

Dealdoc

Development and licensing agreement for abuse-deterrent oral hydrocodone opioid

Egalet Shionogi

Nov 26 2013

Development and licensing agreement for abuse-deterrent oral hydrocodone opioid

Egalet Companies: Shionogi Announcement date: Nov 26 2013 Amendment date: Mar 17 2015

Deal value, US\$m: 425 : sum of upfront, milestone, equity payments

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Details

Announcement date: Nov 26 2013 Amendment date: Mar 17 2015 Start date: Nov 26 2013 Bigpharma Industry sectors: Pharmaceutical Specialty pharma

Compound name: S-718632 **Exclusivity:** Exclusive Compound Asset type: Technology

Central Nervous System » Pain Therapy areas: Public Health » Addiction » Drugs

Drug delivery » Oral delivery » Delayed release Technology types:

Small molecules Development Licensing

Stages of development: Formulation Geographic focus: Worldwide

Deal components:

Financials

Deal value, US\$m: 425 : sum of upfront, milestone, equity payments

Upfront, US\$m: 10 : upfront payment

60: upon successful achievement of specified regulatory milestones for

the first licensed product candidate

42.5 : upon successful achievement of specified regulatory milestones

for a defined combination product candidate

25: upon successful achievement of specified regulatory milestones for Milestones, US\$m:

a second product candidate (other than the defined combination product

candidate)

12.5: upon successful achievement of specified regulatory milestones

for further product candidates

185: based on successful achievement of specified net sales thresholds

of licensed products

n/d: tiered royalties ranging from the mid-single digits to the low double Royalty rates, %:

digits based on the net sales of such products

Mid single digit

Semi-quant royalties: High single digit

Low teens

Equity, US\$m: 15 : common stock in private placement by Shionogi

Funding, US\$m: n/d : all costs associated with development

Termsheet

March 2015

Egalet announced that the investigational new drug (IND) application submitted by Shionogi to the U.S. Food and Drug Administration (FDA) for the hydrocodone product candidate. S-718632 is now open and active triggering a \$10 million milestone payment to Egalet.

November 2013

Egalet has entered into a definitive collaboration and license agreement with Shionogi for the development and potential commercialization of multiple oral abuse-deterrent hydrocodone opioid product candidates using Egalet's proprietary technology.

Egalet will receive a \$10 million upfront payment from Shionogi.

Shionogi has agreed to purchase up to approximately \$15 million in common stock in a private placement to close concurrently with Egalet's recently filed initial public offering.

Egalet is eligible to receive milestone payments upon development and approval of products, which may exceed \$300 million if multiple products are approved.

Shionogi will fund all costs associated with the development of these products.

Shionogi will also have exclusive global rights to commercialize the resulting products.

If any products developed under the collaboration are approved for marketing, Egalet is eligible to receive tiered royalties, ranging from the mid-single digits to the low double digits based on the net sales of such products.

As well as sales-based milestone payments that could exceed \$100 million based on the attainment of specified sales thresholds.

Press Release

March 2015

Egalet Earns \$10 Million Milestone Payment Triggered By Advancement Of Shionogi, Inc.'s Abuse-Deterrent, Extended-Release Hydrocodone, S-718632, Using Egalet's GuardianTechnology

WAYNE, Pa., March 17, 2015 /PRNewswire/ -- Egalet Corporation (Nasdaq: EGLT) ("Egalet"), a fully integrated specialty pharmaceutical company focused on developing, manufacturing and marketing innovative pain treatments, today announced that the investigational new drug (IND) application submitted by Shionogi to the U.S. Food and Drug Administration (FDA) for the hydrocodone product candidate, S-718632 is now open and active triggering a \$10 million milestone payment to Egalet.

S-718632 is in development under a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royaltybearing, worldwide license to develop, manufacture and commercialize abusedeterrent hydrocodonebased product candidates using Egalet's Guardian Technology. Under the agreement Egalet is eligible to receive milestone payments upon development and approval of product candidates under the agreement, which may exceed \$300 million (inclusive of this payment) if multiple product candidates are approved, as well as royalties at percentage rates ranging from midsingle digit to lowteens on net sales of licensed products.

"Development of abuse-deterrent hydrocodone S-718632 is paramount given that hydrocodone is the most frequently prescribed opioid in the United States and is associated with more drug abuse and diversion than any other opioid according to the DEA," said Bob Radie, Egalet's president and chief executive officer. "We are pleased with the progress this collaboration has made to move this important program forward."

About Guardian Technology Egalet's proprietary Guardian Technology was developed to create oral tablets with physical and chemical properties intended to deter the most common and rigorous methods of abuse that are specific to a particular drug, while also offering a tailored release of the active pharmaceutical ingredient (API). Egalet's abuse-deterrent morphine, Egalet-001, was designed to resist crushing in order to swallow, snort or smoke, and dissolving in order to injectone of the most common routes of morphine abuse. Egalet-001 has a specialized matrix created through Egalet's proprietary manufacturing process that allows for controlled release of the API. Egalet's abuse-deterrent oxycodone Egalet-002, which has an added shell surrounding the matrix, was specifically designed to address abuse by crushing and snortingthe most common method of manipulating oxycodonebased products for abuse according to a 2011 article in the Harm Reduction Journal. The Guardian

Technology employs a proven, reproducible, scalable and costefficient manufacturing processinjection moldingwhich involves the simultaneous use of both pressure and heat to form tablets using a customized mold. Egalet's proprietary Guardian Technology platform has the potential to become more broadly used with additional types of pharmaceutical products. The Company believe that the flexibility of the delivery systems can be applied to the administration of other classes of APIs, including combination products, where abuse deterrence or a specific release profile is desired.

About Egalet Egalet, a fully integrated commercial specialty pharmaceutical company, is focused on developing, manufacturing and marketing innovative pain treatments. The Company has two approved products: OXAYDO (oxycodone HCI, USP) tablets for oral use only -CII, the first and only approved immediate-release oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate, and SPRIX® (ketorolac tromethamine) Nasal Spray, a non-steroidal anti-inflammatory drug (NSAID), indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. In addition, using Egalet's proprietary Guardian Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. The lead programs, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and Egalet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate. Egalet's Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles. Full prescribing information for OXAYDO and SPRIX and additional information on Egalet can be found at www.egalet.com.

November 2013

Egalet, Shionogi Limited Ink Opiod Pact Worth \$425 Million+

Egalet Enters Into Development Collaboration and License Agreement With Shionogi Limited for Abuse-Deterrent Oral Hydrocodone Opioid Product Candidates

MALVERN, Pa., Nov. 26, 2013 (GLOBE NEWSWIRE) -- Egalet Corporation ("Egalet") announced today that it has entered into a definitive collaboration and license agreement with Shionogi Limited ("Shionogi") for the development and potential commercialization of multiple oral abuse-deterrent hydrocodone opioid product candidates using Egalet's proprietary technology.

Egalet will receive a \$10 million upfront payment from Shionogi and Shionogi has agreed to purchase up to approximately \$15 million in common stock in a private placement to close concurrently with Egalet's recently filed initial public offering. Egalet is eligible to receive milestone payments upon development and approval of products under the agreement, which may exceed \$300 million if multiple products are approved. Shionogi will fund all costs associated with the development of these products. Shionogi will also have exclusive global rights to commercialize the resulting products. If any products developed under the collaboration are approved for marketing, Egalet is eligible to receive tiered royalties, ranging from the mid-single digits to the low double digits based on the net sales of such products, as well as sales-based milestone payments that could exceed \$100 million based on the attainment of specified sales thresholds.

"With their commitment to pain therapeutics and their strong sales and marketing capabilities, we are pleased to be collaborating with Shionogi for the development and potential commercialization of abuse-deterrent hydrocodone products using our proprietary technology," said Bob Radie, Egalet's President and Chief Executive Officer. "We believe this collaboration provides validation for our proprietary abuse-deterrent drug delivery platform and positions us to capitalize on our technology, both through the products to be developed under the collaboration and by enabling us to develop additional opioid candidates utilizing our platform technology."

Stifel acted as exclusive financial advisor to Egalet in this transaction.

About Hydrocodone

Hydrocodone is an opioid agonist used in the treatment of mild to moderate pain. It is currently available as a single agent or in combination with other analgesics, such as acetaminophen (e.g., Vicodin). Abuse of prescription opioids has become a national epidemic in the United States. A study funded by the National Institutes of Health estimates that approximately 8% of the nation's 12th-graders abused hydrocodone in 2010. There are no abuse-deterrent hydrocodone single-agent or combination products currently on the market.

About Shionogi

Shionogi & Co., Ltd., headquartered in Osaka, Japan, has subsidiaries in Europe (Shionogi Limited), US (Shionogi Inc.), and Asia. Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on meeting the medical needs of patients. In addition, Shionogi & Co., Ltd. is engaged in new research in areas such as pain and infectious diseases. Contributing to the health of patients around the world through innovative research and development is Shionogi & Co., Ltd.'s primary goal. For more details on Shionogi Limited, please visit www.shionogi.eu. For more details on Shionogi Inc, please visit www.shionogi.com. For more information on Shionogi & Co., Ltd., please visit www.shionogi.co.jp.

About Egalet Corporation

Egalet Corporation is a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and other indications. The company has created two distinct drug delivery systems, each with novel abuse-deterrent features and the ability to control the release profile of the active pharmaceutical ingredient. Using its proprietary platform, Egalet has developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation, while also providing tailored release of the active pharmaceutical ingredient. Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. There are currently no commercially available abuse-deterrent formulations of morphine, and we believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. The Egalet technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple APIs with similar or different release profiles.

Filing Data

S1 abstract - 2014

In November 2013, we entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. The collaboration allows Shionogi to develop and commercialize an abuse-deterrent single-agent hydrocodone product candidate and up to 20 different abuse-deterrent combination product candidates containing hydrocodone.

Development and Commercialization. Shionogi is responsible for all development and manufacturing activities related to the licensed product candidates under the agreement. If requested by Shionogi, we will perform, at Shionogi's expense, certain formulation and pre-clinical study activities for the licensed product candidates. In addition, at its own expense, Shionogi will be responsible for all regulatory filings for the licensed product candidates and for commercializing all licensed products resulting from the collaboration. The development of the licensed product candidates will be facilitated by a joint development committee comprised of equal numbers of representatives of the parties, with Shionogi having the right to make all decisions regarding the development, manufacturing and commercialization of the licensed product candidates.

Shionogi has the right to grant sublicenses in certain circumstances. In the event that Shionogi intends to grant a sublicense to commercialize the licensed product candidates, we have a right of first negotiation to obtain those commercialization rights, as long as specified terms and conditions are met.

Additional Products. For a period of six months after the effective date of the agreement, if requested by Shionogi, we have agreed to engage in an exclusive, good faith negotiation of a potential transaction in which Shionogi would receive an exclusive license to develop and commercialize an additional product candidate (other than a morphine- or oxycodone-based opioid) incorporating our technology. During these six months, we may not enter into or otherwise conduct negotiations with any third party for any license or other agreement with respect to any such product candidate. After this six-month period, for an additional period of 18 months, if Shionogi provides us with a proposal for any such additional product candidate, we have agreed to engage in the good faith negotiation, on a non-exclusive basis, of a potential transaction in which Shionogi would receive an exclusive license to such additional product candidate. During this eighteen-month period, we would not be prevented from negotiating a transaction for such additional product with a third party.

In addition, if we choose at any time during the term of the agreement to license to a third party a morphine- and/or oxycodone- based product candidate that incorporates our technology, such as Egalet-001 and Egalet-002, we will notify Shionogi, and Shionogi will have a one-time right to negotiate with us, for a period of 60 days, to obtain an exclusive license to such product candidate(s).

Financial terms. Under the terms of the agreement, we received an upfront payment of \$10.0 million. Shionogi has agreed, subject to specified conditions, to purchase \$15.0 million of our shares in a private placement concurrently with the closing of this offering; however, Shionogi will not be required to purchase our shares to the extent it would result in Shionogi's ownership of the outstanding shares of our common stock exceeding 19.9%. Following its investment, Shionogi will have the right to designate one non-voting observer to attend meetings of our board of directors.

We are eligible to receive regulatory milestone payments under the agreement as follows: (i) up to \$60.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to \$42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to \$25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to \$12.5 million upon successful achievement of specified regulatory milestones for further product candidates. In addition, we are eligible to receive up to an aggregate of up to \$185.0 million based on successful achievement of specified net sales thresholds of licensed products.

If any products are approved for marketing, we are eligible to receive royalties at tiered, mid-single digit to low-teen percentage rates on net sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of all valid claims of the patent rights licensed to Shionogi that cover the manufacture, use, sale, offer for sale or importation of such licensed product in such country, (ii) the expiration of regulatory-based exclusivity for such licensed product in such country, and (iii) the tenth anniversary of the date of first commercial sale of such licensed product in such country. These royalties may be reduced by Shionogi by certain specified percentages if a licensed product experiences generic competition, or if Shionogi determines it is required to in-license necessary third party intellectual property.

Termination. The agreement with Shionogi will remain in effect with respect to each licensed product and country until the expiration of the applicable royalty period for such licensed product in such country. Shionogi may terminate the agreement for convenience in its entirety or with respect to one or more licensed products upon 90 days written notice to us. Either we or Shionogi may terminate the agreement, in its entirety or with respect to one or more licensed products, if the other party is in material breach and fails to cure such breach within the specified cure period. Either we or Shionogi may terminate the agreement in the event of specified insolvency events involving the other party, and we may terminate the agreement in the event that Shionogi brings a challenge against us in relation to the licensed patents.

Contract

COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (the "Agreement") is entered into on this 26th day of November, 2013 (the "Effective Date"), by and among Egalet Limited, a company organized under the laws of England and Wales with its principal place of business at 33 St. James' Square, London SW1Y 4JS, United Kingdom ("Egalet"), Shionogi Limited, a company organized under the laws of England and Wales with its principal place of business at 33 Kingsway, London, WC2B 6UF, United Kingdom ("Shionogi"), and, solely for the purposes of Sections 2.7, 7.1, 7.2, 11.1, 11.3, 11.5 and 12, Egalet Corporation, a company organized under the laws of Delaware with its principal place of business at 101 Lindenwood Blvd., Suite 22, Malvern, PA ("Egalet US"). Egalet and Shionogi may each be referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Egalet owns or otherwise controls certain patents, patent applications, copyrights, know-how, scientific and technical information and other proprietary rights and technology relating to abuse-deterrent oral products for the treatment of pain and other indications;

WHEREAS, Shionogi is engaged in the research, development and commercialization of pharmaceutical products, and desires to collaborate with Egalet to develop and commercialize Products (as defined below), and to receive a worldwide license under Egalet's patents, patent applications, copyrights, know-how, scientific and technical information and other proprietary rights and technology relating to the Products; and

WHEREAS, subject to the terms of this Agreement, Egalet wishes to so collaborate with Shionogi and to grant to Shionogi, and Shionogi desires to receive, such license.

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.
- 1.1. "Active Ingredient" means with respect to any compound, such compound, or any metabolites, prodrugs, solvates (including hydrates), esters, salts, stereoisomers, racemates, tautomers and polymorphs (including crystal forms), of such compound.
- 1.2. "Additional Product" has the meaning set forth in Section 2.6.1.
- 1.3. "Adverse Event" means any adverse medical occurrence in a patient or clinical investigation subject that is administered a pharmaceutical product, as

designated in any Applicable Laws and that is required to be reported to a Regulatory Authority.

- 1.4. "Affected Patent" has the meaning set forth in Section 10.2.3.
- 1.5. "Affiliate(s)" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with such first Person. For purposes of this Section 1.5 control" means (a) to possess, directly or indirectly, the power to direct the management or policies of another Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, legally or beneficially more than fifty percent (50%) of the outstanding voting securities or other comparable ownership interests (or such lesser percentage which is the maximum allowed to be owned by such Person in a particular jurisdiction if such maximum allowable percentage is equal to or greater than forty percent (40%)) of another Person. The Parties hereby agree and stipulate that neither Egalet nor Shionogi shall be deemed Affiliates of one another.
- 1.6. "Applicable Laws" means all applicable statutes, ordinances, regulations, rules or orders of any kind whatsoever of any Governmental Authority.
- $1.7.\ \text{``Applicable Patent Rights and Know-How''}\ has\ the\ meaning\ set\ for th\ in\ Section\ 5.3.2.$
- 1.8. "Business Program" has the meaning set forth in Section 6.3.3.

- 1.9. "Calendar Quarter" means each of the three (3) consecutive month periods ending on March 31, June 30, September 30 and December 31.
- 1.10. "Calendar Year" means each twelve (12) month period ending on December 31st.
- 1.11. "Change of Control" means, with respect to a Party, the following: (i) any Third Party (or group of Third Parties acting in concert) acquires, directly or indirectly, a majority of voting stock or other securities then outstanding of such Party; (ii) the sale of substantially all assets of such Party in a transaction or a series of transactions to a Third Party buyer; (iii) a merger or consolidation of such Party with or into any Third Party, as a result of which the holders of voting stock or other securities of such Party immediately prior to such event hold less than a majority of the outstanding voting stock or other securities of the surviving entity; or (iv) the acquisition by a Third Party of the right to nominate a majority of members of the board of directors of such Party.
- 1.12. "Clinical Trial" means a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing; (b) investigate the safety and efficacy of a pharmaceutical product for its intended use, and to define warnings,

precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed; or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

- 1.13. "Combination Product" means any pharmaceutical product comprised of Hydrocodone and any ** as the Active Ingredients**. For purposes of clarity, ** is a **.
- 1.14. "Commercialization" means any and all activities of marketing, promoting, distributing, importing, offering for sale or selling a Product in the Field in the Territory, including pre-commercial launch market development activities conducted in anticipation of Regulatory Approval to sell or market a Product, seeking pricing and reimbursement approvals for a Product (if applicable), preparing advertising and promotional materials, sales force training. When used as a verb, "Commercialize" means to engage in Commercialization.
- 1.15. "Commercially Capable" means, with respect to any Proposed Sublicense Territory, that Egalet has a meaningful and credible commercial presence in such Proposed Sublicense Territory such that it can reasonably be expected to engage in the contemplated Commercialization in a manner that would be reasonably competitive in the relevant therapeutic market with Third Parties in such Proposed Sublicense Territory.

 Notwithstanding the foregoing, if, at the time of being notified of Shionogi's intent to grant such a sublicense, Eaglet does not have the required commercial presence, as set forth in the preceding sentence, in such Proposed Sublicense Territory, Egalet shall have ten (10) days from the receipt of Shionogi's notice to demonstrate to Shionogi's reasonable satisfaction that Egalet has a feasible and documented plan for establishing such a commercial presence (it being understood that Egalet shall not be considered "Commercially Capable" if its plan for establishing the required commercial presence will delay the commencement of the contemplated Commercialization in the Proposed Sublicense Territory).
- 1.16. "Commercially Reasonable Efforts" means those efforts and resources that a similarly situated pharmaceutical company would reasonably devote to a product or compound owned by it or to which it has rights of the type described hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitive landscape of the global and local marketplace, the pricing and reimbursement strategy for the respective product, the requirements for a successful launch of such product, the proprietary position or exclusivity profile of the product, the profitability and the relative potential safety and efficacy of the product and other relevant factors, including technical, manufacturing, legal, scientific, regulatory or medical factors. With respect to any Specified Territory or country or sub-territory therein, it is understood that factors including pricing and labeling, and their impact either within or outside of that particular country or territory, may make it not commercially reasonable to pursue Development or

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Commercialization in said country or territory. "Commercially Reasonable" as used herein shall be interpreted in a corresponding manner.

- 1.17. "Conceived" means conceived, discovered, developed, or authored by a Person or Party (it being understood that a Person or Party shall be deemed to have conceived, discovered, developed, or authored Technology or any other intellectual property if at least one individual or individuals under an obligation to assign their rights to such Technology or intellectual property to such Person or Party and/or its Affiliates was involved in such conception, discovery, development, or authoring).
- 1.18. "Confidential Information" means, with respect to a Party, all information (and all tangible and intangible embodiments thereof) which is Controlled by such Party and is disclosed by such Party to the other Party pursuant to this Agreement. Any technical information disclosed at a meeting of the JDC or any other committee established pursuant to this Agreement shall constitute Confidential Information unless otherwise specified. For the avoidance of doubt, notwithstanding anything herein to the contrary, any and all information, data, documents, publications and reports that are Conceived by either Party in connection with the Egalet Development Activities shall be deemed Confidential Information of Shionogi, other than to the extent such information, data, documents, publications and/or reports are Egalet Core Technology or Egalet Core Technology Improvements.
- 1.19. "Control" or "Controlled" means, with respect to any intellectual property right, information, documents or materials, that a Party or its Affiliates (a) owns or has a license to such intellectual property right, information, documents or materials (other than pursuant to this

Agreement); and (b) has the ability to grant access, a license or a sublicense to such intellectual property right, information, documents or materials to the other Party as provided in this Agreement without violating an agreement with or other rights of any Third Party, provided that any intellectual property, information, documents or materials Controlled by a Future Acquirer of a Party shall not be treated as "Controlled" by such Party for purposes of this Agreement, except to the extent that, and only to the extent that, such intellectual property, information, documents or materials are actually used by such Party or its Affiliates, or the Future Acquirer, to Develop, Manufacture or Commercialize the Products after the Future Acquirer qualifies as such. Notwithstanding the foregoing, with respect to any intellectual property, information, documents or materials acquired after the Effective Date for which a Party will be required to make payments to any Third Party in connection with the access, licenses and sublicenses granted to the other Party under this Agreement, such intellectual property shall not be treated as "Controlled" by the licensing Party except to the extent that, and only to the extent that and for so long as, the other Party agrees and does promptly pay to the licensing Party all such payments arising out of the grant of the license to the other Party (as mutually agreed between the Parties in good faith).

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- 1.20. "Delay Factors" has the meaning set forth in Section 4.3.3.
- 1.21. "Development" means all activities relating to obtaining, maintaining and/or expanding Regulatory Approval of Products and/or the development thereof including all activities related to research, preclinical testing, test method development and stability testing, toxicology, formulation, Clinical Trials, seeking Regulatory Approval and otherwise handling regulatory affairs, statistical analysis and report writing performed with respect to Products. Development shall not include Manufacturing or Commercialization. When used as a verb, "Develop" means to engage in Development.
- 1.22. "Disclosing Party" has the meaning set forth in Section 6.1.1.
- 1.23. "Effective Date" has the meaning set forth in the Preamble.
- 1.24. "Egalet" has the meaning set forth in the Preamble.
- 1.25. "Egalet API" means an active pharmaceutical ingredient that is not Hydrocodone which is Conceived or otherwise in-licensed or acquired by Egalet or its Affiliates.
- 1.26. "Egalet Core Technology" means, to the extent covered by any Egalet Patent Rights or Egalet Know-How, in each case, Controlled by Egalet and its Affiliates as of the Effective Date,**. For the avoidance of doubt, "Egalet Core Technology" includes the Egalet Patent Rights and Egalet Know-How, in each case, Controlled by Egalet and its Affiliates as of the Effective Date to the extent covered by clause (i), (ii) and/or (iii) above. Notwithstanding anything herein to the contrary, in the event there is a dispute as to whether anything in clause (i), (ii) and/or (iii) above was covered by any such Egalet Know-How as of the Effective Date, Egalet shall have the burden of proof with respect to establishing that it was so covered.
- 1.27. "Egalet Core Technology Improvements" means any Improvements to the Egalet Core Technology, whether or not patentable, that are Conceived after the Effective Date by or on behalf of either Party or its Affiliates, whether alone or with Third Parties, in the course of performing activities under, or in connection with, this Agreement, other than any such Improvements that solely relate to the Development, Manufacture or Commercialization of a Product and which are Conceived after the Effective Date by or on behalf of Shionogi or its Affiliates or, if in the performance of the Egalet Development Activities, by or on behalf of Egalet or its Affiliates. For the avoidance of doubt, if Improvements are Conceived using Egalet Core Technology but are not in and of themselves Improvements to Egalet Core Technology, then such Improvements shall not constitute Egalet Core Technology Improvements.
- 1.28. "Egalet Development Activities" means any Development and Manufacturing activities which are assigned to Egalet by the JDC in accordance with Section 3.1.

- 1.29. "Egalet Development Costs" means the following direct costs which (i) are identifiable to the Egalet Development Activities, and (ii) have been actually incurred by Egalet or its Affiliates after the Effective Date and recorded in accordance with GAAP or IFRS (as applicable): (A) FTE Costs, (B) reasonable costs of supplies and materials and (C) to the extent pre-approved in writing by Shionogi, amounts paid to Third Parties in connection with the Egalet Development Activities. For the avoidance of doubt, as used herein, "direct costs" does not include any overhead costs.
- 1.30. "Egalet Indemnified Party" has the meaning set forth in Section 11.2.
- 1.31. "Egalet Know-How" means Know-How that Egalet or its Affiliates Control on the Effective Date or that comes into the Control of Egalet or its Affiliates during the Term (other than any Know-How which is Shionogi Know-How), to the extent that such Know-How is necessary or useful to Develop, Manufacture, or Commercialize in the Territory, the Products in the Field, including any method of making the Products, any composition or formulations of the Products or any method of using or administering the Products; provided that Egalet Know-How excludes any Know-How to the extent relating to an Egalet API.

- 1.32. "Egalet Patent Rights" means any Patent Right that Egalet or its Affiliates Controls on the Effective Date or that comes into the Control of Egalet or its Affiliates during the Term (other than any Patent Rights which are Shionogi Patent Rights), to the extent that such Patent Right is necessary or useful to Develop, Manufacture, or Commercialize in the Territory, the Products in the Field, including any method of making the Products, any composition or formulations of the Products, or any method of using or administering the Products provided that Egalet Patent Rights excludes any Patent Rights to the extent relating to an Egalet API. The Egalet Patent Rights existing on the Effective Date are set forth on Schedule 1.32.
- 1.33. "Egalet Restricted Product" has the meaning set forth in Section 6.3.2.
- 1.34. "Egalet Technology" means the (a) Egalet Know-How and the Egalet Patent Rights, including Egalet Core Technology (b) the Egalet Core Technology Improvements, and (c) all intellectual property rights therein.
- 1.35. "Egalet US" has the meaning set forth in the Preamble.
- 1.36. "European Union" or "EU" means all countries of the European Union, as may be included from time to time.
- 1.37. "FD&C Act" means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the applicable regulations promulgated thereunder, as amended from time to time.

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- 1.38. "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- 1.39. "Field" means all therapeutic uses of a Product for any condition, disorder or disease indication in humans or non-human animals, including the treatment, palliation, prevention, diagnosis, and management thereof.
- 1.40. "Final Prospectus" has the meaning set forth in Section 7.2(f).
- 1.41. "Financial Records" has the meaning set forth in Section 5.5.5.
- 1.42. "First Commercial Sale" means, with respect to a Product and any country in the Territory, the first sale of such Product under this Agreement for use in the Field to a Third Party in such country, after such Product has been granted Regulatory Approval for distribution, marketing and sale (in each case to the extent required by Applicable Laws) in the Field by the competent Regulatory Authorities in such country. For avoidance of doubt, "First Commercial Sale" excludes sales, transfers or dispositions of a Product (i) to any Affiliate of Shionogi and/or (ii) for any charitable, promotional (including samples), pre-clinical, clinical or regulatory purposes.
- 1.43. "Force Majeure" has the meaning set forth in Section 12.2.
- 1.44. "Force Majeure Party" has the meaning set forth in Section 12.2.
- 1.45. "FTE" means a full-time scientific or technical person, or in the case of less than a full-time scientific or technical person, a full-time equivalent scientific or technical person year, carried out by an appropriately qualified employee of Egalet or its Affiliates, based upon a total of ** weeks (i.e., ** per year).
- 1.46. "FTE Costs" means the actual FTEs employed by Egalet or its Affiliates in the conduct of the Egalet Development Activities multiplied by the FTE Rate, plus expenses of travel incurred by employees of Egalet or its Affiliates at the request of Shionogi, to the extent such expenses comply with Shionogi's standard travel expense reimbursement policy (as modified by Shionogi from time to time), a copy of which, together with all amendments and modifications thereto, shall be provided to Egalet upon Egalet's request.
- 1.47. "FTE Rate" means the following annual FTE rates with respect to employees of Egalet or its Affiliates:

Employee

FTE rate

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Each of the foregoing FTE rates shall be adjusted annually by the percentage increase in the Danish Consumer Price Index as reported by Statistics Denmark during the Term beginning **.

- 1.48. "Future Acquirer" means the Third Party to any Change of Control transaction and any of such Third Party's Affiliates.
- 1.49. "GAAP" means generally accepted accounting principles in the United States, as in effect from time to time.
- 1.50. "Generic Competition" means, with respect to a country in the Territory, as assessed on a Product-by-Product (and dosage-by-dosage and strength-by-strength basis) and Calendar Quarter-by-Calendar Quarter basis, a fraction (expressed as a percentage), the numerator of which shall be the aggregate number of units of such specific Generic Products (for that dosage and strength of the applicable Product) sold in such country during such Calendar Quarter, and the denominator of which shall be the aggregate number of units of such specific Generic Products (for that dosage and strength of the applicable Product) sold in such country during such Calendar Quarter plus the aggregate number of units of Products (for that dosage and strength) sold in such country during such Calendar Quarter, based on data provided by IMS International, or, if such data is not available from IMS International, such other reliable data source as is reasonably determined by the Parties.
- 1.51. "Generic Product" means, on a country-by-country basis, any pharmaceutical product that (a) is sold by a Third Party that is not an Affiliate or Sublicensee of Shionogi under a marketing authorization granted by a Regulatory Authority to a Third Party and (b) results from (i) an abbreviated new drug application including any amended or successor abbreviated route of approval thereof in the United States ("ANDA") or (ii) abbreviated routes of approval in any other countries in the Territory that are comparable to ANDA, which in the case of clause (i) and/or (ii), references the applicable Product, provided that (x) such pharmaceutical product has the same Active Ingredient as the Product and an abuse deterrent system or (y) the Product is the primary basis for the approval of such pharmaceutical product.
- 1.52. "Good Clinical Practice" or "GCP" means the then current standards for clinical trials for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by other Governmental Authorities in countries in which Products are intended to be sold.
- 1.53. "Good Laboratory Practice" or "GLP" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good laboratory practice as are required by other

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Governmental Authorities in countries in which Products are intended to be sold.

- 1.54. "Good Manufacturing Practice" or "GMP" means the then current standards for manufacturing activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by other Governmental Authorities in countries in which Products are intended to be manufactured or sold.
- 1.55. "Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.
- 1.56. "**" means **.
- 1.57. "HSR Approvals" has the meaning set forth in Section 9.1.
- 1.58. "Hydrocodone" means 4,5(alpha)-epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5) including any metabolites, prodrugs, solvates (including hydrates), esters, salts, stereoisomers, racemates, tautomers and polymorphs (including crystal forms), of such compound.
- 1.59. "Hydrocodone Product" means any pharmaceutical product containing Hydrocodone as its sole Active Ingredient that is in a formulation containing the Egalet Technology and which is Developed, Manufactured and Commercialized pursuant to, and in accordance with, this Agreement.
- 1.60. "IFRS" means International Financial Reporting Standards, as in effect from time to time.
- 1.61. "Improvement" means, with respect to any Technology, any improvement, modification or derivative of such Technology, including all Patent Rights resulting therefrom.
- 1.62. "IND" means an effective Notice of Claimed Investigational Exemption for a New Drug or Investigational New Drug Application, as defined in 21 C.F.R. § 312, on file with the FDA, including any amendments thereto. References to IND herein shall include, to the extent applicable, any comparable filings outside of the United States (such as an application for a CTA in the European Union).
- 1.63. "Indemnification Claim Notice" has the meaning set forth in Section 11.3.
- 1.64. "Indemnified Party" has the meaning set forth in Section 11.3.
- 1.65. "Indemnifying Party" has the meaning set forth in Section 11.3.

- 1.66. "Initial Fee" has the meaning set forth in Section 5.1.
- 1.67. "Initial Public Offering" has the meaning set forth in Section 2.7.
- 1.68. "Innovator Protection" means, with respect to a given Product in a given country in the Territory, that at least one (1) Valid Claim of an Egalet Patent Right (including a Patent Right covering the Egalet Core Technology Improvements) in such country claims the manufacture, use, sale, offer for sale or importing of such Product in the Field.
- 1.69. "JDC" has the meaning set forth in Section 3.1.
- 1.70. "JDC Term" has the meaning set forth in Section 3.1.
- 1.71. "Know-How" means all inventions, discoveries, data, information (including scientific, technical or regulatory information), processes, methods, techniques, materials, technology, results, analyses, laboratory data, pre-clinical data and clinical data, and other know-how of any type whatsoever, in any tangible or intangible form, whether or not patentable, including trade secrets, practices, techniques, methods, processes, procedures, developments, specifications, formulations, formulae, software, algorithms, expertise, pharmacology, toxicology, drug stability, manufacturing and formulation data, methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies, and absorption, distribution, metabolism and excretion studies.
- 1.72. "Liability" has the meaning set forth in Section 11.1.
- 1.73. "Litigation Conditions" has the meaning set forth in Section 11.3.
- 1.74. "Manufacturing" means all activities involved in the production of the Products to be Developed or Commercialized under this Agreement including making and having made the Products. When used as a verb, "Manufacture" means to engage in Manufacturing.
- 1.75. "Names and Terms" has the meaning set forth in Section 6.1.6.
- 1.76. "NDA" means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314, or any corresponding application for Regulatory Approval (not including pricing and reimbursement approval) in any country or regulatory jurisdiction other than the United States, including an MAA
- 1.77. "NDA Acceptance" means, with respect to an NDA for a Product in the Field that has been submitted to the FDA by Shionogi or its Affiliate or Sublicensee, the date on which the applicant receives a notification from the FDA indicating that such NDA has been filed pursuant to 21 C.F.R. §314.101(a) or any equivalent or successor regulation.

- 1.78. "NDA Approval" means the Regulatory Approval of an NDA by the FDA for the applicable Product in the Field in the United States obtained by Shionogi or its Affiliates or Sublicensees.
- 1.79. "Net Sales" means the gross amounts invoiced by Shionogi, its Sublicensees or its Affiliates, as applicable, to unrelated Third Parties in arms-length transactions for or on account of the sales or distribution of the Products, less the following deductions to the extent included in the gross invoiced sales price for such Products or otherwise directly paid or incurred by Shionogi, its Sublicensees or its Affiliates with respect to the sale or distribution of such Products: (a) reasonable credits or allowances, if any, on account of price adjustments, recalls, rejection or return of items previously sold; (b) import taxes, export taxes, excises, sales taxes, value added taxes, consumption taxes, duties or other taxes imposed upon and paid with respect to such sales (excluding income or franchise taxes of any kind); (c) separately itemized insurance and transportation costs incurred in shipping Products to such non-selling Persons; (d) trade, quantity and cash discounts actually allowed; (e) governmental or commercial rebates, wholesaler fees, administrative fees to managed care, group purchasing and other similar institutions, chargebacks and retroactive price adjustments and any other similar allowances which effectively reduce the selling price; and (f) any fees generally applicable to the pharmaceutical industry that are imposed under Applicable Laws based on sales (including under the Patient Protection and Affordable Care Act, as amended). Net Sales will be determined in accordance with GAAP, IFRS, or Japan GAAP consistently applied (it being understood that, in the case of clause (f) in the preceding sentence, the fees contemplated therein shall be appropriately allocated, on a sales-based proportional basis, to the Products consistent with GAAP, IFRS, or Japan GAAP, as applicable). Without limiting the generality of the foregoing, transfers or dispositions of a Product for charitable, promotional (including samples), pre-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of a Product among Shionogi and its Affiliates and Sublicensees, unless such Licensed Product is consumed by such Person.

In the event that a Product is sold as a Combination Product and such Combination Product incorporates an active pharmaceutical ingredient (other than Hydrocodone) that is, at the time of the First Commercial Sale of such Combination Product, covered by a Valid Claim of any Shionogi Patent Right, then Net Sales of such Combination Product will be calculated, for each applicable Calendar Quarter, as follows: (with respect to any such Combination Product that does not include **, ** for such Combination Product and (ii) with respect to any Combination Product that does include the **, (A) ** for such Combination Product if the Combination Product is for ** or (B) ** for such Combination Product if the Combination Product is for **.

- 1.80. "Notice" has the meaning set forth in Section 12.5.1.
- 1.81. "Party(ies)" has the meaning set forth in the Preamble.

- 1.82. "Patent Challenge" has the meaning set forth in Section 10.2.3.
- 1.83. "Patent Right" means any and all (a) patent applications filed in any jurisdiction, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon; (b) all 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, including certificates of invention and applications for certificates of invention.
- 1.84. "Person" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture, or similar entity or organization, including a government or political subdivision or department or agency of a government.
- 1.85. "Platform-Related Patent Rights" means any and all Patent Rights included within the Egalet Technology (including within the Egalet Core Technology Improvements), other than the Product-Related Patent Rights.
- 1.86. "Product" means any Hydrocodone Product or Combination Product.
- 1.87. "Product-Related Existing Patent Right" means any Product-Related Patent Right filed with the relevant patent office or Governmental Authority prior to the Effective Date.
- 1.88. "Product-Related Future Patent Right" means any Product-Related Patent Right filed with the relevant patent office or Governmental Authority on or after the Effective Date.
- 1.89. "Product-Related Patent Rights" means any and all Patent Rights included within the Egalet Technology (including within the Egalet Core Technology Improvements), that primarily relate to the Development, Manufacture or Commercialization of any Product.
- 1.90. "Product Term" has the meaning set forth in Section 10.1.
- 1.91. "Proposed Sublicense Territory" means any part of the ** that Shionogi has elected to pursue a sublicensing strategy pursuant to Section 2.3.1.
- 1.92. "Purchased Shares" has the meaning set forth in Section 2.7.
- 1.93. "Receiving Party" has the meaning set forth in Section 6.1.1.
- 1.94. "Recipients" has the meaning set forth in Section 6.1.1.
- 1.95. "Registration Statement" has the meaning set forth in Section 7.2(f).

- 1.96. "Regulatory Approval" means the approval and authorization of a Regulatory Authority in a country or regulatory jurisdiction necessary to develop, manufacture, distribute, sell or market a pharmaceutical product in that country or regulatory jurisdiction. Regulatory Approval shall include pricing and reimbursement approval in any country or regulatory jurisdiction in the Territory other than the United States if such pricing and reimbursement approval is deemed commercially necessary by a Party and such Party has not completed a First Commercial Sale of such pharmaceutical product to a Third Party in such country or regulatory jurisdiction prior to obtaining such pricing and reimbursement approval.
- 1.97. "Regulatory Authority" means any national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country of the world involved in the granting of Regulatory Approval.
- 1.98. "Regulatory-Based Exclusivity" means, on a Product-by-Product and country-by-country basis, that (a) Shionogi or any of its Affiliates or Sublicensees has been granted the exclusive legal right by a Regulatory Authority (or is otherwise entitled to the exclusive legal right by operation of Law) in such country to market and sell the Product or the Active Ingredient comprising such Product in such country, or (b) the data and information submitted by Shionogi or any of its Affiliates or Sublicensees to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval may not be disclosed, referenced or relied upon in any way by any Person other than Shionogi, its Affiliates or Sublicensees (including by relying upon the Regulatory Authority's previous findings regarding the safety or effectiveness of the Product) to support the Regulatory Approval or marketing of any product that is a generic version of the Product by a Third Party in such country.
- 1.99. "Regulatory Submission" means an application for Regulatory Approval, notification or other submission made to or with a Regulatory Authority that is necessary or reasonably desirable to Develop, Manufacture or Commercialize a Product in the Field in a particular country or

regulatory jurisdiction, whether obtained before or after a Regulatory Approval in the country or regulatory jurisdiction. Regulatory Submissions include INDs and NDAs, and amendments 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 a Product in a particular country.

- 1.100. "Restricted Period" has the meaning set forth in Section 6.3.1.
- 1.101. "Right of Reference" has the meaning assigned to such term in 21 C.F.R. §314.3(b) (or any analogous Applicable Laws recognized outside the United States).

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- 1.102. "ROW" means any and all countries of the world and their territories, jurisdictions and possessions, excluding the United States, the European Union and Japan.
- 1.103. "Royalty Period" has the meaning set forth in Section 5.3.1.

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1.104. "**" means **.
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- 1.105. "Securities Act" means the Securities Act of 1933, as amended.
- 1.106. "Securities Regulator" has the meaning set forth in Section 6.1.6(b).
- 1.107. "Shared Facility" has the meaning set forth in Section 4.2.4.

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1.108. "**" means a **.
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1.109. "**" means any **.

1.110. "**" means **.

- 1.111. "**" means (i) with respect to Egalet ** and (ii) with respect to Shionogi, **.
- 1.112. "**" has the meaning set forth in Section 4.2.2.
- 1.113. "Shionogi" has the meaning set forth in the Preamble.
- 1.114. "Shionogi Data" has the meaning set forth in Section 10.3.1(f).
- 1.115. "Shionogi Improvements" means (i) all Technology, whether or not patentable, that is Conceived by Egalet or its Affiliates after the Effective Date in the course of performing the Egalet Development Activities, whether alone or together with Third Parties, excluding any Egalet Core Technology Improvement, and (ii) any Improvement to the Egalet Core Technology, whether or not patentable, that solely relates to the Development, Manufacture or Commercialization of a Product and which is Conceived after the Effective Date by or on behalf of (A) Shionogi or its Affiliates or (B) if in the course of performing the Egalet Development Activities, Egalet or its Affiliates.
- 1.116. "Shionogi Improvement Manufacturing Patent Rights" means any Patent Rights included in the Shionogi Improvements but solely to the extent related to the Manufacture of Products.
- 1.117. "Shionogi Indemnified Party" has the meaning set forth in Section 11.1.
- 1.118. "Shionogi Know-How" means any Know-How that Shionogi Controls on the Effective Date, if any, or that comes into the Control of Shionogi during the Term (other than Know-How which is Egalet Know-How), to the extent that such Know-How is necessary or useful to Develop, Manufacture, or Commercialize in the Territory, the Products in the Field, including any method

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of making the Products, any composition or formulations of the Products or any method of using or administering the Products. Notwithstanding anything herein to the contrary, Shionogi Know-How excludes any Know-How existing as of the Effective Date relating to Xodol.

- 1.119. "Shionogi Patent Rights" means any Patent Right that Shionogi Controls on the Effective Date or that comes into the Control of Shionogi during the Term (other than Egalet Patent Rights licensed to Shionogi pursuant to this Agreement), to the extent that such Patent Right is necessary or useful to Develop, Manufacture, or Commercialize in the Territory, the Products in the Field, including any method of making the Products, any composition or formulations of the Products, or any method of using or administering the Products. Notwithstanding anything herein to the contrary, Shionogi Patent Rights excludes any Patent Rights existing as of the Effective Date relating to Xodol.
- 1.120. "Shionogi Restricted Product" has the meaning set forth in Section 6.3.1.

- 1.121. "Shionogi Technology" means the (a) Shionogi Know-How and the Shionogi Patent Rights, (b) the Shionogi Improvements, and (c) all intellectual property rights therein.
- 1.122. "Shionogi Trademarks" has the meaning set forth in Section 8.4.1.
- 1.123. "Specified Territory" means (i) the United States, (ii) the European Union, or (iii) ROW, as applicable.
- 1.124. "Sublicense" means a license, sublicense, covenant not to sue or other rights granted by a Party to an Affiliate of such Party or a Third Party pursuant to this Agreement.
- 1.125. "Sublicensee" means an Affiliate of a Party or a Third Party that is a party to a Sublicense.
- 1.126. "Sublicensee Material Breach" has the meaning set forth in Section 2.3.5.
- 1.127. "Sublicensee Territory" has the meaning set forth in Section 2.3.5.
- 1.128. "Sued Party" has the meaning set forth in Section 8.6.2.
- 1.129. "Tax Credit" has the meaning set forth in Section 5.5.2(e).
- 1.130. "Tax Deduction" has the meaning set forth in Section 5.5.2(a).
- 1.131. "Technology" means Know-How and Patent Rights.
- 1.132. "Technology Transfer Services" has the meaning set forth in Section 2.4.

- 1.133. "Term" has the meaning set forth in Section 10.1.
- 1.134. "Terminated Countries" has the meaning set forth in Section 10.3.1.
- 1.135. "Terminated Product" has the meaning set forth in Section 10.3.1.
- 1.136. "Territory" means all of the countries of the world and their territories, jurisdictions and possessions.
- 1.137. "Third Party" means any Person other than Egalet and its respective Affiliates and Shionogi and its respective Affiliates.
- 1.138. "Trademark" means any trademark used by the Parties in connection with a Product, other than the Parties' trade names and trademarks used by the Parties to identify their companies generally.
- 1.139. "Twelve Month Period" means any four consecutive Calendar Quarters.
- 1.140. "United States" or "US" means the United States of America, including all of its territories and possessions.
- 1.141. "Valid Claim" means any claim of (a) any issued and unexpired Patent Right in the Territory that has not been (i) revoked or held unenforceable, unpatentable or invalid by a Governmental Authority of competent jurisdiction in a decision that is not appealable or that has not been appealed within the time allowed for appeal or (ii) abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; or (b) any patent application in the Territory that has not been (i) cancelled, withdrawn or abandoned without being refiled in another application in the applicable jurisdiction or (ii) finally rejected by an administrative agency or Governmental Authority of competent jurisdiction in a decision that is not appealable or that has not been appealed within the time allowed for appeal, provided that, on a country-by-country basis, a patent application pending for more than ** from the priority date of such patent application shall not be considered to have any Valid Claim for purposes of this Agreement from and after ** unless and until a patent with respect to such patent application issues.
- 1.142. "VAT" has the meaning set forth in Section 5.5.9.
- 1.143. "**" means the product currently marketed under the brand name ** (it being understood that (x) ** and (y) such product, whether marketed under such different name or any other name in the future, shall be deemed to be ** for the purposes of this Agreement).
- 2. RIGHTS GRANTED.
- 2.1. License to Shionogi. Subject to the terms and conditions of this Agreement, Egalet hereby grants, on behalf of itself and its Affiliates, to Shionogi, effective

on the Effective Date, a royalty-bearing, exclusive (even as to Egalet (except to the extent necessary for Egalet to perform the Egalet Development Activities)) worldwide license, with the right to sublicense as set forth in Section 2.3.1, under the Egalet Technology to Manufacture, Develop and Commercialize the Products in the Field in the Territory.

- 2.2. License to Egalet. Subject to the terms and conditions of this Agreement, Shionogi hereby grants, on behalf of itself and its Affiliates, to Egalet, effective on the Effective Date, a royalty-free, non-exclusive license, with the right to sublicense as set forth in Section 2.3.3, (i) under the Shionogi Technology to the extent necessary for Egalet to perform the Egalet Development Activities and (ii) under any Shionogi Improvement Manufacturing Patent Rights for use other than for the Manufacture, Development and/or Commercialization of the Products in the Field in the Territory.
- 2.3. Sublicensing.
- 2.3.1. Shionogi Right to Sublicense. Shionogi shall have the right to grant sublicenses under the rights granted to Shionogi in Section 2.1 to its Affiliates and to Third Parties. In the event that Shionogi grants any sublicense under this Section 2.3.1, Shionogi shall continue to remain responsible and liable for its obligations under this Agreement including the performance of each of its Sublicensees.
- 2.3.2. Egalet Right of First Negotiation. Notwithstanding Section 2.3.1, if Shionogi intends to grant a Third Party a sublicense to engage in Commercialization in any Proposed Sublicense Territory, then prior to granting any such sublicense, Shionogi shall first provide Egalet with written notice of its desire to enter into such sublicense and the Commercialization that would be the responsibility of such sublicensee, and Egalet shall have a right of first negotiation for a sublicense to conduct such Commercialization in such Proposed Sublicense Territory or portion thereof; provided, however, that Egalet is Commercially Capable in the Proposed Sublicense Territory (it being understood that (i) Egalet may only exercise the foregoing right of first negotiation by providing Shionogi written notice of Egalet's election to exercise such right within ** of receipt of Shionogi's notice; (ii) if Egalet timely exercises such right pursuant to this Section 2.3.2, Egalet and Shionogi agree to negotiate such sublicense in good faith for a period of ** following Egalet's delivery of such notice; (iii) if the Parties enter into negotiations on the basis of submissions by Egalet supporting that it is Commercially Capable in the Proposed Sublicense Territory, Shionogi shall be entitled to insist that the standards and representations set forth in any such submission are met by Egalet; and (iv) if the Parties do not enter into a binding transaction with respect to such sublicense within such ** period, then Shionogi shall thereafter be free to enter into a binding transaction with respect to such sublicense with any Third Party).

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- 2.3.3. Egalet Right to Sublicense. With the prior written approval of Shionogi, Egalet shall have the right to grant Sublicenses under the rights granted to Egalet in Section 2.2 to its Affiliates and to Third Parties. In the event that Egalet grants any Sublicense under this Section 2.3.3, Egalet shall continue to remain responsible and liable for its obligations under this Agreement including the performance of each of its Sublicensees.
- 2.3.4. Sublicense Requirements. Each Sublicense (a) shall be subject and subordinate to, and consistent with, the terms and conditions of this Agreement; (b) shall not diminish, reduce or eliminate any of the sublicensing Party's obligations under this Agreement; (c) shall require the Sublicensee(s) to comply with all applicable terms of this Agreement (except for the payment obligations, for which each Party shall remain financially responsible); and (d) shall prohibit further sublicensing except on terms consistent with this Section 2.3.4. Subject to the following sentence, each Party shall provide the other Party with a complete copy of each Sublicense executed by such Party within thirty (30) days after execution thereof; provided, however, that such Party may redact any Confidential Information from such Sublicense to the extent that such redactions do not reasonably impair the other Party's ability to ensure compliance with this Agreement.
- 2.3.5. Breach of Sublicense. In the event that the non-sublicensing Party notifies the sublicensing Party in writing of an uncured material breach by the applicable Sublicensee under a Sublicense and such breach would constitute a material breach of the sublicensing Party's obligations under this Agreement (a "Sublicensee Material Breach"), the sublicensing Party shall use Commercially Reasonable Efforts to remedy (or cause the applicable Sublicensee to remedy) such Sublicensee Material Breach. In the event that the Sublicensee Material Breach is not cured within ninety (90) days (or such other time period as mutually agreed by the Parties) of receipt of such written notice, such Sublicensee Material Breach shall be deemed to be an uncured material breach by the sublicensing Party under this Agreement but solely with respect to the portion of the Territory licensed to the Sublicensee under the applicable Sublicense (the "Sublicensee Territory") and the non-sublicensing Party shall have the right to terminate this Agreement with respect to that portion of the Territory licensed to the Sublicensee Material Breach has occurred with respect to any Sublicense that includes any portion of any Specified Territory, the Parties acknowledge and agree that the non-sublicensing Party shall only have the right to terminate this Agreement with respect to such Specified Territory if the applicable breach in a portion of such Specified Territory constitutes a material breach of Shionogi's obligations under this Agreement with respect of such Specified Territory taken as a whole. Notwithstanding anything herein to

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the contrary, this Section 2.3.5 shall not apply to any breach by Egalet of a Sublicense in its capacity as a Sublicensee of Shionogi.

2.4. Technology Transfer. Egalet acknowledges and agrees that Shionogi's ability to exercise the rights and licenses granted to Shionogi under this Agreement is dependent on Egalet providing Shionogi with access to (a) the Egalet Technology, (b) documents and information relating to the Egalet Technology to the extent such documents and information are within Egalet's Control at such time and (c) employees of Egalet or its

Affiliates that are familiar with the Egalet Technology. In furtherance of the foregoing, from time to time during the Term, and in any event promptly after the Effective Date and at least once per calendar quarter during the Term, Egalet shall (and shall cause its Affiliates to) provide Shionogi with (i) access to the items noted in clauses (a)-(c) above, and (ii) all reasonable assistance requested by Shionogi to enable Shionogi the ability to exercise the rights and licenses granted to Shionogi under this Agreement (the "Technology Transfer Services"). The Parties acknowledge and agree that it is currently contemplated that **. Without limiting the generality of the foregoing, upon Shionogi's request, Egalet shall also provide Shionogi with **. Shionogi shall **.

- 2.5. No Other Rights. No rights or licenses, other than those expressly set forth in this Agreement, are granted to either Party hereunder, and no additional rights or licenses shall be deemed granted to either Party by implication, estoppel or otherwise. All rights not expressly granted by either Party to the other hereunder are reserved.
- 2.6. Shionogi Option for Additional Products.
- 2.6.1. For a period of one hundred and eighty (180) days after the Effective Date, if requested by Shionogi, Egalet and Shionogi agree to negotiate in good faith a potential transaction pursuant to which Shionogi would receive an exclusive license under the Egalet Technology to Develop, Manufacture and Commercialize an additional product in the Territory based on either an opioid drug (excluding morphine and oxycodone) or a non-opioid drug that incorporates the Egalet Technology (an "Additional Product"). During such time, neither Egalet nor any of its Affiliates may enter into negotiations or otherwise conduct negotiations with any Third Party for any license or other agreement with respect to any pharmaceutical product based on either an opioid drug (excluding morphine and oxycodone) or a non-opioid drug that incorporates the Egalet Technology. Following the expiration of such one hundred and eighty (180) day period and until the second anniversary of the Effective Date, in the event that Shionogi presents a proposal for an Additional Product, Egalet shall negotiate in good faith, for a period of sixty (60) days following Shionogi's delivery of such proposal, a potential transaction pursuant to which Shionogi would receive an exclusive license under the Egalet Technology for such Additional Product (it

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being understood that (a) the foregoing obligation contemplated in this sentence shall not preclude Egalet from engaging in negotiations with any Third Party; provided, however, to the extent any Confidential Information of Shionogi is provided to Egalet in connection with the presentation and/or negotiation of such proposal, such Confidential Information shall only be used by Egalet for the purposes of evaluating the potential transaction with Shionogi; (b) in the event that (i) at the time Shionogi presents such proposal to Egalet, Egalet is then negotiating a potential transaction with a Third Party that would implicate the Commercialization of the Additional Product proposed by Shionogi, (ii) the negotiations with such Third Party have proceeded beyond the stage of an agreed to term sheet addressing in reasonable detail the principal terms of such potential transaction and (iii) the negotiation with Shionogi would reasonably be expected to compromise the consummation of such potential transaction with such Third Party, then the foregoing obligation contemplated in this sentence shall not apply for so long as such negotiations would be so compromised and (c) Shionogi may only invoke the right contemplated in this sentence one time for any proposed Additional Product). Notwithstanding the foregoing, in no event shall Shionogi invoke the right granted in the immediately preceding sentence for the purpose of delaying or otherwise frustrating a Change of Control transaction with any Future Acquirer of Egalet. Following the second anniversary of the Effective Date, neither Party shall have any further obligations under this Section 2.6.1.

- 2.6.2. In the event that Egalet or any of its Affiliates chooses to license to a Third Party a product based on either or both morphine or oxycodone and incorporating the Egalet Technology, Egalet or such Affiliate shall provide Shionogi with written notice thereof, and, with respect to each such product, Shionogi shall have a one-time right of first negotiation for a license to such product by providing Egalet or such Affiliate with written notice exercising such right with ** of receipt of Egalet or such Affiliate's notice. If Shionogi timely exercises such right pursuant to the foregoing sentence, Egalet or such Affiliate and Shionogi agree to negotiate in good faith, for a period of sixty (60) days following Shionogi's delivery of such notice, a transaction pursuant to which Shionogi would receive an exclusive license under the Egalet Technology to such products. If Egalet or its Affiliate and Shionogi do not enter into a binding transaction with respect to such license within such sixty (60) day period, then Egalet or its Affiliate shall thereafter be free to enter into a binding transaction with respect to such product, as applicable, with a Third Party.
- 2.7. Shionogi Commitment to Acquire Egalet US Shares. Subject to the terms and conditions of this Agreement and as otherwise mutually agreed, upon the closing of the sale of shares of common stock of Egalet US in a firm-commitment underwritten public offering pursuant to an effective registration statement under

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the Securities Act, as amended, and pursuant to which such shares are listed on the Nasdaq Global Market (the "Initial Public Offering"), Shionogi (or designated Affiliate thereof) shall purchase and Egalet US shall sell to and issue Shionogi (or such designee) shares of common stock having an aggregate purchase price equal to (or as close as possible to, but no more than) \$15,000,000 or such lesser amount in order to give effect to the proviso at the end of this sentence (the "Purchased Shares") at a purchase price per share equal to the initial offering price to the public in the Initial Public Offering; provided that in no event shall Shionogi be required to purchase shares of common stock of Egalet US to the extent Shionogi's beneficial ownership of Egalet US's total outstanding shares of common stock, pro forma for the consummation of the Initial Public Offering and the issuance of the Purchased Shares to Shionogi pursuant to this Section 2.7, would exceed 19.9%. Upon the purchase of the Purchased Shares, Shionogi shall be granted the right to have one (1) individual attend any meeting of the Egalet US board of directors as a non-voting observer and such observer shall be entitled to participate in discussions of matters brought to the board of directors.

Such observer shall be entitled to be furnished with copies of all notices, board books, presentations, board member preparatory materials, minutes, consents and other materials that Egalet US provides to the members of the board of directors, and such financial and operating data and other information with respect to the business and properties of Egalet US and its Affiliates as Egalet US prepares and compiles for the members of its board of directors in the ordinary course and as the observer may from time to time reasonably request. Notwithstanding the foregoing, Egalet US may, if its board of directors reasonably determines, based on the advice of outside counsel, withhold any information and exclude any such non-voting observer from any portion of any meeting of its board of directors to the extent access to any such information or attendance at any such portion of a meeting (i) would present a direct conflict of interest for such observer, including in connection with the Agreement with Shionogi or its Affiliate, (ii) would expose such observer to competitively sensitive business information which, if known to Shionogi, would reasonably be expected to adversely affect the business or prospects of Egalet US or (iii) would present a risk that discussing a specified matter in the presence of, or providing a specific document to such observer, could result in Egalet US's loss of attorney-client privilege with respect to the specified matter. Egalet US shall grant to Shionogi equivalent registration rights to those described under the caption "Description of Capital Stock— Registration Rights" in the Registration Statement pursuant to a registration rights agreement to be mutually agreed in good faith (the terms of which shall be no less favorable to Shionogi than those granted to any other Person) as promptly as practicable after the date hereof and in no event later than Egalet US entering into a registration rights agreement with any such Person. Upon the request of the underwriters in the Initial Public Offering, Shionogi will enter into a lock-up agreement with the underwriters for the Initial Public Offering substantially in the form entered into by the current stockholders of Egalet US; provided that each executive officer and director of Egalet US and each holder of one-percent or more of Egalet US's outstanding

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capital stock (calculated on an aggregate basis together with each other holder that would be considered a member of a group with the undersigned pursuant to Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, and without giving effect to the Initial Public Offering) has delivered substantially the same lock-up agreement to the underwriters at such time. Shionogi's obligation to purchase the Purchased Shares under this Section 2.7 is conditioned upon the closing of the Initial Public Offering on or prior to **, the accuracy of the representations and warranties of Egalet US under Section 7.2, in all material respects, as of the date of the closing of the Initial Public Offering and the conditions as mutually agreed.

3. DECISION MAKING AND DISPUTE RESOLUTION.

- 3.1. Joint Development Committee. Within thirty (30) days after the Effective Date, the Parties shall establish a joint development committee (the "JDC") that will serve as a forum to facilitate the Parties' collaboration, particularly regarding the generation of Product formulations, and to define and agree upon the Egalet Development Activities. The JDC will be provided (a) an outline of Shionogi's development plans in the Specified Territory which shall be updated to reflect any Combination Products designated by Shionogi pursuant to Section 4.1.2 and/or any other material changes to the outline of Shionogi's development plans and (b) information regarding any material events in the course of Development. The Parties will also exchange their perspectives on the commercial feasibility of Commercialization of Products in different parts of the Specified Territory. Each Party shall participate in the JDC at its own expense, and at no charge to the other Party. Unless terminated sooner pursuant to Section 6.3.1 or otherwise by mutual agreement, the JDC shall continue for so long as Products are being Developed hereunder (the "JDC Term").
- 3.1.1. Membership. The JDC will consist of ** senior representatives from each Party. Shionogi will designate the chairperson of the JDC. The chairperson will be responsible for calling meetings and setting the agenda (which shall include a list of all participants expected at a meeting) and circulating such agenda at least five (5) days prior to each meeting and distributing minutes of the meetings within thirty (30) days following such meeting. JDC members shall have such expertise as may be appropriate to the activities of the JDC from time to time, and the JDC may invite personnel of the Parties having non-clinical safety and animal pharmacology, pharmaceutical development, clinical, biostatistical, regulatory affairs, pharmacovigilance, formulation, manufacturing, commercial, marketing and other expertise to participate in discussions of the JDC from time to time as appropriate to assist in the activities of the JDC. The JDC may appoint additional committees as desired.
- 3.1.2. Meetings. During Development, the JDC will meet at such frequency as shall be established by the Parties (but not less frequently than ** times per Calendar Year, unless otherwise agreed). Meetings of the JDC shall

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alternate between the offices of the Parties, unless otherwise agreed upon by the members of the JDC, or may be held telephonically or by video conference. Meetings of the JDC shall be effective only if at least one (1) representative of each Party is in attendance or participating in the meeting. Members of the JDC shall have the right to participate in and vote at meetings by telephone. Each Party shall be responsible for expenses incurred by its employees and its members of the JDC in attending or otherwise participating in JDC meetings. Each Party shall 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 to attend such meeting in place of the absent representative. Without limiting the generality of the foregoing, the Parties acknowledge and agree that the initial meeting of the JDC shall be held within forty-five (45) days of the Effective Date and shall be devoted to determining the scope of the Egalet Development Activities.

3.1.3. Minutes and Agendas. The minutes of each JDC meeting shall 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. Minutes of each JDC meeting shall be approved or disapproved, and revised as necessary, at the next meeting.

- 3.2. Other Committees. The Parties may establish other committees or sub-committees as the Parties mutually deem appropriate.
- 3.3. Consensus and Dispute Resolution. Each Party's representatives on the JDC will collectively have one (1) vote on all matters that are within the responsibility of the JDC. The members of the JDC will use reasonable efforts to reach unanimous consensus on all decisions. In the event that the members of the JDC are unable to reach consensus on a particular issue within twenty (20) days after such issue is first presented to the JDC, the chairperson appointed by Shionogi shall cast the tiebreaking vote, which vote shall be final and determinative, provided that the chairperson (a) shall reasonably consider Egalet's views and interests in reaching any decision hereunder, (b) may not unilaterally make any decision that would require Egalet to incur any costs not reimbursed by Shionogi (it being understood that nothing in this Section 3.3(b) is intended to otherwise limit Egalet's obligations under Section 2.4), (c) may not make any decision that allocates any responsibility or activity to Egalet without the consent of Egalet, (d) shall make all decisions consistent with Section 4.1.4, or (e) may not unilaterally decide such dispute in a manner that is contrary to the express terms of this Agreement. For the avoidance of doubt, no decision of the JDC may be made that would reduce the obligations of the Parties under this Agreement. The JDC will not have the power to, nor will Shionogi have the power to (i) amend, modify or waive compliance with this Agreement (other than as expressly permitted hereunder), (ii) alter, increase or expand the Parties' rights or obligations under this Agreement, (iii) determine that a Party has fulfilled any obligations under this

Agreement or that a Party has breached any obligation under this Agreement, (iv) make a decision that is expressly stated to require the mutual agreement of the Parties, or (v) determine that milestone events required for the payment of milestone payments have or have not occurred.

- 4. DEVELOPMENT; REGULATORY MATTERS; COMMERCIALIZATION.
- 4.1. Development
- 4.1.1. Development Activities. Subject to Section 4.1.4 and Section 4.2.2, Shionogi shall be responsible for all aspects of the Development of Products in the Territory, including conducting all Clinical Trials for Products for the purpose of obtaining Regulatory Approval for Products in the Territory; provided, however, that Egalet shall be responsible for Egalet Development Activities. Subject to Section 4.2.2, Shionogi shall be responsible for all of its costs associated with the Development of Products in the Territory and for the Egalet Development Costs. Except for the Egalet Development Costs, Shionogi shall not be responsible for any costs incurred by Egalet or its Affiliates in connection with Development of the Products. Each Party shall, and shall cause its Affiliates and Sublicensees, to undertake its respective Development in accordance with GCP, GLP, GMP and Applicable Laws.
- 4.1.2. Combination Products. During the Term, Shionogi shall have the right to designate up to twenty (20) Combination Products to include within the scope of the license granted under Section 2.1 for Development, Manufacturing and Commercialization under this Agreement (it being understood that the designation of a Combination Product shall only occur upon (a) the provision of an outline development plan to the JDC with respect to such Combination Product as contemplated in Section 3.1 and (b) if the JDC ceases to exist for any reason, Shionogi notifying Egalet in writing of the identity of such Combination Product and Shionogi's election that such product be designated as a Combination Product hereunder). After Shionogi has designated its twentieth (20th) Combination Product in accordance with this Section 4.1.2, Shionogi shall not have any rights under Section 2.1 or any other provision of this Agreement with respect to any other Combination Product. In order for Shionogi to be able to provide an outline development plan for any proposed Combination Product to the JDC in a timely manner, the Parties acknowledge and agree that, unless a meeting of the JDC is already scheduled for an earlier date, the JDC shall convene a special meeting within two (2) weeks of being so notified of the identity of such proposed Combination Product.

- 4.1.3. Reports of Development Activities.
- (a) Egalet's Reporting Obligations. Egalet shall promptly report and provide to Shionogi any and all raw data, results and other information related to the Egalet Development Activities in Egalet's possession or control.
- (b) Access to Personnel. Egalet shall, upon the request of Shionogi, make appropriate scientific and regulatory personnel available to Shionogi, either by telephone or in person as the Parties may mutually agree, as reasonably required to keep Shionogi informed of such Egalet Development Activities.
- 4.1.4. Development Diligence Obligations. Shionogi shall use Commercially Reasonable Efforts to Develop Products in each Specified Territory (it being understood that, for the avoidance of doubt, a breach of the foregoing obligation in any country within a Specified Territory shall not be considered a breach or violation of this Section 4.1.4 if such breach is not material to such Specified Territory taken as a whole). Without limiting Egalet's obligations under Section 4.1.1, each Party shall use Commercially Reasonable Efforts to implement and conduct the Development assigned to such Party under this Agreement, and to cooperate with and provide reasonable support to the other Party in such other Party's conduct of Development under this Agreement.
- 4.2. Regulatory Matters.
- 4.2.1. Responsibility For Regulatory Interactions. Subject to the terms and conditions of this Agreement, Shionogi shall be responsible for all regulatory matters relating to Products in the Field in the Territory, including payment of all costs associated with obtaining Regulatory Approvals

for Products in the Territory.

- (a) Shionogi Authority and Responsibilities. Subject to the terms and conditions of this Agreement, Shionogi shall have sole authority in the Territory with respect to (i) filing and maintaining INDs; (ii) obtaining Regulatory Approvals for Products and subsequently maintaining such Regulatory Approvals; (iii) communicating with Regulatory Authorities about Products; and (iv) preparing and submitting supplements, communications, annual reports, Adverse Event reports, manufacturing changes, supplier designations and other related regulatory filings and Regulatory Submissions. Shionogi shall keep the JDC reasonably informed regarding the status and progress of such activities at its regularly scheduled meetings.
- 4.2.2. **. The Parties acknowledge and agree that ** and that as of the Effective Date, the Parties are unable to determine which Party or Parties shall be responsible for **. Upon a Party's reasonable determination that

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- **, such Party shall provide the other Party with prior written notice of its intent to ** and such other Party may, within ten (10) days of receipt of such notice, **. In the event that ** in accordance with the foregoing sentence, (i) the Parties shall ** and (ii) each Party hereby ** (it being understood that, notwithstanding the foregoing, if a Party **, such Party may **. Notwithstanding anything herein to the contrary, ** in accordance with this Section 4.2.2; provided that, where such Party ** in accordance with this Section 4.2.2, such Party may **.
- 4.2.3. Sharing of Other Safety Data. Without limiting Section 4.2.2, to the extent reasonably required by any Regulatory Authority, if requested by a Party, the other Party shall (and shall cause its Affiliates and Sublicensees to) share any and all safety information and data related to the Egalet Core Technology (other than any Shell Safety Study Data) with the requesting Party and its Affiliates and Sublicensees at the requesting Party's cost.
- 4.2.4. Regulatory Audits. If a Regulatory Authority desires to conduct an inspection or audit of a Party's facility, or a facility under contract with such Party, with regard to a Product, then such Party shall promptly notify the other Party and permit and cooperate with such inspection and audit. Following receipt of the inspection or audit observations of such Regulatory Authority (in the case of Egalet, a copy of which Egalet will immediately provide to Shionogi, and, in the case of Shionogi, a copy of which Shionogi will immediately provide to Egalet to the extent such inspection or audit observances relates to a Shared Facility (as defined below) or, with respect to any Shionogi facility, only to the extent it relates to a Product-related issue (it being understood that Shionogi shall have the right to redact such copy to limit the disclosure to such Product-related issue)), the audited Party shall prepare the response to any such observations; provided that, (a) in the case of Egalet in its capacity as the audited Party, Egalet shall (i) provide a copy of such response to Shionogi prior to submitting to the Regulatory Authority and (ii) consult with Shionogi regarding any changes or modifications to such response (it being understood that Egalet shall give due consideration to Shionogi's comments) and (b) in the case of Shionogi in its capacity as the audited Party, Shionogi shall (i) with respect to any inspection or audit of a facility of a Third Party used by both Parties for purposes related to the Product (e.g., the manufacture of the Shell) (a "Shared Facility"), Shionogi shall provide a copy of such response to Egalet and (ii) with respect to any inspection or audit of any Shionogi facility, Shionogi shall only provide a copy of such response to Egalet to the extent that such response relates to a Product-related issue but in no event shall Shionogi be required to provide Egalet its response to any facility-related issue.

- 4.2.5. Adverse Events. Shionogi will be responsible for responding to safety inquiries regarding Products in the Field in the Territory. Egalet will promptly disclose to Shionogi any Adverse Events related to the Products received by Egalet or its Affiliates or Sublicensees. If and when a Party becomes aware of any information that reasonably suggests that a Product sold in the Territory may have caused or contributed to a death or serious injury or has malfunctioned and that the Product would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, such Party agrees to promptly furnish such information to the other Party; provided that, with respect to Shionogi as the reporting Party, the foregoing obligation shall only apply to the extent such Adverse Event primarily relates to Egalet Core Technology or Egalet Core Technology Improvement. During the Development, Shionogi shall provide to Egalet a copy of any submissions Shionogi makes to a Regulatory Authority with respect to any Adverse Events related to the Products. For the avoidance of doubt, the Parties acknowledge and agree that, after the Effective Date, the need for a safety data exchange/pharmacovigilance arrangement will be discussed by the Parties.
- 4.3. Manufacturing and Commercialization.
- 4.3.1. Manufacturing and Commercialization Activities. Subject to the terms and conditions of this Agreement, Shionogi shall have sole right and responsibility at its cost and expense for all aspects of Manufacturing and Commercialization of Products in the Field in the Territory and shall undertake Manufacturing and Commercialization activities in accordance with all Applicable Laws. Without limiting the generality of the foregoing, Egalet acknowledges and agrees that Shionogi shall be permitted to engage ** to Manufacture the Products on Shionogi's behalf and Egalet shall, promptly after the Effective Date, inform ** in writing that Shionogi is an authorized licensee of Egalet, as contemplated in the applicable agreement between Egalet and ** dated **, as amended, and shall take any other actions reasonably required by Shionogi in connection with any of the foregoing.
- 4.3.2. Reports of Commercialization Activities. Shionogi shall provide Egalet with annual reports summarizing its Commercialization activities for the Products in the Specified Territory, including Shionogi's efforts to meet its diligence obligations set forth in Section 4.3.3. In addition, Shionogi shall meet with Egalet, at Egalet's request, no more than **, to report on the activities it has undertaken with regard to Commercializing Products in the Field in the Specified Territory and to provide a forum for Egalet to provide feedback regarding such Commercialization activities,

which feedback shall be reasonably considered by Shionogi in developing its future Commercialization strategy for the Products.

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- 4.3.3. Commercialization Diligence Obligations. Shionogi shall use Commercially Reasonable Efforts to Commercialize Products in the Field in each Specified Territory (it being understood that, for the avoidance of doubt, a breach of the foregoing obligation in any country within a Specified Territory shall not be considered a breach or violation of this Section 4.3.3 if such breach is not material to such Specified Territory taken as a whole). Upon the grant of Regulatory Approval to market and, if necessary, sell a Product in the Field in the United States, Shionogi shall use Commercially Reasonable Efforts to complete a First Commercial Sale of such Product in the United States within ** after obtaining such Regulatory Approval; provided that Shionogi's failure to complete a First Commercial Sale of such Product in the United States within such ** period shall not be a breach or violation of the foregoing obligation in the event that the delay is attributable to factors that may cause such period to be unreasonably short or the launch to be commercially unreasonable, including commercial supply chain disruptions and post-marketing requirements imposed by the FDA (collectively, the "Delay Factors") (it being understood that any such Delay Factor shall not apply to the extent caused by Shionogi's negligence).
- 4.4. Recalls. Shionogi shall have the sole discretion to make a decision for recalling, or issuing an advisory letter or other safety-related communication with respect to, Products in the Territory. Shionogi shall notify Egalet in a timely manner in connection with any such action. Each Party agrees to provide reasonable assistance to the other Party in the event of any recall or issuance of any advisory letter.
- 4.5. Publications. As between the Parties, Shionogi (and its Affiliates and Sublicensees) shall have the sole and exclusive right to produce, prepare and publish any scientific paper, presentation, manuscript or other publication with respect to any Product; provided that, Egalet shall be afforded the opportunity to review and comment on any such scientific paper, presentation, manuscript or other publication to the extent it includes Egalet Core Technology or Egalet Core Technology Improvements that constitutes Confidential Information of Egalet and if requested in writing by Egalet, Shionogi shall redact any such Confidential Information that directly relates to Egalet Core Technology or Egalet Core Technology Improvements. Egalet shall not (and shall cause its Affiliates and Sublicensees not to), without Shionogi's prior written consent, produce, prepare and/or publish any scientific paper, presentation, manuscript or other publication with respect to any Product. Egalet may produce, prepare and publish any scientific paper, presentation, manuscript or other publication with respect to any Egalet Core Technology or Egalet Core Technology Improvements; provided that (a) Shionogi shall have the right to review and comment on any such scientific paper, presentation, manuscript or other distribution and (b) Shionogi shall only have an approval right to the extent any such scientific paper, presentation, manuscript or other

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publication with respect to any Egalet Core Technology or Egalet Core Technology Improvements relates to any Product. To the extent a Party is provided with any right to review or comment on a scientific paper, presentation, manuscript or other publication above, the Party (or its Affiliates or Sublicensees) proposing such scientific paper, presentation, manuscript or other publication shall not unreasonably reject comments furnished by the reviewing and commenting Party.

5. CONSIDERATION.

- 5.1. Upfront Payments. In consideration of the rights granted to Shionogi under this Agreement, Shionogi shall pay to Egalet, within five (5) business days of the Effective Date, Ten Million dollars (\$10,000,000) as an upfront, non-creditable and non-refundable fee (the "Initial Fee").
- 5.2. Milestones. As consideration for the rights granted to Shionogi under this Agreement, Shionogi agrees to pay the following milestone payments, and Shionogi shall report to Egalet the occurrence of such milestones within five (5) business days thereof.
- 5.2.1. First Product Regulatory Milestones. Shionogi shall pay Egalet the following non-creditable, non-refundable amounts within ** after the first occurrence of each of the following events:

EVENT

MILESTONE PAYMENT

The later of: (i) the first FDA acceptance of an IND for a Product, **, and (ii) successful completion of **. For the purposes of determining ** as set forth in clause (ii) above, the Parties shall mutually agree upon the criteria for **.

\$**

The first ** for any Product

¢**

The first ** for a Combination Product that is a **

\$**

\$** 5.2.2. Subsequent Product Regulatory Milestones. Shionogi will pay Egalet the following non-creditable, non-refundable amounts within forty-five (45) days after the first occurrence of each of the following events: **FVFNT** MILESTONE PAYMENT The first ** for a second Product (excluding a Combination Product that is a **) \$** 29 **EVENT** MILESTONE PAYMENT The first ** for a second Product (excluding a Combination Product that is a **) \$** The first ** for each Product other than the Products for which milestones are paid under Section 5.2.1 or in Section 5.2.2 above \$** The first ** for each Product other than the Products for which milestones are paid under Section 5.2.1 or in Section 5.2.2 above \$** For the avoidance of doubt, if multiple Hydrocodone Products are developed, Shionogi shall be obligated to make a milestone payment corresponding to each of the foregoing events in connection with each Hydrocodone Product that achieves such milestone event; Shionogi shall not be obligated to make the same milestone payment more than one time for the same Hydrocodone Product, regardless of the number of times such milestone event occurs for such same Hydrocodone Product. 5.2.3. Sales Milestones. As consideration for the rights granted to Shionogi under this Agreement, Shionogi will pay Egalet the following one-time non-creditable, non-refundable amounts within ** after the end of the Calendar Quarter in which the following events first occur: **EVENT** MILESTONE PAYMENT First instance of Net Sales exceeding \$** in a Twelve Month Period First instance of Net Sales exceeding \$** in a Twelve Month Period \$** First instance of Net Sales exceeding \$** in a Twelve Month Period \$** First instance of Net Sales exceeding \$** in a Twelve Month Period \$** The sales milestones shall only be payable if achieved during the period of time commencing on the First Commercial Sale of a Product and expiring upon the latest of (a) the expiration of Innovator Protection in the U.S. for all Products, (b) the expiration of Regulatory-Based Exclusivity for all Products in the U.S., and (c) the ** anniversary of the date of the last First Commercial Sale of the Products in the U.S. 30

The first ** for a Combination Product that is a **

- 5.3. Royalties. In addition to the payments under Sections 5.1 and 5.2, in consideration for the rights granted to Shionogi under this Agreement, Shionogi shall pay to Egalet the royalty payments set forth in this Section 5.3.
- 5.3.1. Shionogi shall pay to Egalet a non-creditable, non-refundable royalty, in immediately available funds, in an amount equal to:
- (a) ** of that portion of worldwide Net Sales of all Products during a Calendar Year that are equal to or less than \$**;
- (b) ** of that portion of worldwide Net Sales of all Products during a Calendar Year that are greater than \$**; and
- (c) ** of that portion of worldwide Net Sales of all Products during a Calendar Year that are greater than \$**.

Shionogi's royalty obligations under this Section 5.3 shall, on a Product-by-Product and country-by-country basis, commence on the First Commercial Sale of a Product in a country and expire upon the latest of (a) the expiration of Innovator Protection for such Product in such country, (b) the expiration of Regulatory-Based Exclusivity for such Product in such country, and (c) ** of the date of First Commercial Sale of such Product in such country (the "Royalty Period").

For the avoidance of doubt, if multiple Products are developed, Shionogi shall be obligated to make royalty payments in connection with each Product following such Product's First Commercial Sale.

5.3.2. Royalty Reduction — Anti-Stacking. In the event that Shionogi reasonably believes that the Development, Manufacture or Commercialization of any Product in the Territory under this Agreement by or on behalf of Shionogi might infringe or misappropriate any Applicable Patent Rights and Know-How of any Third Party absent a license to such Applicable Patent Rights and Know-How and Shionogi obtains a license under such Applicable Patent Rights and Know-How, then Shionogi may deduct from the royalties due to Egalet pursuant to Section 5.3 ** of any royalty payments actually paid to any such Third Party as consideration for any such license to such Applicable Patent Rights and Know-How; provided that in no event shall the royalties due to Egalet for a given Calendar Quarter be reduced under this Section 5.3.2 by more than ** (it being understood that, notwithstanding the foregoing, any unused credit amounts may be carried over into subsequent Calendar Quarters). For the purposes of this Section 5.3.2, "Applicable Patent Rights and Know-How" means any Patent Rights and/or Know-How relating to **.

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- 5.3.3. Royalty Reduction Generic Competition.
- (a) On a Product-by-Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, if the Generic Competition in a country with respect to a particular strength or dosage of a Product during a Calendar Quarter equals or exceeds ** but is less than **, then Shionogi shall pay to Egalet a reduced royalty rate on Net Sales of such strength or dosage of such Product in such country during such Calendar Quarter equal to ** of the royalty rate applicable under Section 5.3.1; and
- (b) On a Product-by-Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, if the Generic Competition in a country with respect to a particular strength or dosage of a Product during a Calendar Quarter equals or exceeds ** but is less than **, then Shionogi shall pay to Egalet a reduced royalty rate on Net Sales of such strength or dosage of such Product in such country during such Calendar Quarter equal to ** of the royalty rate applicable under Section 5.3.1; and
- (c) On a Product-by-Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, if the Generic Competition in a country with respect to a particular strength or dosage of a Product during a Calendar Quarter equals or exceeds **, then Shionogi's obligation to pay royalties under Section 5.3.1 shall no longer apply.
- 5.3.4. Fully Paid-Up, Royalty-Free License. Following the expiration of the Royalty Period for any Product in a given country in the Territory, no further royalties shall be payable in respect of Development, Manufacturing or Commercialization of such Product in such country and, thereafter, the license granted to Shionogi under Section 2.1 with respect to such Product in such country shall automatically become a fully paid-up, perpetual, irrevocable, royalty-free exclusive license.
- 5.4. Payment of Egalet Development Costs.
- 5.4.1. Egalet Development Cost Report. After the end of each Calendar Quarter during which Egalet has performed Egalet Development Activities pursuant to Section 4.1.1, Egalet shall deliver to Shionogi an invoice of Egalet Development Costs. Such invoice shall set forth the number of FTEs performing services during such Calendar Quarter, a summary of the work done by such FTEs, and the amount of other costs included in such Egalet Development Costs, together with substantiating invoices and other documentation for such costs.
- 5.4.2. Payment of Egalet Development Costs. Shionogi shall pay any invoice delivered by Egalet pursuant to Section 5.4.1 within ** of receipt of any such invoice.

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5.5. Reports and Payments.

5.5.1. Royalty Reports. Within sixty (60) days after the end of each Calendar Quarter beginning with the Calendar Quarter in which the First Commercial Sale is made in a country following receipt of Regulatory Approval in such country, Shionogi shall deliver to Egalet a report setting forth for the previous Calendar Quarter the following information on a Product-by-Product basis: (a) the Net Sales of each Product in each country; (b) the number of units sold by Shionogi, its Affiliates or Sublicensees; (c) the basis for any adjustments to the royalty payable for the sale of each Product; (d) the royalty due hereunder for the sales of each Product; and (e) the applicable exchange rate as determined in accordance with this Agreement. The total royalty due for the sale of Products during such Calendar Quarter shall be remitted at the time such report is made. No such reports shall be due for any Product after the relevant Royalty Period for such Product has expired.

5.5.2. Taxes and Withholding.

- (a) All payments under this Agreement shall be made free and clear of, and without withholding or deduction for or on account of, any present or future taxes, duties, assessments or governmental charges of a similar nature (a "Tax Deduction"), unless the Tax Deduction is required by Applicable Laws.
- (b) A Party making a payment under this Agreement shall: notify the recipient of that payment promptly upon becoming aware that it is required by Applicable Laws to make a Tax Deduction; make that Tax Deduction and any payment required in connection with that Tax Deduction within the time allowed and in the minimum amount required by Applicable Laws; and deliver to the recipient evidence reasonably satisfactory to that other Party that the Tax Deduction has been made or (as applicable) any appropriate payment paid to the relevant taxing authority.
- (c) The Parties shall co-operate in completing any procedural formalities necessary for a Party to obtain an appropriate authorization from a taxing authority for a payment under this Agreement to be made without a Tax Deduction.
- (d) Where a payment to be made under this Agreement by Shionogi to Egalet (or to any Affiliate designated by Egalet): (i) is subject to a Tax Deduction arising only by reason of Shionogi having assigned or transferred its rights and/or obligations to an Affiliate or a Third Party or by reason of Shionogi having become resident for tax purposes in a jurisdiction other than the United Kingdom; and (ii) at the date on which the payment falls due, Egalet (or its Affiliate,

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as the case may be) is a company which is resident for tax purposes in the United Kingdom and is beneficially entitled to the payment in question, then Shionogi shall pay, in addition to that payment, such additional amounts as will result in receipt by Egalet (or its Affiliate, as the case may be) after the imposition of such Tax Deduction of such amounts as it would have received had no such Tax Deduction been imposed (including any Tax Deduction imposed on amounts payable as provided in this paragraph (d)). Save as provided in this paragraph (d), no Party (and, for the avoidance of doubt, no Affiliate of a Party, nor any assignee or transferee of a Party in accordance with this Agreement) will be obliged to pay additional amounts in respect of a Tax Deduction imposed on a payment to be made under this Agreement.

- (e) If Shionogi pays an additional amount in respect of a Tax Deduction pursuant to paragraph (d) above and the recipient is entitled to a credit against, relief from, or repayment of tax which is attributable to such additional amount or to such Tax Deduction (a "Tax Credit"), the recipient will use reasonable endeavours to obtain such Tax Credit, and on obtaining such Tax Credit shall pay an amount to Shionogi which will leave the recipient in the same after-tax position as it would have been in had the additional amounts not been required to be paid under paragraph (d).
- (f) For the purposes of this Section 5.5.2, Egalet represents to Shionogi that it is currently a company which is resident for tax purposes in the United Kingdom and is beneficially entitled to the payments to be made to it under this Agreement (including, for the avoidance of doubt, such payments to the extent they are received by Egalet on behalf of any of its Affiliates under this Agreement). Egalet undertakes to Shionogi (i) promptly to notify Shionogi in writing if the representation contained in this paragraph ceases to be true during the life of this Agreement; and (ii) to procure that any Affiliate it designates to receive a payment due to it, and any other assignee or transferee of its rights and/or obligations under this Agreement, notifies Shionogi in writing, at the time of such designation, assignment or transfer, whether or not such Affiliate, assignee or transferee (as the case may be) is a company which is resident for tax purposes in the United Kingdom and is beneficially entitled to the payments to be made to it under this Agreement.
- (g) For the purposes of this Section 5.5.2, Shionogi represents to Egalet that it is currently a company which is resident for tax purposes in the United Kingdom.

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5.5.3. Currency. All amounts payable and calculations hereunder shall be in US Dollars. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Egalet hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on currency exchange rates for the calendar quarter for which remittance is made for royalties. For each quarter and each currency, such exchange rate will equal the arithmetic average of the daily exchange rates (obtained as described below) during such calendar quarter; each daily exchange rate shall be the telegraphic transfer middle (TTM) rate obtained from www.OANDA.com or, if not so available, as otherwise agreed by the Parties. For purposes of calculating the Net Sales thresholds set forth in Sections 5.3.1, the aggregate Net Sales with respect to each calendar quarter within a calendar year will be calculated based on the currency exchange rates for the calendar quarter in which such Net Sales occurred, in a manner consistent with the exchange rate procedures set forth in the immediately preceding sentence.

- 5.5.4. Method of Payment. Each payment hereunder shall be made by electronic transfer in immediately available funds via a bank wire transfer, an automated clearing house (ACH) mechanism or any other means of electronic funds transfer, at Shionogi's election, to a bank account designated by Egalet in writing to Shionogi at least sixty (60) days before the payment is due.
- 5.5.5. Record Keeping. Shionogi shall keep, and shall causes its Affiliates and Sublicensees to keep, books and accounts of record in connection with the sale of Products in the Territory, including records of Net Sales, exchange rates and royalty payments (collectively, the "Financial Records"), in accordance with GAAP, IFRS or Japan GAAP and in sufficient detail to permit accurate determination of all figures necessary for verification of royalty and milestone payments to be made by Shionogi under this Section 5. Shionogi shall maintain, and shall causes its Affiliates and Sublicensees to maintain, such Financial Records for a period of at least ** after the end of the Calendar Quarter in which they are generated.
- 5.5.6. Audits. Upon thirty (30) days prior written notice from Egalet, Shionogi shall permit **, as selected by Egalet and reasonably acceptable to Shionogi, to examine, at Egalet's sole expense, the relevant Financial Records of Shionogi, and its Affiliates and Sublicensees, as may be reasonably necessary to verify the amounts reported by Shionogi in accordance with Section 5.5.1, and the royalty and milestone payments made by Shionogi in accordance with this Section 5. Egalet shall be entitled to conduct an audit in accordance with this Section 5.5.6 not more than once in any Calendar Year and such audit shall be limited to the pertinent Financial Records from any Calendar Year ending not more

- than ** prior to the date of the request. The accounting firm shall be provided access to such Financial Records at the facility(ies) of Shionogi, and its Affiliates and Sublicensees, where such Financial Records are normally kept and such audit shall be conducted during the normal business hours of Shionogi, its Affiliate or its Sublicensee, as applicable. Upon completion of the audit, the accounting firm shall provide both Parties with a written report disclosing any discrepancies in the reports submitted by Shionogi or payments made by Shionogi, if any, and in each case, the specific details concerning any discrepancies. Any information provided by Shionogi to the accounting firm and the written report of the accounting firm shall be the Confidential Information of Shionogi.
- 5.5.7. Underpayments/Overpayments. If a report of an independent certified public accounting firm submitted to the Parties in accordance with Section 5.5.6 shows any underpayment of royalties or Sales Milestone payments due under this Section 5, the Parties shall discuss the discrepancy in good faith. Shionogi shall remit to Egalet within ** after receipt of such report by Shionogi, (a) the amount of such underpayment and (b) if such underpayment exceeds ** of the total amount owed to Egalet for the Calendar Year then being audited, the reasonable fees and expenses of such accounting firm performing the audit, subject to reasonable substantiation thereof. If such accounting firm's written report shows, or either Party discovers, any overpayment of royalties or Sales Milestone payments due under this Section 5, Shionogi shall receive a credit equal to such overpayment against the royalties and Sales Milestone payments due under this Section 5 otherwise payable to Egalet or a refund in immediately available cash, as specified by Shionogi.
- 5.5.8. Interest. Any payment of any undisputed sums properly due and payable to Egalet under Section 5 that is more than ** past due shall be subject to interest at an annual percentage rate of then-current base rate of **. Likewise, any overpayment that is not refunded within thirty (30) days after the date upon which notice of such overpayment was received shall thereafter be subject to interest at an annual percentage rate of then-current base rate of **.
- 5.5.9. VAT. All amounts expressed in this Agreement as being payable by any party hereto are expressed as exclusive of any VAT which may be chargeable thereon and the amount of any VAT shall be payable in addition thereto, subject to receipt by the payer of a valid VAT invoice. "VAT" means value added tax chargeable under the United Kingdom Value Added Tax Act 1994 ("VATA"), the Danish equivalent of VATA or under Directive 2006/112/EC of the Council of the European Union ("the Directive") or under any rule, regulation, order or instrument authorized to be made by VATA, by the Danish equivalent of VATA or by the Directive or any identical or substantially similar tax which may

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replace such value added tax. For the purposes of this Section 5.5.9, (i) Shionogi represents to Egalet that it is a relevant business person who belongs in the United Kingdom for the purposes of VATA; and (ii) Egalet represents to Shionogi that it is a person who belongs in a country other than the United Kingdom for the purposes of VATA, as respects the supplies to be made under this Agreement; and (iii) each Party will notify the other if there is a change to the country in which it belongs for the purposes of VATA.

- 6. CONFIDENTIALITY; OTHER COVENANTS.
- 6.1. Confidentiality.
- 6.1.1. Confidential Information. Except to the extent expressly permitted by this Agreement and subject to the provisions of Sections 6.1.2 and 6.1.3, at all times during the Term and for ** years thereafter, each Party receiving any Confidential Information (the "Receiving Party") of the other Party (the "Disclosing Party") in connection with this Agreement: (a) shall keep completely confidential and shall not publish or otherwise disclose any Confidential Information furnished to it by the Disclosing Party, except to those of the Receiving Party's employees, Affiliates, consultants or representatives and, with respect to Shionogi, its Sublicensees, who have a need to know such information (collectively, "Recipients") to perform such Party's obligations or exercising its rights hereunder; and (b) shall not use Confidential Information of the Disclosing Party directly or indirectly for any purpose other than performing its obligations or exercising its rights hereunder. The Receiving Party shall be liable for any breach by any of its Recipients of the restrictions set forth in this Agreement.

- 6.1.2. Exceptions to Confidentiality. The Receiving Party's obligations set forth in Section 6.1 shall 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 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
- 6.1.3. Authorized Disclosure. Notwithstanding the provisions of Section 6.1.1, the Receiving Party and its Recipients may disclose Confidential Information belonging to the Disclosing Party to the extent that such disclosure is reasonably necessary to:
- (a) prosecute or defend litigation:
- (b) comply with Applicable Laws (including requirements of a national securities exchange or another similar regulatory body); and
- (c) make filings and submissions to, or correspond or communicate with, any Governmental Authority.

In the event that the Receiving Party or its Recipients, as applicable, deem it reasonably necessary to disclose Confidential Information belonging to the Disclosing Party pursuant to this Section 6.1.3, the Receiving Party shall, to the extent possible, provide the Disclosing Party with reasonable advance notice of such disclosure and take reasonable measures to ensure confidential treatment of such information. In addition, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to any Third Party who is performing diligence in connection with a transaction with the Receiving Party (including potential Sublicensees and licensees), provided that, each such Third Party has signed a written confidentiality agreement with the Receiving Party no less strict than the terms hereof.

- 6.1.4. Notification. The Receiving Party shall notify the Disclosing Party immediately, and cooperate with the Disclosing Party as the Disclosing Party may reasonably request, upon the Receiving Party's discovery of any loss or compromise of the Disclosing Party's Confidential Information.
- 6.1.5. Destruction of Confidential Information. Upon the expiration or earlier termination of this Agreement, except with respect to Confidential Information necessary or useful for a Receiving Party to exercise any rights or perform any obligations under this Agreement surviving such expiration or termination, the Receiving Party shall (a) destroy all tangible embodiments of Confidential Information of the Disclosing Party, including any and all copies thereof, and those portions of any documents, memoranda, notes, studies and analyses prepared by the

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Receiving Party or its Recipients that contain, incorporate or are derived from such Confidential Information and provide written certification of such destruction to the Disclosing Party in a form reasonably acceptable to the Disclosing Party, provided that the legal department of the Receiving Party shall have the right to retain one (1) copy of any such tangible embodiments for archival purposes, which copy shall continue to be maintained on a confidential basis subject to the terms of this Agreement; and (b) immediately cease, and shall cause its Recipients to cease, use of such Confidential Information as well as any information or materials that contain, incorporate or are derived from such Confidential Information.

- 6.1.6. Use of Name and Disclosure of Terms.
- (a) Except to the extent expressly permitted by this Agreement, each Party shall keep the existence of, the terms of and the transactions covered by this Agreement confidential and shall not disclose such information to any Third Party through a press release or otherwise, or mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates (such indicia, together with the existence of, the terms of and the transactions covered by this Agreement collectively, the "Names and Terms") in any manner without the prior written consent of the other Party in each instance (which shall not be unreasonably withheld); provided, however, that a Party may disclose the Names and Terms without the prior consent of the other Party to any Third Party who is performing diligence in connection with a potential transaction with such Party (including potential Sublicensees and Licensees) so long as each such Third Party has signed a written confidentiality agreement with such Party no less strict than the terms hereof, which confidentiality agreement shall require such Third Party to keep the Names and Terms confidential and shall prohibit use of the Names and Terms other than for performing such diligence. Further, the

restrictions imposed on each Party under this Section 6.1.6 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to Section 6.1.1.

(b) Each Party acknowledges and agrees that the other Party may submit this Agreement to the U.S. Securities and Exchange Commission or any national securities exchange in any jurisdiction (collectively the "Securities Regulators"), and if a Party does submit this Agreement to any Securities Regulators, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for

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such agreement. The Parties shall use reasonable efforts within ten (10) days following the Effective Date to prepare a mutually acceptable redacted version of this Agreement to be filed with any Securities Regulator in connection with such confidential treatment request. Notwithstanding the foregoing, if a Party is required by Applicable Law or any Securities Regulators in any jurisdiction to make a disclosure of the terms of this Agreement in a filing with or other submission to any Securities Regulator, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Applicable Law. Notwithstanding anything to the contrary herein, it is hereby understood and agreed that if a Party seeking to make a disclosure to a Securities Regulator as set forth in this Section 6.1.6, and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith consider incorporating such comments.

6.1.7. Publicity. Egalet may issue the press release attached hereto as Exhibit A promptly after execution of this Agreement. In all other cases, subject to this Section 6.1.7, each Party agrees not to, and agrees to cause their Affiliates not to, issue any press release or other public statement disclosing any information relating to this Agreement, the activities hereunder or thereunder, or the transactions contemplated hereby or thereby. Notwithstanding the foregoing, any disclosure that is required by Applicable Laws (including the Securities Act and the Securities Exchange Act of 1934, as amended) or the rules of any Securities Regulator or the securities regulations of any state or other jurisdiction, or by judicial process shall be in accordance with Sections 6.1.3 and 6.1.6, as applicable. Without limiting the foregoing, each Party agrees to provide to the other Party a copy of any public announcement covered by this Section 6.1.7 as soon as reasonably practicable under the circumstances prior to its scheduled release. Except under extraordinary circumstances, each Party shall provide the other Party with an advance copy of any such announcement at least three (3) business days prior to its scheduled release. Each Party shall have the right to expeditiously review and recommend changes to any such announcement and, except as otherwise required by Applicable Laws or such rules or regulations,

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the Party whose announcement has been reviewed shall remove any Confidential Information of the reviewing Parties that the reviewing Parties deem to be inappropriate for disclosure and request in writing that the publishing Party remove from such announcement within the applicable review period (not to exceed three (3) business days).

- 6.1.8. Remedies. The Parties acknowledge and stipulate that the restrictions set forth in Section 6.1 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 Section 6.1 will result in irreparable injury to the other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of Section 6.1 by a Party, the other Party shall be authorized and entitled to obtain from any court of competent jurisdiction 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 shall 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; or (b) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 6.1.8 is intended, or shall be construed, to limit the Parties' rights to equitable relief or any other remedy for a breach of any provision of this Agreement.
- 6.2. Compliance with Law. Each Party hereby covenants and agrees to comply with all Applicable Laws with respect to its activities connected with the Development, Manufacture and Commercialization (as applicable) of Products. Without limiting the generality of the foregoing:
- 6.2.1. Patient Information. Each Party agrees to abide by all Applicable Laws concerning the confidentiality or protection of patient identifiable information or patients' protected health information in the course of their performance under this Agreement.
- 6.2.2. Export Controls. This Agreement is made subject to any restrictions concerning the export of products or technical information from any country in the Territory which may be imposed upon or related to Egalet or Shionogi from time to time. Each Party agrees that it shall not export, directly or indirectly, any technical information acquired from the other Party pursuant to this Agreement or any Products using such technical information to a location or in a manner that at the time of export requires an export license or other approval from a Governmental Authority, without first obtaining the written consent to do so from the appropriate Governmental Authority.

6.2.3. Debarment. Each Party agrees that it shall not knowingly use, in any capacity, in connection with any of its obligations to be performed under this Agreement any individual who has been debarred under the FD&C Act or the Generic Drug Enforcement Act or any similar Applicable Laws in any regulatory jurisdiction or country in the Territory.

6.3. Non-Competition.

6.3.1. Shionogi Non-Compete. With respect to each Specified Territory, during the period commencing on the Effective Date and ending on the earlier of (a) ** (the "Restricted Period"), Shionogi and its Affiliates shall not directly commercialize, and shall not collaborate with, license or otherwise authorize any Third Party for the primary purpose of commercializing, in such Specified Territory any products containing Hydrocodone as an Active Ingredient (each such product, a "Shionogi Restricted Product"), other than the Products under this Agreement (it being understood that, for the avoidance of doubt, a breach of the foregoing obligation in any country within a Specified Territory shall not be considered a breach or violation of this Section 6.3.1 if such breach is not material to such Specified Territory taken as a whole; provided, that if Shionogi fails to cure any such breach in any such country within ninety (90) days after Shionogi receives written notice from Egalet specifying the nature of the breach and demanding its cure, Egalet shall have the right to terminate this Agreement with respect to any such country). For the avoidance of doubt, for the purposes of this Section 6.3.1, licensing or authorizing any Third Party in connection with any patent challenge, interference proceeding or as part of a patent portfolio settlement or cross-licensing arrangement shall not be construed as licensing or authorization for the "primary purpose of commercializing"; provided that, except as expressly provided herein, Shionogi shall not otherwise assist such Third Party in developing or commercializing any Shionogi Restricted Product. Notwithstanding anything in this Agreement to the contrary, nothing shall restrict Shionogi from continuing to sell ** and/or sublicense to Shionogi's existing sublicensee the rights Shionogi obtained from** relating to **.

6.3.2. Egalet Non-Compete. With respect to each country in the Territory, during the Restricted Period, Egalet and its Affiliates shall not directly or indirectly develop, manufacture or commercialize, and shall not collaborate with, license or otherwise authorize any Third Party to develop, manufacture or commercialize, in such country any products containing Hydrocodone as an Active Ingredient (each such product, an "Egalet Restricted Product"), other than the Products to the extent permitted under this Agreement. Notwithstanding anything in this Agreement to the contrary, and without limiting any other remedies available to Shionogi in the event of a breach of this Section 6.3.2 or if Eaglet sells an Egalet Restricted Product after the end of the Egalet

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Restricted Period by Egalet, Shionogi shall no longer be required to (A) provide updates or information with respect to its Development to Egalet and/or (B) participate in any applicable committee under this Agreement.

6.3.3. Change of Control Exception. Notwithstanding Section 6.3.1 or 6.3.2, as applicable, if a Change of Control occurs with respect to a Party and, in each case, the Third Party (or any of such Third Party's then-existing Affiliates) already has, or the acquired assets contain, as applicable, a program that existed prior to, or was planned prior to and is demonstrably to be implemented shortly after, the Change of Control that would otherwise violate Section 6.3.1 or 6.3.2, as applicable, at the time of such Change of Control (a "Business Program"), then such Third Party (or such Third Party's Affiliate) or such Party, as applicable, shall be permitted to continue such Business Program after the closing of such Business Acquisition and such continuation shall not constitute a violation of Section 6.3.1 or 6.3.2, as applicable, provided that (a) none of the other Party's Technology shall be used in the Business Program, (b) the research or development activities required under this Agreement shall be segregated from any research or development activities directed to such Business Program, including the maintenance of separate lab notebooks and records (password-protected to the extent kept on a computer network) and the use of separate personnel to perform the activities under this Agreement and the activities covered under such Business Program, and (c) in the case of a Change of Control of Egalet involving a Business Program, Shionogi shall no longer be required to provide updates or information with respect to its Development, Manufacturing or Commercialization to Egalet, except for (i) safety data as required by Section 4.2.2 and 4.2.3, as applicable and (ii) royalty and milestone related information required by Section 5. The Party undergoing the Change of Control shall adopt reasonable procedures to limit the dissemination of the other Party's Confidential Information to only those personnel having a need to know such Confidential Information in order for such Party or the Third Party, as applicable, to perform its obligations or to exercise its rights under this Agreement, including adopting reasonable procedures and policies that prohibit and limit the use and disclosure of such Confidential Information in a competitive manner against the other Party and its Affiliates, and adopting reasonable procedures and policies that prohibit or limit such Confidential Information from being disclosed to or used by any Person who is also working on or making scientific, intellectual property or commercial decisions regarding the Hydrocodone Products at the time of receipt or use of any such Confidential Information, or within three (3) years following receipt or use of any such Confidential Information.

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6.4. Non-Solicitation.

6.4.1. During the JDC Term and for one (1) year thereafter, unless otherwise agreed by the Parties, neither Shionogi nor any of its Affiliates shall, directly or indirectly, anywhere in the world employ, solicit for employment, or recommend for employment any person engaged in the development, manufacture or commercialization of the Products employed by Egalet or any Affiliate of Egalet, during the period such person is so employed or for one (1) year after termination of such person's employment with Egalet (or any Affiliate of Egalet). For purposes of this Section 6.4.1, "solicit" shall mean initiation of contact or communication for the purpose of inviting or requesting any of Egalet's or its Affiliates' employees to become employed by Shionogi or its Affiliates, and, for avoidance of doubt, the use of non-targeted employment advertisements

and other non-specific recruiting efforts shall not be deemed to be a direct or indirect solicitation for employment.

6.4.2. During the JDC Term and for one (1) year thereafter, unless otherwise agreed by the Parties, neither Egalet nor any of its Affiliates shall, directly or indirectly, anywhere in the world employ, solicit for employment, or recommend for employment any person engaged in the development, manufacture or commercialization of the Products employed by Shionogi or any Affiliate of Shionogi, during the period such person is so employed or for one (1) year after termination of such person's employment with Shionogi (or any Affiliate of Shionogi). For purposes of this Section 6.4.2, "solicit" shall mean initiation of contact or communication for the purpose of inviting or requesting any of Shionogi's or its Affiliates' employees to become employed by Egalet or its Affiliates, and, for avoidance of doubt, the use of non-targeted employment advertisements and other non-specific recruiting efforts shall not be deemed to be a direct or indirect solicitation for employment.

7. REPRESENTATIONS AND WARRANTIES.

- 7.1. Representations and Warranties of Each Party. As of the Effective Date, each Party hereby represents and warrants to the other Party 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;

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- (d) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions does not and shall not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (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; and
- (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.
- 7.2. Additional Representations and Warranties of Egalet and Egalet US. Egalet hereby represents and warrants to Shionogi with respect to (a) through (e), and Egalet US hereby represents and warrants to Shionogi with respect to (f), below that as of the Effective Date:
- (a) Schedule 1.32 sets forth a complete and correct list of all Egalet Patent Rights owned by Egalet and its Affiliates, and Egalet, together with its Affiliates, is the sole and exclusive owner of, and has the sole right, title and interest in and to, the Egalet Patent Rights listed on Schedule 1.32 and the Egalet Know-How;
- (b) All of the Egalet Patent Rights listed on Schedule 1.32 are in force or pending and have not been abandoned as of the Effective Date;
- (c) Neither Egalet nor any of its Affiliates has granted any license, option or other rights of any kind to or in favor of a Third Party under the Egalet Technology in the Territory that would conflict with the rights and licenses granted to Shionogi under this Agreement;
- (d) Neither Egalet nor any of its Affiliates has received any written claim of ownership, inventorship or patent infringement, or any other written claim of intellectual property misappropriation or violation, from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Egalet or any of its Affiliates or any of their predecessors) with respect to the Egalet Technology;
- (e) There are no claims, judgments or settlements pending against Egalet or its Affiliates with respect to any Egalet Technology, and neither Egalet nor any of its Affiliates have not received notice that any such claims, judgments or settlements are threatened; and

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(f) The Registration Statement, as of the date it is declared effective by the Securities and Exchange Commission and as of such date will conform in all material respects to the requirements of the Securities Act, and the rules and regulations thereunder and will not include any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. Other than with respect to any disclosure related to this Agreement and the Common Stock Purchase Agreement, dated as of November 26, 2013, by and between Egalet US and Shionogi, the preliminary prospectus contained in the Registration Statement as of the date hereof does not include any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. The Final Prospectus, (A) at the time of filing of the Final Prospectus pursuant to Rule 424(b) and (B) on the date of Closing, will conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder and will not include any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. "Registration Statement" means the registration statement of Egalet US on Form S-1 (File No. 333-191759) as amended, including any prospectus filed and to be filed pursuant to Rule 424 under the Securities Act, and any free writing

prospectuses, relating to the Initial Public Offering. "Final Prospectus" means the prospectus of Egalet US filed pursuant to Rule 424 under the Securities Act that discloses the public offering price, other information included pursuant to Rule 430A and other final terms of the common stock and otherwise satisfies Section 10(a) of the Securities Act.

- 7.3. Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and stipulates that it has participated in the drafting. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.
- 7.4. No Inconsistent Agreements. Neither Party has in effect, and after the Effective Date neither Party shall 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 Section 2 of this Agreement.
- 7.5. Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF NONINFRINGEMENT, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY

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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, MANUFACTURE OR COMMERCIALIZATION OF ANY PRODUCT UNDER THIS AGREEMENT WILL BE SUCCESSFUL.

- 8. INTELLECTUAL PROPERTY.
- 8.1. Ownership.
- 8.1.1. Ownership of Technology.
- (a) Subject to Section 8.1.1(b), ownership of any Patent Right or patentable Know-How shall be determined in accordance with the standards of inventorship under the patent laws of the United States.
- (b) Subject to the license grants set forth in Section 2 of this Agreement, as between the Parties, (i) Egalet shall exclusively own all right, title and interest in and to the Egalet Technology and (ii) Shionogi shall exclusively own all right, title and interest in and to the Shionogi Technology. Subject to the license grants set forth in Section 2 of this Agreement, Shionogi hereby assigns all of its right, title and interest in and to the Egalet Core Technology Improvements (and all intellectual property rights thereto) to Egalet. Egalet hereby assigns all of its right, title and interest in and to the Shionogi Improvements (and all intellectual property rights thereto) to Shionogi. In the event inventorship and ownership of any Technology developed in the performance of activities under this Agreement cannot be resolved by the Parties with advice of their respective intellectual property counsel, such dispute shall be resolved through the dispute resolution mechanism set forth in Section 12.1.
- 8.1.2. Employee Assignment. To the extent permissible under Applicable Laws, each Party will cause each employee and contractor conducting work on such Party's behalf under this Agreement to sign a contract that (a) compels disclosure to the Party of all Egalet Technology and Shionogi Technology, as applicable, conceived, reduced to practice, developed or authored by such employee or contractor during any performance under this Agreement; (b) automatically assigns at the time of invention to the Party all right, title and interest in and to all such Technology and all Patent Rights included within such Technology; and (c) obligates such persons to similar obligations of confidentiality as set forth in Section 6.1. Each Party will require each employee and contractor conducting work on such Party's behalf under this Agreement

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to maintain records in sufficient detail and in a good scientific manner appropriate for patent purposes to properly reflect all work done.

- 8.2. Intellectual Property Working Group. The Parties shall promptly establish an intellectual property working group comprised of at least one (1) senior patent attorney designated by each Party, together with business development personnel and such other representatives of the Parties as the Parties may determine to be appropriate from time to time, to review and discuss the patent strategy for inventions made in the course of the Development, and to determine patent strategy relating to Patent Rights in the Territory arising under this Agreement (to the extent that such Patent Rights in the Territory are necessary or useful to Develop, Manufacture or Commercialize the Products).
- 8.3. Filing, Prosecution and Maintenance of Patent Rights.
- 8.3.1. Egalet Patent Rights. Egalet shall have the sole and exclusive right to prepare, file, prosecute, maintain and extend the Platform-Related Patent Rights and Product-Related Existing Patent Rights. Egalet shall keep Shionogi advised on the status of preparation, filing and prosecution of all patent applications included within the Platform-Related Patent Rights and Product-Related Existing Patent Rights in the Territory and the maintenance, extension and post-grant proceedings of any issued patents within the Platform-Related Patent Rights or Product-Related Existing Patent Rights in the Territory. Shionogi and its employees will cooperate with Egalet to the extent necessary for Egalet to prepare, file, and prosecute patent applications relating to the Platform-Related Patent Rights and Product-Related Existing Patent Rights, and to conduct or participate in post-grant proceedings relating to the Platform-Related Patent Rights or Product-Related Existing Patent Rights.

8.3.2. Shionogi Patent Rights. Shionogi shall have the sole and exclusive right to prepare, file, prosecute, maintain and extend the Shionogi Patent Rights (including Patent Rights included within the Shionogi Improvements) and the Product-Related Future Patent Rights. Shionogi shall keep Egalet advised on the status of preparation, filing and prosecution of all patent applications included within the Product-Related Future Patent Rights and Shionogi Improvements in the Territory and the maintenance, extension and post-grant proceedings of any issued patents within the Product-Related Future Patent Rights and Shionogi Improvements. Egalet and its employees will cooperate with Shionogi to the extent necessary for Shionogi to prepare, file, and prosecute patent applications relating to the Product-Related Future Patent Rights and Shionogi Improvements, and to conduct or participate in post-grant proceedings relating to issued patents within the Product-Related Future Patent Rights and Shionogi Improvements.

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- 8.3.3. Shionogi Right to Comment on Platform-Related Patent Rights. Egalet shall consult and reasonably cooperate with Shionogi with respect to the preparation, filing, prosecution, maintenance, extension, and post-grant proceedings of such any Platform-Related Patent Rights filed with the applicable Governmental Authority on or after the Effective Date to the extent they relate to any Product, including: (a) allowing Shionogi a reasonable opportunity and reasonable time to review and comment regarding relevant material communications and drafts of any material responses or proposed filings by Egalet before any applicable filings are submitted to any relevant patent office or Governmental Authority; and (b) incorporating any reasonable comments offered by Shionogi in any final filings submitted by Egalet to any relevant patent office or Governmental Authority.
- 8.3.4. Egalet Right to Comment on Product-Related Future Patent Rights. Shionogi shall consult and reasonably cooperate with Egalet with respect the preparation, filing, prosecution, maintenance, extension, and post-grant proceedings of the Product-Related Future Patent Rights and Shionogi Improvement Manufacturing Patent Rights, including: (a) allowing Egalet a reasonable opportunity and reasonable time to review and comment regarding relevant material communications and drafts of any material responses or proposed filings by Shionogi before any applicable filings are submitted to any relevant patent office or Governmental Authority; and (b) incorporating any reasonable comments offered by Egalet in any final filings submitted by Shionogi to any relevant patent office or Governmental Authority.
- 8.3.5. Reversion Rights.
- (a) If Egalet decides not to file, prosecute, maintain or extend or otherwise decides to abandon any Platform-Related Patent Rights or Product-Related Existing Patent Rights, to the extent such Patent Right is necessary or useful to Develop, Manufacture or Commercialize the Products, it shall give Shionogi reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Patent Right to permit Shionogi to carry out such activity. After such notice, Shionogi may, in its sole discretion, file, prosecute, maintain or extend such Patent Right, as applicable, at its sole cost and expense. If Shionogi does so elect, then Egalet shall provide such cooperation to Shionogi, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such patent activities, and shall assign all of its right, title and interest to such Patent Right to Shionogi.
- (b) If Shionogi decides not to file, prosecute, maintain or extend or otherwise decides to abandon any Product-Related Future Patent

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Rights or Patent Rights included within the Shionogi Improvements, it shall give Egalet reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Patent Right to permit Egalet to carry out such activity. After such notice, Egalet may, in its sole discretion, file, prosecute, maintain or extend such Patent Right, as applicable, at its sole cost and expense. If Egalet does so elect, then Shionogi shall provide such cooperation to Egalet, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such patent activities and, with respect to Patent Rights including within the Shionogi Improvements, shall assign all of its right, title and interest to such Patent Right to Egalet.

- 8.3.6. Patent Term Extensions. The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future wherever applicable to Patent Rights that are applicable to the Products. The Parties shall, if necessary and appropriate, use reasonable efforts to agree upon a joint strategy relating to patent term extensions. All fillings for such extensions shall be made by the Party responsible for extending the relevant Patent Right pursuant to Section 8.3.1 or 8.3.2.
- 8.3.7. Costs and Expenses. Except as provided in Section 8.3.5, Egalet shall pay all costs for filing, prosecuting, maintaining and extending the Platform-Related Patent Rights and Product-Related Existing Patent Rights in the Territory, and Shionogi shall pay all costs for filing, prosecuting, maintaining and extending the Shionogi Patent Rights (including Patent Rights included within the Shionogi Improvements) and the Product-Related Future Patent Rights in the Territory.
- 8.4. Trademarks.
- 8.4.1. Product Trademarks in the Territory. Shionogi shall select and own the Trademarks for the Products in the Territory (the "Shionogi Trademarks") and shall be solely responsible for applying for and maintaining the registrations for the Shionogi Trademarks, and all goodwill associated therewith will inure to the benefit of Shionogi. Shionogi shall bear all costs of applying for and maintaining registrations for the Shionogi Trademarks. Shionogi shall assume full responsibility, at its sole costs and expense, for prosecuting or litigating any infringement of a Shionogi Trademark by a Third Party, and shall be entitled to retain all recoveries in connection therewith. Shionogi shall own the Shionogi

Trademarks, and all applications and registrations therefor.

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- 8.5. Enforcement of Technology Rights.
- 8.5.1. Notice. Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of (a) any Egalet Patent Right, including any Product-Related Patent Right or Platform-Related Patent Right, by any Third Party in the Field in the Territory, or (b) any Shionogi Patent Right, including any Patent Right included within the Shionogi Improvements, by any Third Party in the Territory.

8.5.2. Enforcement.

(a) As between Shionogi and Egalet, Egalet shall have the first right (except as otherwise provided in this Section 8.5.2(a)), but not the obligation, to institute litigation or take other steps to remedy an actual, potential or suspected infringement of the Platform-Related Patent Rights in the Territory, and Shionogi shall have the first right, but not the obligation, to institute litigation or take other steps to remedy an actual, potential or suspected infringement of the Product-Related Patent Rights (including Product-Related Existing Patent Rights and Product-Related Future Patent Rights) and Patent Rights within the Shionogi Improvements in the Territory. Any litigation or remedial steps taken by a Party pursuant to this Section 8.5.2(a) shall be at such Party's expense, provided that any recoveries resulting from such litigation or remedial steps relating to a claim of infringement, after deducting such Party's out of pocket expenses (including counsel fees and expenses) in pursuing such claim, will be allocated evenly between the Parties. The Party having the first right to initiate litigation or other remediation of infringement pursuant to this Section shall have full control of such litigation or steps but shall not, without the prior written consent of the other Party (which shall not be unreasonably withheld, delayed or conditioned), enter into any compromise or settlement relating to such litigation that (i) admits the invalidity or unenforceability of any Platform-Related Patent Rights or Product-Related Patent Rights or Patent Rights within the Shionogi Improvements; (ii) requires the abandonment of any Platform-Related Patent Rights or Product-Related Patent Rights or Patent Rights within the Shionogi Improvements; or (iii) licenses the patent(s) at issue or otherwise allows the alleged infringer to practice the patent(s) before the expiration thereof. In order to establish standing, the other Party, upon request of the Party instituting litigation or other action pursuant to this Section, agrees to timely commence or to join in any such litigation or action, at the first Party's expense, and in any event to cooperate with the first Party in such litigation or steps at the first Party's expense. The Party not bringing the litigation or other action will have the right to consult with the other Party about such litigation

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or action, and to participate in and be represented by independent counsel in such litigation or action at its own expense.

If a Party having the first right to institute such litigation or otherwise take steps to remedy an infringement in the Territory fails to do so within sixty (60) days of its receipt of notice thereof, then the other Party shall have the right, but not the obligation, upon twenty (20) days' prior notice to the first Party, at such other Party's expense, to institute any such litigation and any proceeds from such litigation shall be retained by such other Party; provided, that such other Party shall reasonably consult with the first Party prior to instituting such litigation and shall offer to the first Party the right to elect to itself institute such litigation. The first Party shall, at the other Party's expense, cooperate with the other Party in any such litigation instituted by the other Party. The first Party shall have the right to consult with the other Party about such litigation, and to participate in and be represented by independent counsel in such litigation at its own expense. The other Party shall not, without the prior written consent of the first Party (which shall not be unreasonably withheld, delayed or conditioned), enter into any compromise or settlement relating to such litigation that (x) admits the invalidity or unenforceability of any Platform-Related Patent Rights or Product-Related Patent Rights or Patent Rights within the Shionogi Improvements; (y) requires the abandonment of any Platform-Related Patent Rights or Product-Related Patent Rights or Product-Related Patent Rights or pursued pursuant to this Section 8.5.2(a) or any unfavorable decision resulting therefrom, including any decision holding any Platform-Related Patent Rights or Product-Related Patent Rights within the Shionogi Improvements invalid or unenforceable.

(b) Notwithstanding Section 8.5.2(a), in the event of a "Paragraph IV Certification" (as defined in Title 21 of the Code of Federal Regulations) by a Third Party against a licensed Product in the United States (or a similar action outside the United States in the Territory) with respect to one or more patents in the Platform-Related Patent Rights or Product-Related Patent Rights or Patent Rights within the Shionogi Improvements, Egalet shall within fifteen (15) days consult with Shionogi as to the commercial reasonableness of suing such Third Party for patent infringement within the forty-five (45) days of receipt of such notice as required by U.S. law to trigger the up to thirty (30) months stay of FDA

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approval of the Third Party's regulatory application. Following such discussion, Egalet and Shionogi shall commence such action on which they believe reasonable grounds exist to proceed within forty-five (45) days of the receipt of such notice; provided, however, that any failure to sue a Third Party who submits a Paragraph IV Certification shall not be construed as lacking a reasonable basis to assert the patent(s) at issue as other valid business reasons may exist not to litigate. To minimize legal fees and expenses, Egalet and Shionogi will use commercially reasonable efforts to engage one law firm to represent both Parties with all fees and expenses borne by Shionogi (it being understood that Shionogi shall control the litigation). To the extent that the Hatch Waxman Act is amended or successor legislation enacted, and such amended or successor legislation requires action in a time frame more expeditious than that in force at the Effective Date, the Parties shall make appropriate adjustments to the time periods set forth herein to allow for a timely response under such amended or successor legislation.

- (c) As between Shionogi and Egalet, subject to Section 8.3.5, Shionogi shall have the sole right, but not the obligation, to institute litigation or take other steps to remedy an actual, potential or suspected infringement of the Shionogi Patent Rights throughout the world.
- 8.6. Third Party Claims.
- 8.6.1. Third Party Claims Course of Action. If the Development, Commercialization or Manufacture of a Product under this Agreement is alleged by a Third Party to infringe a Third Party's Patent Right(s) or misappropriate a Third Party's trade secret, the Party becoming aware of such allegation shall promptly notify the other Party thereof, in writing, reasonably detailing the claim.
- 8.6.2. Third Party Suit. If a Third Party sues a Party (the "Sued Party") alleging that the development, manufacture or commercialization of any Product by the Sued Party or its Affiliate, Licensee or Sublicensee infringes or shall infringe said Third Party's Patent Right(s) 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 shall provide reasonable assistance to the Sued Party for such defense and shall join such suit if deemed a necessary party. The Sued Party shall keep the other Party, if such other Party has not joined in such suit, reasonably informed on a quarterly basis, in person or by telephone, prior to and during the pendency of any such suit. The Sued Party shall not admit the invalidity of any patent within the Egalet Patent Rights or the Shionogi Patent Rights, nor settle

any such suit, without the prior written consent of the other Party, such consent not to be unreasonably withheld. Subject to the Parties' respective indemnity obligations pursuant to Section 11.1 and 11.2, all litigation expenses, including settlement costs, royalties paid in settlement of any such suit, and the payment of any damages to the Third Party will be paid by the Sued Party.

- 8.7. Patent Marking. Each Party shall mark, and its Affiliates, Licensees and Sublicensees shall have marked, all Products (or their containers or labels) in accordance with Applicable Laws in the country or countries of manufacture and sale thereof.
- 8.8. No Implied Licenses. Except as expressly set forth in this Agreement, no right or license under any Egalet Technology or Shionogi Technology or any Party's Trademarks is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement.
- 8.9. Privileged Communications. In furtherance of this Agreement, it is expected that Shionogi and Egalet 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 shall remain confidential, that 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 Egalet and Shionogi, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of Egalet Patent Rights and Shionogi Patent Rights.
- 8.10. Create Act. This Agreement includes a joint research agreement as defined in 35 U.S.C. § 103(c)(3).
- 9. GOVERNMENT APPROVALS.
- 9.1. Shionogi's and Egalet's Obligations. Each of Shionogi and Egalet represents and warrants that it has obtained all consents and approvals required from any governmental authority to execute and deliver this Agreement and enter into the transactions contemplated by this agreement, except that: (i) Shionogi represents and warrants that to enter into the transactions contemplated by this Agreement no consents or approvals are required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder ("HSR Approvals"), and (ii) Egalet makes no representation or warranty regarding HSR Approvals. Each of Shionogi and Egalet shall use its good faith efforts to eliminate any concern on the part of any court of Governmental Authority regarding the legality of the proposed transaction.

- 9.2. Additional Approvals. Shionogi, Egalet and Egalet US shall cooperate and use respectively all reasonable efforts to make all 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 shall be required, however, to divest or out-license products or assets or materially change its business if doing so is a condition of obtaining approval of the transactions contemplated by this Agreement.
- 10. TERM AND TERMINATION.
- 10.1. Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Section 10, shall continue in full force and effect on a Product-by-Product and country-by-country basis until the expiration of the applicable Royalty Period in such country (each, a "Product Term"). For purposes of this Agreement, the "Term" shall mean the period beginning on the Effective Date and ending on the last-to-expire Product Term.
- 10.2. Rights of Termination.

- 10.2.1. Termination for Material Breach. In the event that a Party commits a material breach of its obligations under this Agreement (other than payment obligations) that is not cured within ninety (90) days (or such other time period as mutually agreed by the Parties), or a material breach of its payment obligations under this Agreement that is not cured within thirty (30) days, after such Party receives written notice from the non-breaching Party, which notice shall specify the nature of the breach and demand its cure, the non-breaching Party may, subject to the terms and conditions of this Agreement, terminate this Agreement upon written notice to the breaching Party.
- 10.2.2. Shionogi Right of Termination for Convenience. Prior to its expiration, this Agreement may be terminated in its entirety or on a Product-by-Product basis, in its sole discretion, at any time by Shionogi effective upon at least ninety (90) days prior written notice to Egalet for any reason.
- 10.2.3. Egalet's Right of Termination for Patent Challenge. Egalet will have the right to terminate this Agreement in full upon written notice to Shionogi in the event that Shionogi or any of its Affiliates challenges, or any of them direct or otherwise help a Third Party (including a Sublicensee) to challenge, in a legal or administrative proceeding the patentability, enforceability or validity of any Egalet Patent Rights (the "Affected Patent") (with respect to any Affected Patent a "Patent Challenge") and such Patent Challenge is not withdrawn in a timely manner so as not to prejudice the rights of Egalet in and to such Affected Patent to the extent

such Patent Challenge can be withdrawn without prejudicing such rights (it being understood that, notwithstanding the foregoing, Egalet shall have no such right to terminate where the challenge is in response to a patent infringement action initiated by Egalet or any of its Affiliates). For the avoidance of doubt, the Parties acknowledge and agree that neither (a) compliance with any Third Party subpoena nor (b) any disputes under this Agreement regarding ownership of Technology or other intellectual property rights shall constitute or be deemed to constitute a Patent Challenge.

10.2.4. Bankruptcy. This Agreement may be terminated by written notice by a Party at any time during the Term if the other Party shall file 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 shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make a general assignment for the benefit of its creditors.

10.3. Effects of Termination.

- 10.3.1. Effects of Termination by Shionogi for Convenience, or by Egalet for Cause or Shionogi Bankruptcy. If this Agreement is terminated by Shionogi pursuant to Section 10.2.2, or by Egalet pursuant to Sections 10.2.1, 10.2.3 or 10.2.4, the provisions of this Section 10.3.1 shall apply with respect to the Territory or, if the Agreement is terminated by Egalet pursuant to Section 10.2.1 or Shionogi pursuant to Section 10.2.2, in either case, only with respect to a particular product or products ("Terminated Product") or particular country or countries in the Territory (the "Terminated Countries"), the provisions of this Section 10.3.1 shall apply with respect to the Terminated Product or Terminated Countries, as applicable.
- (a) All licenses granted by Egalet to Shionogi hereunder shall automatically terminate with respect to the Territory, the Terminated Countries or the Terminated Products, as applicable, (other than the license granted pursuant to Section 5.3.4).
- (b) All licenses granted to Egalet hereunder shall terminate, except for the license granted to Egalet pursuant to Section 2.2(ii), which shall survive and be perpetual and irrevocable.
- (c) Shionogi shall assign, and hereby assigns, on behalf of itself and its Affiliates, to Egalet all right, title and interest in and to all

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Regulatory Submissions and Regulatory Approvals Controlled by Shionogi in the Territory or the Terminated Countries, as applicable (but in all cases excluding Japan), solely pertaining to the Egalet Technology or Products, excluding any Regulatory Submissions and Regulatory Approvals to the extent relating to any Combination Products which has an Active Ingredient covered by a Valid Claim of any Shionogi Patent Right (whether as a compound composition of matter, method of treatment or method of manufacture; provided that with respect to method of manufacture, such Shionogi Patent Right relates to a compound in-licensed or acquired by Shionogi or its Affiliates).

- (d) With respect to any Shionogi Trademark that is used in Commercialization as of the date of such termination, Shionogi shall grant, and hereby grants, on behalf of itself and its Affiliates, to Egalet an exclusive (even as to Shionogi), fully paid-up license, with the right to freely sublicense, under all of Shionogi's interest in any such Shionogi Trademark (including the goodwill symbolized by such Shionogi Trademark) throughout the world or in the Terminated Countries, as applicable (but in all cases excluding Japan).
- (e) Shionogi shall grant, and hereby grants, on behalf of itself and its Affiliates and Sublicensees, to Egalet and its Affiliates and Sublicensees an exclusive Right of Reference to all data generated in Clinical Trials undertaken by Shionogi, its Affiliates or Sublicensees with respect to the Territory or the Terminated Countries, as applicable (but in all cases excluding Japan), in accordance with this Agreement (including all such Regulatory Submissions, Regulatory Approvals and Clinical Trial data related to Combination Products in which the other active ingredients are

non-proprietary, but excluding any Regulatory Submissions, Regulatory Approvals and Clinical Trial data to the extent relating to any Combination Products covered by a Valid Claim of any Shionogi Patent Right) solely for the development and commercialization of the Product in the Field, and Shionogi shall provide a signed statement to this effect, if requested by Egalet, in accordance with 21 C.F.R. § 314.50(g)(3) (or any analogous Applicable Laws recognized outside of the United States);

(f) Shionogi shall grant, and hereby grants, on behalf of itself and its Affiliates, to Egalet a worldwide, perpetual, royalty-free, irrevocable, non-exclusive license to use the data generated in Clinical Trials undertaken by Shionogi, its Affiliates or Sublicensees hereunder, including all such Regulatory Submissions, Regulatory Approvals and Clinical Trial data related to Combination Products in which the other active ingredients are

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non-proprietary but excluding any Regulatory Submissions, Regulatory Approvals and Clinical Trial data to the extent relating to any Combination Products covered by a Valid Claim of any Shionogi Patent Right (collectively, the "Shionogi Data") solely for the development and commercialization of the Egalet Technology or Products in the Field in the Territory or the Terminated Countries, as applicable (but in all cases excluding Japan).

- (g) All licenses granted to Egalet hereunder shall terminate (other than the licenses set forth in Sections 2.2(ii), 10.3.1(d), (e) and (f), and this Section 10.3.1(b)) with respect to the Territory or the Terminated Countries, as applicable, and Shionogi shall grant, and hereby grants, on behalf of itself and its Affiliates, to Egalet, an exclusive (even as to Shionogi), royalty-free license (with the right to sublicense on terms consistent with Section 2.3.4) under the Shionogi Technology (excluding any Shionogi Technology to the extent relating to any Combination Products covered by a Valid Claim of any Shionogi Patent Right) solely to the extent necessary or useful to develop, manufacture or commercialize the Products in the Field throughout the world or in the Terminated Countries, as applicable (but in all cases excluding Japan).
- (h) Shionogi shall reasonably cooperate with Egalet to assure a smooth transition, at Egalet's expense, of any Clinical Trials or other studies in progress related to the Products in the Territory or the Terminated Countries or Terminated Products, as applicable (but in all cases excluding Japan), which Egalet determines to continue in compliance with Applicable Laws and ethical guidelines applicable to the transfer or termination of any such Clinical Trials or studies. In the event that Egalet informs Shionogi that it does not intend to continue specific Development then in progress, costs incurred in closing out such activities shall be borne by Shionogi. In addition, Shionogi will return all Egalet Confidential Information relating to the Territory, the Terminated Countries, or the Terminated Products, as applicable (but in all cases excluding Japan), to Egalet and Egalet will return all Shionogi Confidential Information relating to the Territory, the Terminated Countries, or Terminated Products, as applicable, to Shionogi (except that each Party shall be permitted to retain, through its legal counsel, one (1) copy of the other Party's Confidential Information to the extent required under any Applicable Laws or to the extent necessary to exercise any rights surviving termination of this Agreement);
- (i) Until termination is effective, each Party shall continue to perform its applicable Development obligations then in effect with respect to the Territory or the Terminated Countries, as applicable, and pay

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all costs allocated for it to pay in accordance with any budgets then in effect, except with respect to activities that Egalet elects to discontinue;

(j) Shionogi will return all Egalet Confidential Information to Egalet and Egalet will return all Shionogi Confidential Information to Shionogi (except that each Party shall be permitted to retain, through its legal counsel, one (1) copy of the other Party's Confidential Information to the extent required under any Applicable Laws or to the extent necessary to exercise any rights surviving termination of this Agreement);

Subsection (a) above will be effective upon any such termination, and subsections (b), (c), (d), (e), (f), (g), (i) and (j) above shall be effective upon termination, or if such termination is by Shionogi pursuant to Section 10.2.2, upon the earlier of such termination or Egalet earlier election.

Notwithstanding the foregoing, subsections (a), (b), (c), (d), (e), (f), (g), (i) and (j) above shall not be applicable for any Product in any Terminated Countries with respect to which the license granted to Shionogi under Section 2.1 becomes a fully paid-up license pursuant to Section 5.3.4.

- 10.3.2. Effects of Termination by Shionogi for Cause or Egalet Bankruptcy. If this Agreement is terminated by Shionogi pursuant to Section 10.2.1 or 10.2.3, the provisions of this Section 10.3.2 shall apply.
- (a) Egalet will return all Shionogi Confidential Information to Shionogi (except that Egalet shall be permitted to retain, through its legal counsel, one (1) copy of the Shionogi's Confidential Information to the extent required under any Applicable Laws or to the extent necessary to exercise any rights surviving termination of this Agreement);
- (b) All licenses granted by Shionogi to Egalet, including under Section 2.2(i), shall automatically terminate, except for the license granted to Egalet pursuant to Section 2.2(ii), which shall survive and be perpetual and irrevocable;
- (c) All rights and licenses granted to Shionogi by Egalet under this Agreement, including the exclusive license granted under Section 2.1, shall become perpetual and irrevocable, subject to all the milestone and royalty payment obligations under this Agreement and to Shionogi's obligations under Sections 2, 4.1 and 4.3; provided, however, that Shionogi may pay into escrow with a Third Party on customary terms any

royalties payable hereunder until after a determination of any damages that may be owed by Egalet to Shionogi in connection with Egalet's breach of the Agreement and following such determination, Shionogi may offset against any amounts in escrow the damages owed by Egalet to Shionogi, if any, prior to releasing such amounts from escrow to Egalet.

(d) The JDC and all other committees shall be abolished and thereafter Shionogi shall have the right to make the decisions and take the actions previously reserved to the JDC and such other committees.

Subsections (a), (b) and (c) above will be effective upon any such termination, and subsection (d) above shall be effective upon termination or Shionogi's earlier election.

- 10.3.3. Effects of Expiration of the Product Term. On a Product-by-Product and country-by-country basis, following the expiration of the applicable Product Term, the license granted to Shionogi under Section 2.1 shall automatically become a fully paid-up, perpetual, irrevocable, royalty-free exclusive license.
- 10.4. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Egalet and Shionogi are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the United States Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the United States Bankruptcy Code, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefor, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by the bankrupt Party upon written request therefor by the other Party.
- 10.5. Survival of Certain Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing before such expiration or termination. Sections 1, 2.2(ii), 4.2.2 (to the extent of each Party's right to use the Shell Safety Study Data thereunder) 5.5, 6.1, 8.1, 10, 11, 12, and all provisions of this Agreement necessary to give effect to the foregoing Sections, shall survive expiration or termination of this Agreement.

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11. PRODUCT LIABILITY, INDEMNIFICATION AND INSURANCE.

- 11.1. Indemnification by Egalet and Egalet US. Egalet and Egalet US shall indemnify, defend and hold harmless Shionogi and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, a "Shionogi Indemnified Party") from and against any and all losses, damages, liabilities, settlements, penalties, fines and expenses (including reasonable attorneys' fees and expenses) (collectively, "Liability") that the Shionogi Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of:
- (a) any Egalet or Egalet US representation or warranty set forth herein being untrue in any material respect when made or any material breach by Egalet or Egalet US of any of its covenants or obligations hereunder (with respect to Section 7.2(f), determined without regard to any qualification contained therein relating to materiality); or
- (b) the gross negligence or willful misconduct by or of Egalet or Egalet US, its Affiliates, Licensees or Sublicensees, or any of their respective employees, officers, directors and agents; or
- (c) any claims arising from or related to Egalet's or its Affiliates', Licensees' or Sublicensees' development, manufacture or commercialization of the Products;

except in each case, to the extent caused by the gross negligence or willful misconduct of Shionogi or any Shionogi Indemnified Party, or by breach of this Agreement by Shionogi.

- 11.2. Indemnification by Shionogi. Shionogi shall indemnify, defend and hold harmless Egalet and its Affiliates, and each of its and their respective employees, officers, directors and agents (each, an "Egalet Indemnified Party") from and against any and all Liabilities that the Egalet Indemnified Party may be required to pay to one or more Third Parties to the extent resulting from or arising out of:
- (a) any Shionogi representation or warranty set forth herein being untrue in any material respect when made or a material breach by Shionogi of any of its covenants or obligations hereunder; or
- (b) the gross negligence or willful misconduct by or of Shionogi, its Affiliates or Sublicensees, or any of their respective employees, officers, directors and agents; or

(c) any claims arising from or related to Shionogi's or its Affiliates' or Sublicensees' development, manufacture or commercialization of the Products:

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except in each case, to the extent caused by the gross negligence or willful misconduct of Egalet or any Egalet Indemnified Party, or by breach of this Agreement by Egalet.

11.3. Procedure. Each Party shall 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 Section 11. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Section 11, such Party (the "Indemnified Party") shall provide the other Party (the "Indemnifying Party") with prompt written notice of such proceeding (the "Indemnification Claim Notice"). Promptly after the Indemnifying Party receives the Indemnification Claim Notice, the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any claims that are the subject matter of such proceeding. At its option, the Indemnifying Party may assume the defense of any Third Party claim subject to indemnification as provided for in this Section 11.3 by giving written notice to the Indemnified Party within thirty (30) days (or within such time provided in any applicable extension to appropriately answer any complaint, if any, but no longer than seventy (70) days, provided that the Indemnified Party makes all reasonable efforts to obtain any such extension) after the Indemnifying Party's receipt of an Indemnification Claim Notice, provided that (a) the claim solely seeks monetary damages and (b) the Indemnifying Party expressly agrees in writing that, as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party shall be solely obligated to satisfy and discharge the claim in full (the matters described in (a) and (b), the "Litigation Conditions"). The Indemnified Party may, at any time, assume all such defense if the Litigation Conditions are not satisfied. Upon assuming the defense of a Third Party claim in accordance with this Section 11.3, the Indemnifying Party shall be entitled to appoint lead counsel in the defense of the Third Party claim. Should the Indemnifying Party assume and continue the defense of a Third Party claim, except as otherwise set forth in this Section 11.3, the Indemnifying Party will not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party claim. Without limiting this Section 11.3, any Indemnified Party will be entitled to participate in, but not control, the defense of a Third Party claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnified Party's own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing; (ii) the Indemnifying Party has failed to assume and actively further the defense and employ counsel in accordance with this Section 11.3 (in which case the Indemnified Party will control the defense); or (iii) the Indemnifying Party no longer satisfies the Litigation Conditions. With respect to any Liability relating solely to the payment of money damages in connection with a Third Party claim that will not result in the Indemnified Party's becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner, and as to which the Indemnifying Party will have acknowledged in writing the obligation to

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indemnify the Indemnified Party hereunder, and subject to the Litigation Conditions being satisfied, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Liability, on such terms as the Indemnifying Party, in its reasonable discretion, will deem appropriate (provided that such terms shall include a complete and unconditional release of the Indemnified Party from all liability with respect thereto), and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time of the entry of judgment. With respect to all other Liabilities in connection with Third Party claims, where the Indemnifying Party has assumed the defense of the Third Party claim in accordance with this Section 11.3, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Liability, provided that it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's reasonable discretion). The Indemnifying Party that has assumed the defense of the Third Party claim in accordance with this Section 11.3 will not be liable for any settlement or other disposition of a Liability by an Indemnified Party (but in no event to include any court judgment or judicial or administrative order or disposition) that is reached without the written consent of such Indemnifying Party. No Indemnified Party will admit any liability with respect to, or settle, compromise or discharge, any Third Party claim without first offering to the Indemnifying Party the opportunity to assume the defense of the Third Party claim in accordance with this Section 11.3. If the Indemnifying Party chooses to defend or prosecute any Third Party claim, the Indemnified Party will cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with such Third Party claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party claim, and making employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such

- 11.4. Insurance. The Parties shall maintain insurance with creditworthy insurance companies or self insure in accordance with Applicable Laws against such risks and in such amounts as are usually maintained or insured against by other companies of established repute engaged in the same or a similar business.
- 11.5. Liability Limitations. NOTWITHSTANDING THE FOREGOING, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES UNDER THIS AGREEMENT, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT OR ARE PAYABLE IN CONNECTION WITH A PARTY'S

INDEMNIFICATION OBLIGATIONS UNDER THIS SECTION 11 FOR LIABILITY OWED TO THIRD PARTIES.

- 12. MISCELLANEOUS.
- 12.1. Governing Law, Jurisdiction; Dispute Resolution.
- 12.1.1. Governing Law. The interpretation and construction of this Agreement shall 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.
- 12.1.2. Jurisdiction. Each Party (a) irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in New York County, New York, with respect to actions or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof; (b) agrees that all claims in respect of such actions or proceedings may be heard and determined only in any such court; and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto.
- 12.1.3. Dispute Resolution. In the event of a dispute arising out of or relating to this Agreement either Party shall provide written notice of the dispute to the other, in which event the dispute shall be referred to the executive officers designated below or their successors, for attempted resolution by good faith negotiations within thirty (30) days after such notice is received. Said designated officers are initially as follows:

For Egalet and Egalet US:

Egalet's Chief Executive Officer

For Shionogi:

Shionogi's Chief Executive Officer

In the event the designated executive officers do not resolve such dispute within the allotted thirty (30) days, either Party may, after the expiration of the thirty (30) day period, seek to resolve the dispute through the courts in accordance with this Section 12.1. Notwithstanding the foregoing, the Parties acknowledge that the failure of the JDC to reach consensus as to any matter, which failure does not involve a breach by a Party of its obligations hereunder, shall not be deemed a dispute which may be referred for resolution by the Parties under this Section 12.1.

- 12.2. Force Majeure. No liability shall result from, and no right to terminate shall 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 (other than payment obligations) 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, strike, lock-out or other industrial/labor dispute, war, riot, civil commotion, terrorist act, malicious damage, epidemic, quarantine, fire, flood, storm, natural disaster or compliance with any law or governmental order, rule, regulation or direction, whether or not it is later held to be invalid or inapplicable. The Party affected by a Force Majeure (the "Force Majeure Party") shall within ten (10) days of the occurrence of the Force Majeure, give written notice to the other Party stating the nature of the Force Majeure, its anticipated duration and any action being taken to avoid or minimize its effect. Any suspension of performance shall be of no greater scope and of no longer duration than is reasonably required and the Force Majeure Party shall use reasonable effort to remedy its inability to perform; provided, however, that if the suspension of performance continues or is anticipated to continue for thirty (30) days after the date of the occurrence, the unaffected Party shall 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 (1) year from the date of the occurrence and the Parties are not able to agree on appropriate amendments within such period, such other Party shall have the right, notwithstanding the first sentence of this Section 12.2, to terminate this Agreement immediately by written notice to the Force Majeure Party, in which case neither Party shall have any liability to the other except for those rights and liabilities that accrued prior to the date of termination and the consequences of termination pursuant to Section 10.3, as if such termination was a termination as to which such consequences applied.
- 12.3. Additional Approvals. The Parties shall cooperate and use respectively all Commercially Reasonable Efforts to make all 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 shall 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.
- 12.4. 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 shall 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.

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The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Laws or otherwise available except as expressly set forth herein.

12.5. Notices.

12.5.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a "Notice") shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 12.5.2 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 12.5.1. Such Notice shall be deemed to have been given on the date delivered by hand or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 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.

12.5.2. Address for Notice.

Egalet and Egalet US:

Egalet Limited

33 St. James' Square

London SW1Y 4JS, United Kingdom

Attn: Chief Executive Officer

With a copy to:

Dechert LLP

1775 I Street, NW

Washington D.C. 20006

Fax number: (202) 261-3333

Tel number: (202) 261-3440

Attn: David Schulman

Shionogi:

Shionogi Limited

33 Kingsway

London, WC2B 6UF, United Kingdom

Attn: Chief Executive Officer

Fax number: +44 (0)20 3053 4199

With a copy to:

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Shionogi Inc.

300 Campus Drive, Suite 300

Florham Park, NJ 07932

Attn: General Counsel

Fax number: (973) 307-3840

Tel number: (973) 307-3340

and

Davis Polk & Wardwell LLP

450 Lexington Avenue

New York, New York 10017

Attn: Michael Davis

Fax number: (212) 701-5800

- 12.6. 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 hereof. 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 Schedules or Exhibits 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 Schedules or Exhibits and this Agreement, the terms of this Agreement shall govern.
- 12.7. Amendment. Any amendment or modification of this Agreement must be in writing and signed by authorized representatives of both Parties.
- 12.8. 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 each Party shall always have the right, without such consent, (a) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates; and (b) 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 (i) any of its Affiliates, or (ii) a successor of all or substantially all of the assets or business of such Party to which this Agreement pertains, whether by way of merger, sale of stock, sale of assets or other transaction (or series of transactions); provided, however, this exception shall not apply to Egalet US with respect to its obligations under Section 2.7. Any permitted successor or assignee of rights or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights or obligations. Notwithstanding the foregoing, each Party shall remain responsible for any failure to perform on the part of any such Affiliates. Any attempted assignment or delegation in violation of this Section shall be void.

- 12.9. 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 shall not be construed as conferring any rights in any other persons except as otherwise expressly provided in this Agreement.
- 12.10. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. An executed signature page of this Agreement delivered by facsimile transmission shall be as effective as an original executed signature page.
- 12.11. Severability. To the fullest extent permitted by Applicable Laws, 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 shall not form part of this Agreement. To the fullest extent permitted by Applicable Laws and if the rights or obligations of any Party will not be materially and adversely affected, all other provisions of this Agreement shall 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 Laws and achieves, as nearly as possible, the original intention of the Parties.
- 12.12. Further Assurance. Each Party shall perform all further acts and things and execute and deliver such further documents as may be reasonably necessary or as the other Party may reasonably require to implement or give effect to this Agreement.
- 12.13. Publicity. Notwithstanding Section 6.1.6, it is understood that the Parties will issue a press release announcing the execution of this Agreement in such form as the Parties shall mutually agree. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of any subsequent press releases relating to the 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 Applicable Laws (including requirements of a national securities exchange or another similar regulatory body) or which are consistent with information disclosed in prior releases properly made hereunder.
- 12.14. Relationship of the Parties. The status of a Party under this Agreement shall be that of an independent contractor. Nothing contained in this Agreement shall 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

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by a Party or any of its Affiliates shall be 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 shall be for the account and expense of such Party or its Affiliates, as applicable.

12.15. Subcontracting. Each Party may, in its sole discretion, use one or more Affiliates or Third Party contractors to perform any or all of its obligations under this Agreement, provided that such Party shall remain responsible for its obligations under the Agreement and shall be responsible for the performance of each such Affiliate and Third Party subcontractor and any such use of Third Party contractors by Egalet shall be subject to Shionogi's prior written approval.

12.16. Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement and any descriptions of Schedules and Exhibits or descriptions of cross references are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. The terms "including," "include(s)," "such as," and "for example" as used in this Agreement mean including the generality of any description preceding such term and shall be deemed to be followed by "without limitation." Notwithstanding the definition of "Party" set forth in Section 1.81, for the purposes of Section 7.1 and Section 12, it is understood and agreed that any and all references to (i) "Party" shall mean Shionogi on the one hand and Egalet US on the other hand and (ii) "Parties" shall mean collectively Egalet, Egalet US and Shionogi.

[Remainder of page intentionally left blank]

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

SHIONOGI LIMITED

EGALET LIMITED

Ву

/s/ Takashi Takenoshita

Ву

/s/ Robert S. Radie

Name: Takashi Takenoshita

Name: Robert S. Radie

Title: Chief Executive Officer

Title: President and Chief Executive Officer

and solely for the purposes of Sections 2.7, 7.1, 7.2, 11.1, 11.3, 11.5 and 12

EGALET CORPORATION

Ву

/s/ Robert S. Radie

Name: Robert S. Radie

Title: President and Chief Executive Officer

[Signature Page to Collaboration and License Agreement]

Schedule 1.32

Egalet Family Country Patent No. Appl. No. P05 US ** US ** ΕP P07 US US ΕP P09 US CA ** JΡ ** IN ** НΚ ** HK ΑТ

EGALET PATENT PORTFOLIO

BE ** СН ** DE ** DK ** ES ** FR GB ΙE ** IT ** NL ** DE DK ** FR ** GB ** ΙE ** ΑТ ΒE **

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EXHIBIT A
GRAPHIC
For Immediate Release
Egalet Enters into Development Collaboration and License Agreement with Shionogi Limited for Abuse-deterrent Oral Hydrocodone Opioic Product Candidates

Egalet licenses rights to preclinical hydrocodone-based product candidates to be developed using Egalet's proprietary abuse-deterrent delivery technology; Egalet to receive upfront and milestone payments plus potential royalties on net sales

Malvern, PA - November 26, 2013 - Egalet Corporation ("Egalet") announced today that it has entered into a definitive collaboration and license agreement with Shionogi Limited ("Shionogi") for the development and potential commercialization of multiple oral abuse-deterrent hydrocodone opioid product candidates using Egalet's proprietary technology.

Egalet will receive a \$10 million upfront payment from Shionogi and Shionogi has agreed to purchase up to approximately \$15 million in common stock in a private placement to close concurrently with Egalet's recently filed initial public offering. Egalet is eligible to receive milestone payments upon development and approval of products under the agreement, which may exceed \$300 million if multiple products are approved. Shionogi will fund all costs associated with the development of these products. Shionogi will also have exclusive global rights to commercialize the resulting products. If any products developed under the collaboration are approved for marketing, Egalet is eligible to receive tiered royalties,

ranging from the mid-single digits to the low double digits based on the net sales of such products, as well as sales-based milestone payments that could exceed \$100 million based on the attainment of specified sales thresholds.

"With their commitment to pain therapeutics and their strong sales and marketing capabilities, we are pleased to be collaborating with Shionogi for the development and potential commercialization of abuse-deterrent hydrocodone products using our proprietary technology," said Bob Radie, Egalet's President and Chief Executive Officer. "We believe this collaboration provides validation for our proprietary abuse-deterrent drug delivery platform and positions us to capitalize on our technology, both through the products to be developed under the collaboration and by enabling us to develop additional opioid candidates utilizing our platform technology."

Stifel acted as exclusive financial advisor to Egalet in this transaction.

About Hydrocodone

Hydrocodone is an opioid agonist used in the treatment of mild to moderate pain. It is currently available as a single agent or in combination with other analgesics, such as acetaminophen (e.g., Vicodin). Abuse of prescription opioids has become a national epidemic in the United States. A study funded by the National Institutes of Health estimates that approximately 8% of the nation's 12th-graders abused hydrocodone in 2010. There are no abuse-deterrent hydrocodone single-agent or combination products currently on the market.

About Shionogi

Shionogi & Co., Ltd., headquartered in Osaka, Japan, has subsidiaries in Europe (Shionogi Limited), US (Shionogi Inc.), and Asia. Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on meeting the medical needs of patients. In addition, Shionogi & Co., Ltd. is engaged in new research in areas such as pain and infectious diseases. Contributing to the health of patients around the world through innovative research and development is Shionogi & Co., Ltd.'s primary goal. For more details on Shionogi Limited, please visit www.shionogi.eu. For more details on Shionogi Inc, please visit www.shionogi.com. For more information on Shionogi & Co., Ltd., please visit www.shionogi.co.jp.

About Egalet Corporation

Egalet Corporation is a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and other indications. The company has created two distinct drug delivery systems, each with novel abuse-deterrent features and the ability to control the release profile of the active pharmaceutical ingredient. Using its proprietary platform, Egalet has developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation, while also providing tailored release of the active pharmaceutical ingredient. Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. There are currently no commercially available abuse-deterrent formulations of morphine, and we believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. The Egalet technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple APIs with similar or different release profiles.

Safe Harbor Statement

Certain statements in this news release regarding future expectations and plans for future activities may be regarded as "forward-looking statements." These statements are indicated by the words "may," "will," "plans," "believes," "expects," "anticipates," "potential," "should," and similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Factors that might cause future results to differ include, but are not limited to, the following: timely and successful discovery and development by Egalet of abuse-deterrent hydrocodone-based products; the ability to successfully commercialize any approved abuse-deterred hydrocodone-based products; the availability and pricing of third-party sourced products and materials; the ability to obtain and enforce patents and other intellectual property rights; the strength of the United States dollar relative to international currencies, particularly the Japanese yen; competitive economic and regulatory factors in the pharmaceutical and healthcare industry; general economic conditions; and other risks and uncertainties described in Egalet's Registration Statement on Form S-1 originally filed with the Securities and Exchange Commission on October 16, 2013, and the amendments thereto, including those factors discussed under the caption "Risk Factors" in such filings. Egalet does not undertake any responsibility to revise or update any forward-looking statements contained herein, except as expressly required by law.

This announcement is neither an offer to sell nor a solicitation of an offer to buy any of securities of Egalet, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale is unlawful.