwood or any Ironwood Indemnified Party with respect to any Product sold by or on behalf of Ironwood or its Affiliates or licensees after the date of such termination. Ironwood will have the right to convene a Safety Panel during such [*] year period upon written notice to AstraZeneca. Each Party will reasonably cooperate with and provide any reasonably requested information to such Safety Panel.

8.6. Survival of Certain Obligations. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing before such expiration or termination. The provisions of this Agreement that survive expiration or termination of this Agreement are: Articles 1, 4 (with respect to any costs or expenses incurred, or Net Sales made, prior to the effective date of such expiration or termination, or costs and expenses incurred after such date if expressly contemplated as costs and expenses that may be incurred hereunder following the expiration or termination hereof and included as Program Expenses notwithstanding such expiration or termination (e.g., Section 3.3.2)), Sections 2.2, 2.3 (solely with respect to the rights granted to Ironwood and their Affiliates under this Agreement or the Commercialization of the Product in the Territory to which any termination relates after providing notice of termination for a material safety issue under Section 8.2.2; and

and

(e) If, within [*] years after the effective date of a termination of this Agreement pursuant to Section 8.2.2, either (i) Ironwood receives express authorization from a Regulatory Authority to recommence or continue the development and commercialization of the Product or (ii) a Safety Panel determines that it is reasonable for Ironwood to continue the development and commercialization of the Product, taking into account all safety issues with the Product, then Ironwood shall be afforded the more expanded reversion rights with respect to the Product as to which it would have been entitled had AstraZeneca terminated this Agreement pursuant to Section 8.3; provided, however, that Ironwood’s indemnification obligations with respect to the Product shall remain in effect and AstraZeneca shall no longer have any indemnification obligation to Ironwood or any Ironwood Indemnified Party with respect to any Product sold by or on behalf of Ironwood or its Affiliates or licensees after the date of such termination. Ironwood will have the right to convene a Safety Panel during such [*] year period upon written notice to AstraZeneca. Each Party will reasonably cooperate with and provide any reasonably requested information to such Safety Panel.

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is reasonably necessary or useful for Ironwood to exercise its rights hereunder after the effective date of such termination (but such right of retention shall not be construed to expand the scope of the rights granted to Ironwood hereunder);

(d) AstraZeneca will provide such documentation in its possession and control relating thereto and discuss such safety issue with Ironwood in good faith as reasonably requested by Ironwood for at least [*] days after the effective date of such termination to assist Ironwood and to identify, further characterize, and fully document such safety issue. AstraZeneca’s out-of-pocket costs for such assistance, if any, shall be paid by Ironwood. For clarity, AstraZeneca will not be required to generate any new information regarding such material safety issue or undertake any Development or Commercialization activities in the portion of the Territory to which any termination relates after providing notice of termination for a material safety issue under Section 8.2.2; and

(e) If, within [*] years after the effective date of a termination of this Agreement pursuant to Section 8.2.2, either (i) Ironwood receives express authorization from a Regulatory Authority to recommence or continue the development and commercialization of the Product or (ii) a Safety Panel determines that it is reasonable for Ironwood to continue the development and commercialization of the Product, taking into account all safety issues with the Product, then Ironwood shall be afforded the more expanded reversion rights with respect to the Product as to which it would have been entitled had AstraZeneca terminated this Agreement pursuant to Section 8.3; provided, however, that Ironwood’s indemnification obligations with respect to the Product shall remain in effect and AstraZeneca shall no longer have any indemnification obligation to Ironwood or any Ironwood Indemnified Party with respect to any Product sold by or on behalf of Ironwood or its Affiliates or licensees after the date of such termination. Ironwood will have the right to convene a Safety Panel during such [*] year period upon written notice to AstraZeneca. Each Party will reasonably cooperate with and provide any reasonably requested information to such Safety Panel.

8.6. Survival of Certain Obligations. Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing before such expiration or termination. The provisions of this Agreement that survive expiration or termination of this Agreement are: Articles 1, 4 (with respect to any costs or expenses incurred, or Net Sales made, prior to the effective date of such expiration or termination, or costs and expenses incurred after such date if expressly contemplated as costs and expenses that may be incurred hereunder following the expiration or termination hereof and included as Program Expenses notwithstanding such expiration or termination (e.g., Section 3.3.2)), Sections 2.2, 2.3 (solely with respect to the rights granted to Ironwood thereunder), 2.4 (solely with respect to the rights granted to Ironwood thereunder), 3.3.2 (for Product sold in the Territory during the Term), 4.7, 5.1, 6.6, Article 7 (solely with respect to those provisions relating to Joint Technology or Development Data), Sections 7.2, 7.12, and Articles 8, 9 and 10. Any expiration or early termination of this Agreement will be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination. In no event will any milestone payment be due hereunder after the date on which a notice of termination is provided hereunder. In addition, Sections 4.4, 4.5, 4.6 and 4.8 shall apply with respect to payments due hereunder after expiration or termination of this Agreement.

9. PRODUCT LIABILITY, INDEMNIFICATION, AND INSURANCE

9.1. Sharing of Liability Expenses. The Parties will share all losses, damages, liabilities, settlements, penalties, fines and expenses (including reasonable attorneys’ fees and expenses) arising from claims against the Parties or their respective Affiliates or any of their respective employees, officers, directors, agents or permitted Sublicensees by Third Parties (collectively, “Liabilities” and such claims, “Third Party Claims”) to the extent such Liabilities relate to the Development or Manufacturing of the Licensed Compound or Product for the Territory under this Agreement or the Commercialization of the Product in the Territory, including any (a) the death or bodily injury of any person (or similar claims) (“Product Liability Claims”) in the Territory on account of the use of any Product sold in the Territory during the Term, (b) any recall or withdrawal of Product sold in the Territory during the Term, or (c) any infringement claims brought by any Third Parties in the Territory, which are the subject of Section 7.7 (collectively, “Shared Liability Claims”), as if such Liabilities were Program Expenses at the time such Liabilities were incurred by the applicable Party, except to the extent that one of the Parties would be responsible for such Liabilities (assuming they were incurred by the other Party) under Section 9.2 or 9.3.

9.2. Indemnification by Ironwood. Ironwood shall indemnify, defend and hold harmless AstraZeneca, its Affiliates, and each of its and their respective employees, officers, directors and permitted Sublicensees (each, a “AstraZeneca Indemnified Party”) from and against any and all Liabilities arising out of Third Party Claims to the extent resulting from or arising out of:

(a) any intentional misconduct or negligence on the part of Ironwood or any of its Affiliates or Sublicensees in performing any activity contemplated by this Agreement or any Ancillary Agreement;

(b) any Ironwood representation or warranty set forth in this Agreement or any Ancillary Agreement being untrue;
Section 7.7, the procedures in Article 7 will control.

Indemnity relates that are the subject matter of such proceeding. Notwithstanding the foregoing, if there is a conflict between this Section 9.4 and the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on claims to which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnifying Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnifying Party will not be liable for any settlement of any proceeding unless effected with its written consent. The Indemnifying Party will not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of 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 to which the indemnity relates that are the subject matter of such proceeding. Notwithstanding the foregoing, if there is a conflict between this Section 9.4 and Section 7.7, the procedures in Article 7 will control.

9.4. Procedure. Each Party will notify the other in the event it becomes aware of a claim for which indemnification may be sought hereunder or for which Liability is shared pursuant to this Article 9, such Party (the “Indemnified Party”) will promptly notify the other Party (the “Indemnifying Party”) in writing and the Indemnifying Party and Indemnified Party will meet to discuss how to respond to any Third Party Claims to the extent resulting from or arising out of:

(a) any intentional misconduct or negligence on the part of AstraZeneca or any of its Affiliates or Sublicensees in performing any activity contemplated by this Agreement or any Ancillary Agreement;
(b) any AstraZeneca representation or warranty set forth in this Agreement or any Ancillary Agreement being untrue;
(c) any breach by AstraZeneca of any of its covenants or obligations hereunder or under any Ancillary Agreement; or
(d) any exploitation of the Joint Technology or the Development Data by AstraZeneca or its Affiliates, licensees of Ironwood and Sublicensees of AstraZeneca hereunder) of rights under Section 2.2, including any exploitation of the Joint Technology or the Development Data for purposes other than exploitation of the Licensed Compound and Products by Ironwood, its Affiliates, licensees or Sublicensees under this Agreement or any Ancillary Agreement;

except, in each case, to the extent AstraZeneca is obligated to indemnify Ironwood for such Liabilities pursuant to Section 9.3.

9.3. Indemnification by AstraZeneca. AstraZeneca shall indemnify, defend and hold harmless Ironwood, its Affiliates, Sublicensees, distributors and each of its and their respective employees, officers, directors and agents (each, an “Ironwood Indemnified Party”) from and against any and all Liabilities arising out of Third Party Claims to the extent resulting from or arising out of:

(a) any intentional misconduct or negligence on the part of AstraZeneca or any of its Affiliates or Sublicensees in performing any activity contemplated by this Agreement or any Ancillary Agreement;
(b) any AstraZeneca representation or warranty set forth in this Agreement or any Ancillary Agreement being untrue;
(c) any breach by AstraZeneca of any of its covenants or obligations hereunder or under any Ancillary Agreement; or

9.2. Indemnification by Ironwood. Ironwood shall indemnify, defend and hold harmless AstraZeneca, its Affiliates, Sublicensees, distributors (including Forest, Almirall and Astellas) or Sublicensees (i) after the end of the Term (including any use of any intellectual property or materials that revert to Ironwood following expiration or termination of this Agreement), (ii) outside the Territory or (iii) outside the Field in the Territory;

(e) any breach by Ironwood of any of its covenants or obligations hereunder or under any Ancillary Agreement or (except to the extent due to a breach of this Agreement by AstraZeneca) under the Existing Agreements; or

(f) the exercise by Ironwood, its Affiliates, licensees or Sublicensees (excluding such exercise by AstraZeneca, its Affiliates, and Sublicensees as licensees of Ironwood and Sublicensees of AstraZeneca hereunder) of rights under Section 2.2, including any exploitation of the Joint Technology or the Development Data for purposes other than exploitation of the Licensed Compound and Products by Ironwood, its Affiliates, licensees or Sublicensees under this Agreement or any Ancillary Agreement;

except, in each case, to the extent Ironwood is obligated to indemnify AstraZeneca for such Liabilities pursuant to Section 9.3.

9.4. Procedure. Each Party will notify the other in the event it becomes aware of a claim for which indemnification may be sought hereunder or for which Liability is shared pursuant to this Article 9. In case any proceeding (including any governmental investigation) is instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 9, such Party (the “Indemnified Party”) will promptly notify the other Party (the “Indemnifying Party”) in writing and the Indemnifying Party and Indemnified Party will meet to discuss how to respond to any claims that are the subject matter of such proceeding. The Indemnifying Party, upon request of the Indemnified Party, will retain counsel reasonably satisfactory to the Indemnified Party to represent the Indemnified Party and will pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party will have the right to retain its own counsel, but the fees and expenses of such counsel will be at the expense of the Indemnified Party unless (i) the Indemnifying Party and the Indemnified Party will have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses incurred pursuant to Section 9.2 or 9.3 will be reimbursed as they are incurred. The Indemnifying Party will not be liable for any settlement of any proceeding unless effected with its written consent. The Indemnifying Party will not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of 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 to which the indemnity relates that are the subject matter of such proceeding. Notwithstanding the foregoing, if there is a conflict between this Section 9.4 and Section 7.7, the procedures in Article 7 will control.
9.5. Insurance. Each Party further agrees to use Commercially Reasonable Efforts to obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers to cover its indemnification obligations under Sections 9.1, 9.2 or 9.3; provided that [**].

9.6. Liability Limitations. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR ANY ANCILLARY AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES, OR FOR LOST PROFITS, LOST MILESTONES, OR LOST ROYALTIES UNDER THIS AGREEMENT OR ANY ANCILLARY AGREEMENT, WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (a) THE DEVELOPMENT, COMMERCIALIZATION, USE OR SALE OF ANY LICENSED COMPOUND OR PRODUCT DEVELOPED, OR COMMERCIALIZED HEREUNDER OR UNDER ANY ANCILLARY AGREEMENT, OR (b) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY ANCILLARY AGREEMENT. THE FOREGOING LIMITATIONS IN THIS SECTION 9.6 SHALL NOT APPLY TO (I) ANY LIABILITY OF EITHER PARTY ARISING FROM ITS OR ITS AFFILIATE’S OR SUBCONTRACTOR’S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, (II) ANY CLAIMS UNDER SECTION 9.1, 9.2 OR 9.3 OR (III) ANY LIABILITY OF EITHER PARTY FOR BREACH OF SECTION 5.1 OR SECTIONS 5.2.1 or 5.2.2.

10. MISCELLANEOUS.

10.1. Governing Law; Jurisdiction; Dispute Resolution.

10.1.1. Governing Law. The interpretation and construction of this Agreement will be governed by the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

10.1.2. Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement other than a matter governed by Sections 3.1.1(f), 3.4.1(f), and 3.5.1(f), either Party will provide written notice of the dispute to the other, in which event the dispute will be referred to the executive officers designated below or their successors, for attempted resolution by good faith negotiations within [**] days after such notice is received. The designated officers are initially as follows:

For Ironwood: Its Chief Executive Officer or his designate

For AstraZeneca: Its Regional VP for Asia Pacific or his designate

In the event the designated executive officers do not resolve such dispute within the allotted [**] days, either Party may, after the expiration of the 30 day period, seek to resolve the dispute through arbitration in accordance with Section 10.1.3. The Parties acknowledge that (a) the failure of the JDC, JOC or JCC to resolve a JDC Deadlock, JOC Deadlock or JCC Deadlock, as applicable, which failure does not involve a breach by a Party of its obligations hereunder will not be deemed a dispute subject to this Section 10.1.2 or Section 10.1.3 and (b) a matter that is subject to the final decision-making of a Party or its committee representatives hereunder is not subject to this Section 10.1.2 or Section 10.1.3 (except to extent a dispute arises to whether such Party has exercised such decision-making authority in accordance with its obligation to use Commercially Reasonable Efforts hereunder).

10.1.3. Arbitration.

(a) Claims. Any claim, dispute, or controversy of whatever nature arising between the Parties out of or relating to this Agreement that is subject to but not resolved under Section 10.1.2 within the required [**] day time period, including any action or claim based on tort, contract, or statute (including any claims of breach or violation of statutory or common law protections from discrimination, harassment and hostile working environment), or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement ("Claim"), will be resolved by final and binding arbitration before a panel of three experts with relevant industry experience (the “Arbitrators”). One Arbitrator will be chosen by Ironwood and one Arbitrator will be chosen by AstraZeneca within 15 days from the notice of initiation of arbitration. The third Arbitrator will be chosen by mutual agreement of the Arbitrator chosen by Ironwood and the Arbitrator chosen by AstraZeneca within 15 days of the date that the last of such Arbitrators were appointed. If the decisions of the Arbitrators will be enforced in China, the Arbitrators will be administered by the Hong Kong International Arbitration Center in Hong Kong in accordance with the then-effective International Chamber of Commerce ("ICC") arbitration rules or procedures regarding commercial or business disputes. For all other Claims, the Arbitrators will be administered by the ICC in
[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

determine whether a party is the prevailing party, and if so, to award to that prevailing party reimbursement for its reasonable attorneys’ fees, costs and disbursements (including, for example, expert witness fees and expenses, photocopy charges, travel expenses, etc.), or the fees and costs of the administrator of the arbitration and the Arbitrators.

(d) Compliance with this Agreement. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties will continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding.

(e) Injunctive or Other Equity Relief. Nothing contained in this Agreement will deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction applying the laws of that court in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding.

10.2. Force Majeure. No liability will result from, and no right to terminate will arise, in whole or in part, based upon any delay in performance or non-performance, in whole or in part, by either of the Parties to this Agreement to the extent that such delay or non-performance is caused by an event of Force Majeure. “Force Majeure” means an event that is beyond a non-performing Party’s reasonable control, including an act of God, act of the other Party, war, riot, civil commotion, strike, terrorist act, malicious damage, epidemic, quarantine, fire, flood, storm, natural disaster, whether or not it is later held to be invalid or inapplicable. The Force Majeure Party will within ten days of the occurrence of the Force Majeure event, give written notice to the other Party stating the nature of the Force Majeure event, its anticipated duration and any action being taken to avoid or minimize its effect. Any suspension of performance will be of no greater scope and of no longer duration than is reasonably required and the Force Majeure Party will use reasonable effort to remedy its inability to perform; provided, however, if the suspension of performance continues or is anticipated to continue for 30 days after the date of the occurrence, the unaffected Party will have the right but not the obligation to perform on behalf of the Force Majeure Party for a period of such Force Majeure and such additional period as may be reasonably required to assure a smooth and uninterrupted transition of such activities. If such failure to perform would constitute a material breach of this Agreement in the absence of such event of Force Majeure, and continues for one year from the date of the occurrence and the Parties are not able to agree on appropriate amendments within such period, such other Party will have the right, notwithstanding the first sentence of this Section 10.2, to terminate this Agreement immediately by written notice to the Force Majeure Party. In the case of such a termination, neither Party will have any liability to the other except for those rights and liabilities that accrued prior to the date of termination or that survive termination of this Agreement.

10.3. Additional Approvals. AstraZeneca and Ironwood will 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 things necessary or desirable for the consummation of the transactions as contemplated hereby. Neither Party will be required, however, to divest or out-license products or assets or materially change its business if doing so is a condition of obtaining any governmental approvals of the transactions contemplated by this Agreement.

10.4. Waiver and Non-Exclusion of Remedies. A Party’s failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy will not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all
provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing. The rights and remedies provided in this Agreement are cumulative and do not exclude any other right or remedy provided by law or otherwise available except as expressly set forth in this Agreement.

10.5. Notices.

10.5.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement must be in writing, must refer specifically to this Agreement and will be deemed given only if delivered by hand, sent by facsimile transmission (with transmission confirmed), by PDF e-mail attachment with digital return receipt, or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 10.5.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 10.5.1. Such Notice will be deemed to have been given as of the date delivered by hand, transmitted by facsimile (with transmission confirmed) or by PDF e-mail attached with digital return receipt, or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 10.5.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

10.5.2. Address for Notice.

For Ironwood:
Ironwood Pharmaceuticals, Inc.
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[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

301 Binney Street
Cambridge, MA 02142
United States of America
Attention: General Counsel
Fax: +1 (617) 494-0480
E-mail: [**]

With a copy to:
Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
United States of America
Attention: Marc A. Rubenstein, Esq.
Fax: +1 (617) 235-0706
E-mail: marc.rubenstein@ropesgray.com

For AstraZeneca:
AstraZeneca Shanghai Zhangjiang Park
No. 199 Liangjing Road
201203
China
10.6. Entire Agreement. This Agreement, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each Party confirms that it is not relying on any representations, warranties or covenants of the other Party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud. All Exhibits or Schedules referred to in this Agreement are intended to be and are hereby specifically incorporated into and made a part of this Agreement. In the event of any inconsistency between any such Exhibits or Schedules and this Agreement, the terms of this Agreement will govern.

10.7. Language. Meetings of the JDC, JOC and JCC and all other meetings between the Parties will be conducted in English. All documents prepared by one Party hereunder for the purpose of distribution to the other Party shall be written in English except as otherwise agreed by the Parties in writing or in any Ancillary Agreement. Any other documents generated by AstraZeneca or its Affiliates or received by AstraZeneca or its Affiliates and required to be provided to Ironwood hereunder shall first be translated into English by or on behalf of AstraZeneca. The Parties shall coordinate regarding any other translations required in order to conduct activities with respect to the Licensed Compound and Products hereunder in order to avoid duplicative effort and expense. The costs and expenses relating to any translation for which AstraZeneca is responsible under this Section 10.7 or that is required in order to make Regulatory Submissions in the Territory as contemplated hereunder or other filings required by Applicable Law [*]. Notwithstanding the foregoing, in case of non-English language documents that were prepared by way of a certified translation of an English language document, provision of the original English language document (and upon request, the applicable certification) shall constitute a substitute for translation. With regard to particular classes of documents, the applicable committee hereunder may modify the foregoing provisions regarding translation as needed by consensus of the Parties’ representatives.

10.8. Amendment. Any amendment or modification of this Agreement must be in writing and signed by authorized representatives of both Parties.

10.9. Assignment. Neither Party may assign its rights or delegate its obligations under this Agreement, in whole or in part without the prior written consent of the other Party, except that, subject to the other terms of this Agreement, (a) each Party will always have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, (ii) on written notice to the other Party, assign any or all of its rights and delegate or subcontract any or all of its obligations hereunder to any of its Affiliates, and (iii) to assign this Agreement in its entirety to a Future Acquirer in connection with a Change of Control of such Party and (b) Ironwood may, without such consent, monetize all or a portion of the value of the milestone payments to which it may be entitled under Section 4.2 and payments it is entitled to receive under Section 4.2 by assigning to one Third Party (a “Revenue Buyer”) the right to receive such milestone payments and other payments (a “Monetization Transaction”), subject to compliance with the following:

[*] Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.
A) Ironwood shall provide to AstraZeneca a copy of the agreement(s) effecting the Monetization Transaction (or any amendments thereto) reasonably in advance of execution thereof in order to allow AstraZeneca an opportunity to confirm that the agreement complies with the provisions of this Agreement. Ironwood shall also provide AstraZeneca with an executed copy of the Monetization Transaction and any amendments thereto. Copies provided pursuant to this clause (A) may be redacted with respect to information not pertinent to compliance with this Agreement.

B) AstraZeneca shall make such payments to the Revenue Buyer as directed by Ironwood, provided that AstraZeneca is not required under this Agreement to make payments to more than one account.

C) Ironwood has put in place adequate and customary confidentiality provisions at least as stringent as those applicable to Ironwood hereunder (including a term of confidentiality at least as long as the Term) with the Revenue Buyer and no Confidential Information disclosed by AstraZeneca to Ironwood will be disclosed to any of AstraZeneca’s competitors that are engaged in the business of developing and commercializing pharmaceutical products.

D) AstraZeneca shall not incur any incremental tax liability as a result of the Monetization Transaction (other than tax liability Ironwood reimburses in advance of any payment by AstraZeneca and if not AstraZeneca may deduct such incremental tax liability from the payments made to the Revenue Buyer).

E) Ironwood has not assigned any rights to enforce any provision of this Agreement to the Revenue Buyer (including the right to audit), provided that Ironwood’s agreement to exercise its rights hereunder at the direction of a Revenue Buyer will not be deemed such an assignment.

F) AstraZeneca is not required to deliver notices or provide reports directly to the Revenue Buyer and Ironwood shall not disclose any documents that would cause AstraZeneca to waive attorney-client privilege.

G) All other provisions set forth in the Monetization Transaction that would affect AstraZeneca are reasonable and customary.

H) For clarity, AstraZeneca shall not be required to generate any additional reports or new information to be provided to the Revenue Buyer and shall not be required to deliver any reports or information directly to the Revenue Buyer.

I) Notwithstanding anything in this Section 10.9, each Party will remain responsible for any failure to perform on the part of any of its Affiliates. Any attempted assignment or delegation in violation of this Section 10.9 will be void.

10.10. No Benefit to Others. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights in any other persons except as otherwise expressly provided in this Agreement.

10.11. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original and all of which taken together will be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission, including signatures in a fixed electronic format such as a PDF, will be as effective as an original executed signature page.

10.12. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then such provision will be given no effect by the Parties and will not form part of this Agreement. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement will remain in full force and effect and the Parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.

10.13. Further Assurance. Each Party will perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

10.14. Publicity. Notwithstanding Section 5.1.6, the Parties will issue press release(s) in the form of Exhibit E. The Parties will consult with each other reasonably and in good faith with respect to the text and timing of any subsequent press releases relating to this Agreement or the activity hereunder prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such releases, and that either Party may issue such press releases as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure or which are consistent with information disclosed in prior releases properly made hereunder.
10.15. Certain Conventions. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit will be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) all definitions set forth herein will be deemed applicable whether the words defined are used herein with initial capital letters in the singular or the plural, (b) the word “will” will be construed to have the same meaning and effect as the word “shall,” (c) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments).

10.16. Relationship of the Parties. The status of a Party under this Agreement will be that of an independent contractor. Nothing contained in this Agreement will be construed as creating a partnership, joint venture, or agency relationship between the Parties or, except as otherwise expressly provided in this Agreement, as granting either Party the authority to bind or contract any obligation in the name of or on the account of the other Party or to make any statements, representations, warranties, or commitments on behalf of the other Party. All Persons employed by a Party or any of its Affiliates are employees of such Party or its Affiliates and not of the other Party or such other Party’s Affiliates and all costs and obligations incurred by reason of any such employment will be for the account and expense of such Party or its Affiliates, as applicable.

IN WITNESS WHEREOF, duty authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

IRONWOOD PHARMACEUTICALS, INC.

By:
/s/ Michael J. Higgins

Name:
Michael J. Higgins

Title:
Senior Vice President, Finance

ASTRAZENECA AB

By:
/s/ Jan-Olof Jacke

Name:
Jan-Olof Jacke

Title:
EXHIBIT A

Initial Development Plan

EXHIBIT B

Supply Agreement Terms and Related Matters

I. Supply Agreement Terms

II. Supply Price Definition

"Supply Price" means

III. Supply Price Breakdown

(a) Standard costs

The JOC will discuss appropriate standard cost reporting forms and any changes necessary to the forms below to report substantially the same information.

Dose / market variant

$/pack

Dose / market variant

$/pack

API

a) [

b) [

c) [

d) [

Formulation

e) [

f) [

g) [**]
Packaging

Royalty costs included in standard costs (o)

Total cost per pack [**]

[**]  
[**]  

(b) Budget for one-off periodic costs for Territory to include:

Q1
$  

Q2
$  

Q3
$  

Q4
$  

[**]  
[**]  

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

(c) Cost of goods trending

For each pack:

Current
Year -2
Actual
$/pack

Current
Year -1
Actual
$/pack
Current Year Budget $/pack
Current Year +1 Forecast $/pack
Current Year +2 Forecast $/pack
China market trade
China market sample
Market A trade
Market A sample
Market B trade
Market B sample

[**] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

IV. Supply Price Estimate

[**]

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EXHIBIT C

This exhibit provides an illustrative example of the quarterly reconciliation for the purpose of cash settlement between the Parties, in consideration of the Collaboration in China.

To determine the Reconciliation Report in accordance with Section 4.2.5, each Party will exchange the information below on a monthly basis (WD+3). Net Sales must be determined pursuant to Section 1.114, Supply Costs pursuant to Section 1.160, Procurement Costs pursuant to Section 1.132, Development Expenses pursuant to Section 1.54, Commercialization Expenses pursuant to Section 1.41 and [**]

Within [**] days after the end of each Calendar Quarter, AstraZeneca will then prepare the Reconciliation Report to reflect the information from both Parties and determine the cash settlement due to/from each Party.

The Parties will issue invoices consistent with Indirect Tax requirements for any amounts payable, even though the sums may be netted for settlement purposes.

In this illustrative example, Ironwood would be entitled to a true-up payment of [**] from AstraZeneca, representing Ironwood’s share of the Net Sales less share of Program Expenses as determined by the Collaboration Agreement.

[**]

[**]
<table>
<thead>
<tr>
<th>Document/Interaction</th>
<th>Rights/Obligations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artwork and package insert for Products</td>
<td>Ironwood to provide mock-up artwork and package insert for the Products (for both clinical and commercial supply), including all amendments and supplements thereto, to AstraZeneca at least [**] business days prior to anticipated submission to the applicable Regulatory Authority.</td>
</tr>
<tr>
<td></td>
<td>AstraZeneca to review and provide comments within [**] business days.</td>
</tr>
<tr>
<td></td>
<td>Ironwood may not unreasonably reject comments provided by AstraZeneca</td>
</tr>
<tr>
<td>Clinical trial data</td>
<td>Subject to JDC review and approval</td>
</tr>
<tr>
<td>Clinical trial protocol documents</td>
<td>Subject to JDC review and approval</td>
</tr>
<tr>
<td>Major clinical trial application submissions</td>
<td>Ironwood to provide AstraZeneca English-language versions of the final drafts of all clinical trial application documents other than the clinical trial data and clinical trial protocol documents that are subject to JDC review and approval, including all amendments and supplements thereto, at least [**] business days prior to anticipated submission to the applicable Regulatory Authority.</td>
</tr>
<tr>
<td></td>
<td>AstraZeneca to review and approve English-language versions of the documents within [<strong>] business days (the remaining [</strong>] business days are for Chinese translation, proofreading and finalization of the submission materials)</td>
</tr>
<tr>
<td>Labeling filings and labeling supplements (including Trade name filings)</td>
<td>Subject to JDC review and approval</td>
</tr>
<tr>
<td>Clinical Study Report</td>
<td>Subject to JDC review and approval</td>
</tr>
<tr>
<td>Clinical summary documents</td>
<td>Subject to JDC review and approval</td>
</tr>
<tr>
<td>Major Import Drug License (IDL) submissions</td>
<td>Ironwood to provide AstraZeneca English-language versions of the final drafts of all other IDL documents not otherwise addressed above, including all amendments and supplements thereto, at least [**] business days prior to anticipated submission to the applicable Regulatory Authority.</td>
</tr>
<tr>
<td></td>
<td>AstraZeneca to review and approve English-language versions of the documents within [<strong>] business days (the remaining [</strong>] business days are for Chinese translation, proofreading and finalization of the submission materials)</td>
</tr>
<tr>
<td>Communications (written or electronic) from Regulatory Authorities</td>
<td>Subject to JDC review and approval</td>
</tr>
</tbody>
</table>
- Ironwood to provide AstraZeneca a copy of all written or electronic communications received by Ironwood from any Regulatory Authorities

- Responses to Regulatory Authority Questions (written)
- Subject to JDC review and approval unless agreed otherwise by both parties

- Post-approval regulatory commitments from Regulatory Authority
- Subject to JDC review and approval

- Product risk management plans
- Per Pharmacovigilance Agreement

- Safety reports (annual or periodic)
- Per Pharmacovigilance Agreement

- Meeting Materials (e.g., briefing documents) for Meetings with Regulatory Authorities regarding Clinical Trial Applications, IDL applications and other major Regulatory Meetings
- Meeting Materials are subject to JDC review and approval or JDC delegation to appropriate personnel

- Meetings with Regulatory Authorities
- Party receiving the meeting request to notify other Party within [**] business days of the initial request
- AstraZeneca has the right lead the preparation and coordination of the meetings and participate in the meetings

- Inspections by Regulatory Authorities
- If either Party receives notification of an Inspection request from a Regulatory Authority, that Party must notify the other Party within [**] business days of the initial request
- AstraZeneca has the right to be present at any Inspection

- Inspections Findings
- Ironwood to provide copies of Inspection Findings to AstraZeneca within [**] business days of receipt
- Significant Inspection Findings should be escalated to the JDC

- Safety-Related Communications
- Ironwood to provide AstraZeneca copies of safety letters communicated to Healthcare Professionals (or any other communications relating to safety issues) outside the Territory within [**] business days

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The Parties acknowledge and agree that in certain circumstances a shorter review and comment/approval period by AstraZeneca may be necessary or sufficient to maintain the regulatory timelines in the Development Plan, in which case the Parties shall agree to such shorter period as may be reasonably necessary to maintain the regulatory timelines in the Development Plan; provided, that in any event AstraZeneca must have a reasonable period of time to provide any comments/approvals. For all cases not addressed above, the Parties shall agree on an appropriate review timeline on a case-by-case basis.

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EXHIBIT E

Press Release

(See Attached)

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Astrazeneca and Ironwood Pharmaceuticals, Inc. announced today an agreement to co-develop and co-commercialise Ironwood’s linaclotide in China. Linaclotide is the first and only guanylate cyclase-C (GC-C) agonist approved by the US Food and Drug Administration, in August, for irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

In May, Ironwood filed a clinical trial application with the State Food and Drug Administration in China for a Phase III clinical trial to assess the efficacy and safety of linaclotide in adult patients suffering from irritable bowel syndrome with constipation (IBS-C). IBS-C, which is characterised by symptoms of abdominal pain and constipation, is a chronic and prevalent functional gastrointestinal disorder in China and there are currently few treatment options for this condition.

"China is one of the fastest growing prescription medicines markets in the world and linaclotide represents a valuable opportunity to meet the needs of local patients by providing an innovative new treatment option," said Mark Mallon, Regional Vice-President for Asia Pacific and President, Astrazeneca China. "We are pleased to be collaborating with Ironwood for linaclotide in China, which capitalises on our leadership in the gastrointestinal sector in the emerging markets."

Peter Hecht, Ironwood’s Chief Executive Officer, said: “As we continue to advance our efforts to make linaclotide available to patients around the world, we are excited about this opportunity to collaborate in China with Astrazeneca, one of the world’s most successful companies in gastrointestinal medicine.”

Astrazeneca and Ironwood are jointly responsible for strategic oversight of the development and commercialisation of linaclotide in China. Astrazeneca will have primary responsibility for the local operational execution.

Under the terms of the collaboration, Astrazeneca will make an upfront payment of $25 million to Ironwood and will share the net profits and losses associated with linaclotide in China, with Astrazeneca carrying 55 percent of each until a certain specified milestone is achieved, moving to a 50/50 split thereafter. Ironwood will also be eligible for $125 million in additional commercial milestone payments contingent on the achievement of certain sales targets.

In addition, the companies also announced today their agreement that Ironwood’s sales force of approximately 160 experienced clinical sales specialists will promote Astrazeneca’s NEXIUM® (esomeprazole magnesium) in the US. NEXIUM is a leading prescription drug currently approved to treat the symptoms of gastroesophageal reflux disease (GERD). This agreement will augments Astrazeneca’s existing interactions with gastroenterologists and primary care physicians on behalf of NEXIUM and the patients who need it. It will also provide Ironwood with an opportunity to increase its presence with the key gastrointestinal physicians in the US.

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“A large percentage of adult patients who have IBS-C or who have CIC, may also suffer from GERD.” said Thomas McCourt, Chief Commercial Officer, Senior Vice-President, Marketing and Sales, Ironwood Pharmaceuticals. “This agreement provides our experienced clinical sales specialists with the opportunity to bring two different and effective therapies to physicians for managing their patients who have these prevalent and troublesome gastrointestinal disorders.”

— ENDS —

NOTES TO EDITORS

About Linaclotide

Linaclotide is a guanylate cyclase-C agonist (GCCA) that is provided as an oral capsule intended for once-daily administration.

It binds to guanylate cyclase C locally in the intestine, with no measurable blood plasma concentrations, resulting in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevations in intracellular cGMP are believed to stimulate secretion of intestinal fluid and accelerate gastrointestinal transit resulting in increased frequency of bowel movements. Elevations in extracellular cGMP are believed to decrease activity of pain-sensing nerves, which is thought to be responsible for a reduction in intestinal pain, according to non-clinical models.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals is an entrepreneurial pharmaceutical company dedicated to the art and science of great drug-making. Ironwood is located in Cambridge, Mass. To learn more, visit www.ironwoodpharma.com.
About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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Meredith Kaya
IRONWOOD AND ASTRAZENECA ANNOUNCE LINACLOTIDE

COLLABORATION FOR CHINA

CAMBRIDGE, Mass., and LONDON, October 23, 2012 — AstraZeneca and Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today an agreement to co-develop and co-commercialize Ironwood’s linaclotide in China. Linaclotide is the first and only guanylate cyclase-C (GC-C) agonist approved by the US Food and Drug Administration, in August.

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About Ironwood Pharmaceuticals
Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Ironwood is located in Cambridge, Mass. To learn more, visit www.ironwoodpharma.com.

This press release contains forward looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, the development plans for linaclotide in China, the potential for linaclotide to be approved for marketing by the State Food and Drug Administration in China, the commercialization opportunity for linaclotide in China, the potential for Ironwood to receive sales-related milestones, and the opportunity for Ironwood to promote NEXIUM in the United States. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement.

Applicable risks and uncertainties include the risks that advancements in the linaclotide development program in China do not proceed as expected, the State Food and Drug Administration in China does not agree with the Phase III clinical trial design, Ironwood and AstraZeneca are unable to successfully complete the Phase III clinical trial or to demonstrate the efficacy of linaclotide in patients in China in order to obtain marketing authorization, serious adverse events arise in patients that are deemed to be definitely or probably related to linaclotide treatment, Ironwood and AstraZeneca are unable to effectively commercialize linaclotide in China, Ironwood is unable to successfully co-promote NEXIUM in the U.S., Ironwood or AstraZeneca terminates all or part of the collaboration or co-promotion arrangement, as well as risks related to the difficulty of predicting regulatory approvals and the acceptance of and demand for new pharmaceutical products. Applicable risks also include those that are listed in Ironwood’s Quarterly Report on Form 10-Q

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for the quarter ended June 30, 2012, in addition to the risk factors that are listed from time to time in its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any subsequent SEC filings. Ironwood undertakes no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. These forward-looking statements speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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Karl Härd
SOURCES: Ironwood Pharmaceuticals, Inc. and AstraZeneca

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Schedule 1.104

LICENSED COMPOUND

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Schedule 6.2(a)

IRONWOOD PATENT RIGHTS

Ironwood Ref. No.

Title

Country

Status

Application Date

Application No.

Registration No.

Ownership

IW003PCT1CN1

Methods and Compositions for the Treatment of Gastrointestinal Disorders

China

Registered

January 28, 2004

200480008533.9

200480008533.9
Stable Solid Formulation of a GC-C Receptor Agonist Polypeptide Suitable for Oral Administration

China
Pending
August 14, 2009
200980140931.9
Ironwood
IW057PCT1CN1HK1

Stable Solid Formulation of a GC-C Receptor Agonist Polypeptide Suitable for Oral Administration

Hong Kong
Pending
August 14, 2009
200980140931.9
Ironwood
IW057PCT1CN1

Treatments for Gastrointestinal Disorders

China
Pending
February 17, 2011
TBD
Ironwood
IW087PCT1

Treatment of Constipation-Predominant Irritable Bowel Syndrome

PCT
Pending
September 9, 2011
PCT/US2011/051080
[**]
Ironwood
IW082PCT1

Linaclotide Formulations

PCT
Pending
August 8, 2011
PCT/US2011/047434

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Schedule 6.3

CERTAIN EXISTING AZ IN-LICENSED PRODUCTS