Licensing agreement for Relistor (updated)

Progenics Pharmaceuticals
Salix Pharmaceuticals
Valeant Pharmaceuticals

Feb 07 2011
Licensing agreement for Relistor (updated)

Companies:
- Progenics Pharmaceuticals
- Salix Pharmaceuticals
- Valeant Pharmaceuticals

Announcement date: Feb 07 2011
Amendment date: Jul 26 2016
Deal value, US$m: 350 : sum of upfront and milestone payments

Details

- Industry sectors: Pharmaceutical
- Brand name: Relistor
- Asset type: Product
- Therapy areas: Gastrointestinal » Symptoms » Bowel movement
- Oncology » Symptoms » Cancer pain
- Technology types: Small molecules
- Deal components: Licensing
- Stages of development: Phase III
- Geographic focus: Worldwide
- Excluded geography: Asia » Japan

Financials

- Deal value, US$m: 350 : sum of upfront and milestone payments
- Upfront, US$m: 60 : upfront payment
- Milestones, US$m: 90 : development milestones contingent upon the achievement of certain US regulatory milestones
- 200 : sales-based milestones
- 40 : milestone payment received for FDA approval in October 2014
- 50 : milestone payment received from marketing approval announced on July 2016
- Royalty rates, %: n/d : royalties on product sales in the US
- 60 : of all revenue received from non-US sublicensees
- Semi-quant royalties: Thirty plus
- Funding, US$m: n/d : Salix will fund all development, registration and commercialization activities for RELISTOR in markets worldwide other than in Japan

Term sheet

July 2016
Progenics Pharmaceuticals has received a $50 million milestone payment from its worldwide collaboration partner, Valeant Pharmaceuticals International, Inc., resulting from the US Food and Drug Administration's marketing approval last week of RELISTOR® Tablets for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.

Under a 2011 collaboration with Salix Pharmaceuticals, Inc. (acquired by Valeant in April 2015), Progenics is also entitled to receive up to $200 million of sales milestone payments based on specified U.S. sales targets.

The sales milestone payments range from $10 million when calendar-year U.S. net sales first exceed $100 million, to $75 million when such sales first exceed $1 billion.

Each sales milestone payment is payable one time only, and one or more, or all, sales milestones could become payable within the same calendar year if the specified sales levels are met.

Progenics also earns tiered royalties on total RELISTOR U.S. net sales, as follows: 15% on U.S. net sales up to $100 million, 17% on the next $400 million in U.S. net sales, and 19% on U.S. net sales over $500 million.

Outside of the U.S. Progenics is entitled to receive 60% of any up-front milestone, royalty and other revenue, net of certain costs, as specified in our license agreement with Valeant.

7 October 2014

Progenics Pharmaceuticals received a $40 million milestone payment from its worldwide collaboration partner, Salix Pharmaceuticals, upon the US Food and Drug Administration’s approval last week of RELISTOR Subcutaneous Injection for opioid-induced constipation in patients with chronic non-cancer pain.

Progenics also provided additional information on its commercial arrangements with Salix for the expanded indication.

7 February 2011

Exclusive worldwide (except Japan) agreement by which Salix has licensed rights to RELISTOR (methylnaltrexone bromide).

RELISTOR Subcutaneous Injection is indicated for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

Use of RELISTOR beyond 4 months has not been studied.

Financial terms of the transaction include a $60 million up-front payment and development milestones totaling $90 million, contingent upon the achievement of certain U.S. regulatory milestones.

Salix also will pay sales-based milestones of up to $200 million plus royalties on product sales in the U.S., as well as 60% of all revenue received from non-U.S. sublicensees.

Salix will fund all development, registration and commercialization activities for RELISTOR in markets worldwide other than in Japan, where Progenics has licensed to Ono Pharmaceuticals the rights to develop and commercialize subcutaneous RELISTOR.

Salix will market RELISTOR directly through its specialty sales force in the U.S., and outside the U.S., RELISTOR will be marketed with sublicenses to regional companies.

The parties plan an April 2011 transition of RELISTOR commercial and development responsibility to Salix from Pfizer Inc, which acquired Progenics’ former RELISTOR partner, Wyeth Pharmaceuticals.

While Salix effects a country-by-country transition of ex-U.S. commercialization rights, Wyeth will remain the Marketing Authorization Holder for RELISTOR and will continue to supply product.

In the interim, Wyeth remains responsible for all manufacturing, clinical, medical and regulatory activities for RELISTOR outside of the U.S. and Japan.

Press Release

July 2016

TARRYTOWN, N.Y., July 26, 2016 (GLOBE NEWSWIRE) -- Progenics Pharmaceuticals, Inc. (Nasdaq:PGNX) announced today that it has received a $50 million milestone payment from its worldwide collaboration partner, Valeant Pharmaceuticals International, Inc. (NYSE:VRX), resulting from the US Food and Drug Administration's marketing approval last week of RELISTOR® Tablets for the treatment of opioid-induced constipation in adults with chronic non-cancer pain.
We are pleased that our partner Valeant can now offer RELISTOR in a more convenient tablet form to patients in need,” said Mark Baker, Chief Executive Officer of Progenics. “This and other sales milestone payments that we may receive from sales of RELISTOR provide an important source of non-dilutive financing for our Company as we approach topline, registrational data on AZEDRA® and advance our diverse pipeline of prostate cancer imaging agents and therapeutics.”

Under a 2011 collaboration with Salix Pharmaceuticals, Inc. (acquired by Valeant in April 2015), Progenics is also entitled to receive up to $200 million of sales milestone payments based on specified U.S. sales targets. The sales milestone payments range from $10 million when calendar-year U.S. net sales first exceed $100 million, to $75 million when such sales first exceed $1 billion. Each sales milestone payment is payable only once, and one or more, or all, sales milestones could become payable within the same calendar year if the specified sales levels are met. Progenics also earns tiered royalties on total RELISTOR U.S. net sales, as follows: 15% on U.S. net sales up to $100 million, 17% on the next $400 million in U.S. net sales, and 19% on U.S. net sales over $500 million. Outside of the U.S., Progenics is entitled to receive 60% of any up-front milestone, royalty and other revenue, net of certain costs, as specified in our license agreement with Valeant.

About Opioids, Constipation and RELISTOR (methylnaltrexone bromide)

Opioid analgesics are frequently prescribed for patients with chronic pain, including patients with advanced illness. An estimated 27 million patients in the U.S. take opioids for chronic pain. Constipation is one of the most common and distressing side effects in patients receiving opioid therapy. Approximately 40% of chronic pain patients, or nearly 11 million patients, receiving opioid therapy will experience OIC. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC.

RELISTOR Subcutaneous Injection was approved in the United States in 2008 for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied in the advanced illness population. The drug is also approved for use in over 50 countries worldwide, including the European Union, Canada, and Australia. In the 28 member countries of the EU, as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of OIC in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. Applications in additional countries are pending. RELISTOR is under license to Salix Pharmaceuticals, Inc. from Progenics Pharmaceuticals, Inc.

For more information about RELISTOR, please visit www.RELISTOR.com
Important Safety Information about RELISTOR

RELISTOR® (methylnaltrexone bromide) Subcutaneous Injection is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician.

Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR.

Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia. Take into account the overall risk-benefit profile when using RELISTOR in such patients. Monitor for adequacy of analgesia and symptoms of opioid withdrawal in such patients.

Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

RELISTOR may precipitate opioid withdrawal in a fetus and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

In the clinical study in adult patients with opioid-induced constipation and chronic non-cancer pain, the most common adverse reactions (= 1%) were abdominal pain, nausea, diarrhea, and hyperhidrosis, hot flush, tremor, and chills.

In clinical studies in adult patients with opioid-induced constipation and advanced illness, the most common adverse reactions (= 5%) were abdominal pain, flatulence, nausea, dizziness, and diarrhea.

Please see complete Prescribing Information for RELISTOR.

About Progenics

Progenics Pharmaceuticals, Inc. is developing innovative medicines for oncology, with a pipeline that includes several product candidates in later-stage clinical development. Progenics' first-in-class PSMA targeted technology platform for prostate cancer includes an antibody drug conjugate therapeutic in a two-cohort phase 2 clinical trial and a small molecule imaging agent that has completed patient dosing in a phase 2 trial. Among other assets in its pipeline of targeted radiotherapy and molecular imaging compounds is Azedra™, an ultra-orphan radiotherapy candidate also in a phase 2 study under an SPA. Progenics' first commercial product, RELISTOR (methylnaltrexone bromide) Subcutaneous Injection for opioid-induced constipation, is partnered with and marketed by Salix Pharmaceuticals, Inc. For additional information, please visit www.progenics.com.

This press release may contain projections and other forward-looking statements regarding future events. Such statements are predictions only, and are subject to risks and uncertainties that could cause actual events or results to differ materially. These risks and uncertainties include, among others, the cost, timing and results of clinical trials and other development activities; the unpredictability of the duration and results of regulatory review of New Drug Applications and Investigational NDAs; market acceptance for approved products; generic and other competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting matters, litigation and other risks. More information concerning Progenics and such risks and uncertainties is available on its website, and in its press releases and reports it files with the U.S. Securities and Exchange Commission. Progenics is providing the information in this press release as of its date and does not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise.

Additional information concerning Progenics and its business may be available in press releases or other public announcements and public filings made after this release.

Information on or accessed through our website or social media sites is not included in the company's SEC filings.

7 February 2011

Progenics Pharmaceuticals, Inc. (PGNX) and Salix Pharmaceuticals, Ltd. (SLXP) Announce Worldwide License Agreement for RELISTOR®

2/7/2011
Opioid analgesics are frequently prescribed to manage pain in patients with advanced illness. Constipation commonly occurs in palliative-care patients receiving opioid therapy for pain. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC in these patients. Opioids relieve pain by specifically interacting with mu-opioid receptors within the brain and spinal cord of the central nervous system (CNS). However, opioids also interact with mu-opioid receptors found outside the CNS, such as those within the gastrointestinal tract, resulting in constipation that can be debilitating. RELISTOR is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications in the gastrointestinal tract without affecting their ability to relieve pain. The methylnaltrexone license includes intellectual property from the University of Chicago, Progenics Pharmaceuticals, and Wyeth Pharmaceuticals, including patents and applications with expiration dates that will range from 2017 through 2031. RELISTOR was approved in the United States in 2008, and currently the drug is approved for use in over 50 countries worldwide. In 2010, RELISTOR single-use, pre-filled syringes were approved for use in the United States, Canada and the European Union. Worldwide net sales of RELISTOR totaled $16 million in 2010.

Financial terms of the transaction include a $60 million up-front payment and development milestones totaling $90 million, contingent upon the achievement of certain U.S. regulatory milestones. Salix also will pay sales-based milestones of up to $200 million plus royalties on product sales in the U.S., as well as 60% of all revenue received from non-U.S. sublicensees. Salix will fund all development, registration and commercialization activities for RELISTOR in markets worldwide other than in Japan, where Progenics has licensed to Ono Pharmaceuticals the rights to develop and commercialize subcutaneous RELISTOR.

Commenting on the transaction, Mark R. Baker, President, Progenics, stated, “Our agreement with Salix represents the culmination of our search for a partner with the skills, experience and passion to effectively market and develop RELISTOR. With the strength of Salix's sales force and development team behind this product, I believe that RELISTOR's full potential can be achieved -- to the benefit of OIC patients.”

“Paul J. Maddon, M.D., Ph.D., Founder, Chief Executive and Chief Science Officer, Progenics, stated, “Our partnership with Salix maximizes the global development, commercialization and market potential of the RELISTOR franchise. Progenics and Salix share a vision of expanding the use of this important therapy among the millions of patients who suffer from the debilitating side effects of opioid pain medications.”

Carolyn Logan, President and CEO, Salix, stated, “Constipation is a common, and often debilitating, gastrointestinal consequence of the use of opioid analgesics to manage pain. We are pleased to add RELISTOR Subcutaneous Injection, a first-in-class treatment for OIC in advanced illness, to our product portfolio. We believe RELISTOR represents a valuable asset that merits additional development and targeted commercialization. Currently an oral formulation of RELISTOR is in phase 3 development to potentially address OIC in patients with chronic, non-cancer pain. We look forward to utilizing our specialty sales force in the United States and our existing business partners worldwide to provide physicians with a solution to address the opioid-induced constipation experienced by their patients.”

Salix will market RELISTOR directly through its specialty sales force in the U.S., and outside the U.S., RELISTOR will be marketed with sublicenses to regional companies. The parties plan an April 2011 transition of RELISTOR commercial and development responsibility to Salix from Pfizer Inc, which acquired Progenics' former RELISTOR partner, Wyeth Pharmaceuticals. While Salix effects a country-by-country transition of ex-U.S. commercialization rights, Wyeth will remain the Marketing Authorization Holder for RELISTOR and will continue to supply product. In the interim, Wyeth remains responsible for all manufacturing, clinical, medical and regulatory activities for RELISTOR outside of the U.S. and Japan.

Conference Calls and Audiocasts

Members of Progenics' senior management team will host a conference call today at 8:00 a.m. ET. To participate in the conference call, please dial 800-419-9895 (domestic) or 913-312-9308 (international) and reference the access code 7236120. A replay of the call will be available from 11:00 a.m. ET on Monday, February 7, 2011 until midnight on Sunday, February 20, 2011. To access the replay, please dial 888-203-1112 (domestic) or 719-457-0820 (international) and reference the access code 7236120. The archived webcast will be available for 14 days in the Events section of the Progenics website at http://www.progenics.com/events.cfm.

Members of Salix's senior management team will host a conference call today at 9:00 a.m. ET. To participate in the conference call, please dial 866-454-4205 (domestic) or 913-312-0662 (international) and reference the access code 8513768. A replay of the call will be available from 11:30 a.m. ET on Monday, February 7, 2011 until midnight on Sunday, February 20, 2011. To access the replay, please dial 888-203-1112 (domestic) or 719-457-0820 (international) and reference the access code 8513768.

About Opioids, Constipation and RELISTOR (methylnaltrexone bromide)

Opioid analgesics are frequently prescribed to manage pain in patients with advanced illness. Constipation commonly occurs in palliative-care patients receiving opioid therapy for pain. RELISTOR is the first approved medication that specifically targets the underlying cause of OIC in these patients. Opioids relieve pain by specifically interacting with mu-opioid receptors within the brain and spinal cord of the central nervous system (CNS). However, opioids also interact with mu-opioid receptors found outside the CNS, such as those within the gastrointestinal tract, resulting in constipation that can be debilitating. RELISTOR is a peripherally acting mu-opioid receptor antagonist that decreases the constipating effects of opioid pain medications without affecting their ability to relieve pain. RELISTOR selectively displaces opioids from the mu-opioid receptors outside the CNS, including those located in the gastrointestinal tract, thereby decreasing their constipating effects. Because
of its chemical structure, RELISTOR does not affect the opioid-mediated analgesic effects on the CNS.

RELISTOR Subcutaneous Injection is approved in the United States for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied. In Canada, the drug is approved for use in over 50 countries worldwide, including the European Union, Canada, and Australia. In the 27 member states of the E.U., as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of opioid-induced constipation in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. Applications in additional countries are pending.

Important Safety Information for RELISTOR

• RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction • If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician • Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients. Use RELISTOR with caution in patients with known or suspected lesions of the GI tract • Use of RELISTOR has not been studied in patients with peritoneal catheters • The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%) • Safety and efficacy of RELISTOR have not been established in pediatric patients RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com.

RELISTOR Development Programs

Subcutaneous Methylnaltrexone in chronic, non-malignant pain and OIC

A 1,034-patient, one-year, open-label, international, phase 3 safety study to evaluate the long-term safety and tolerability of methylnaltrexone bromide subcutaneous injection in chronic, non-malignant pain patients with opioid-induced constipation was completed in September 2010. Efforts are underway to submit a supplemental New Drug Application for this potential indication to the FDA in the first half of 2011.

Oral Methylnaltrexone in chronic, non-malignant pain and OIC

A 700-patient, international, randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of oral methylnaltrexone to treat opioid-induced constipation in chronic, non- malignant pain patients was initiated in September 2010, and is anticipated to complete enrollment by year-end 2011.

About Progenics

Progenics Pharmaceuticals, Inc., of Tarrytown, NY, is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Principal programs are directed toward gastroenterology, oncology and infectious diseases. Progenics is developing RELISTOR® (methylnaltrexone bromide) for the treatment of opioid-induced constipation. RELISTOR is now approved in over 50 countries, including the U.S., E.U., Canada and Australia. Ono Pharmaceutical Co., Ltd. has an exclusive license from Progenics for development and commercialization of subcutaneous RELISTOR in Japan. In oncology, the Company is conducting a phase 1 clinical trial of PSMA ADC, a human monoclonal antibody-drug conjugate for the treatment of prostate cancer. PSMA is a protein found on the surface of prostate cancer cells as well as in blood vessels supplying other solid tumors. In virology, Progenics is also developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody which binds to co-receptor CCR5 to inhibit human immunodeficiency virus (HIV) infection. PRO 140 is currently in phase 2 clinical testing. In early development, Progenics is evaluating novel antibodies to toxins produced by the bacteria C. difficile, as well as single-agent multiplex PI3-Kinase inhibitors as a potential strategy to combat some of the most aggressive forms of cancer, and is also seeking to identify novel entry-inhibitors of HCV infection.

For more information, please visit www.progenics.com.

(PGNX-G)

About Salix

Salix Pharmaceuticals, Ltd., headquartered in Raleigh, North Carolina, develops and markets prescription pharmaceutical products for the prevention and treatment of gastrointestinal diseases. Salix’s strategy is to in-license late-stage or marketed proprietary therapeutic drugs, complete any required development and regulatory submission of these products, and market them through the Company’s gastroenterology specialty sales and marketing team.

Filing Data

10K abstract - 2013
In February 2011, we acquired an exclusive worldwide license to develop and commercialize the products containing methylnaltrexone bromide, or the MNTX Compound, marketed under the name Relistor, from Progenics and a non-exclusive license to manufacture the MNTX Compound and products containing that compound. These licenses are worldwide, except in Japan, where Ono Pharmaceutical Co. Ltd., or Ono Pharmaceutical, has licensed the subcutaneous formulation of the drug from Progenics. We paid Progenics an up-front license fee payment of $60.0 million. In addition, we are obligated to pay Progenics up to $90.0 million contingent upon achieving specified regulatory approvals and up to $200.0 million contingent upon achieving specified targets for net sales over the term of the agreement. None of the milestones had been achieved, and therefore none of these payments had been made, as of December 31, 2013. Because these milestone payments are conditioned upon events that might never occur, we do not consider the potential milestone payments as purchase obligations or a commitment to be reported in our contractual commitments table in Management’s Discussion and Analysis of Financial Condition and Results of Operations. We must pay Progenics 60% of any revenue received from sublicensees in respect of any country outside the United States. We must pay Progenics royalties based on a percentage ranging from the mid- to high-teens of net sales of any product containing the MNTX Compound. We are responsible for the future costs of the development programs for MNTX Compounds (excluding sales by ex-U.S. sublicensees). The royalty period generally runs until the later of (i) the expiration of the last valid relevant patent claim, (ii) the date on which there is no marketing exclusivity right with respect to the product, and (iii) the 15th anniversary of the first commercial sale subject, in the case of clause (iii), to earlier termination if unauthorized generic competition exceeds specified thresholds. Either party may terminate the license agreement upon an uncured material breach or specified bankruptcy events. In addition, we may terminate the agreement for safety or efficiency issues, or upon specified prior notice at any time on or after the first anniversary of the agreement, subject to Progenics’ right to postpone such latter termination in certain circumstances. Upon the termination of the agreement, all licenses granted to Salix by Progenics will terminate other than respecting any product the royalty period for which has expired in a particular country.

Contract

LICENSE AGREEMENT

by and between

SALIX PHARMACEUTICALS, INC.

and

PROGENICS PHARMACEUTICALS, INC.

PROGENICS PHARMACEUTICALS NEVADA, INC.

and

EXCELSIOR LIFE SCIENCES IRELAND LIMITED

Dated as of 3 February 2011

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TABLE OF CONTENTS

Page

1. DEFINITIONS 6

2. LICENSE GRANTS AND RELATED MATTERS 27

2.1. License from Progenics to Salix 27

2.2. Sublicenses 27

2.3. Direct Licenses to Affiliates 28

2.4. Certain Matters Relating to the University of Chicago 29

2.5. License from Salix to Progenics 29

2.6. Enforcement of Non-Assertion of Rights Covenants 29

2.7. Non-Assertion of Progenics’s Rights; Non-Exclusive License Grant; Non-Assertion by Salix 30

2.8. Fully Paid-Up, Royalty Free License 30

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11.3. Procedure 86
11.4. Insurance 87

12. REGULATORY MATTERS, PRODUCT SAFETY ISSUES, PRODUCT RECALLS 88
12.1. Regulatory Matters 88
12.2. Rights of Cross-Reference 88
12.3. Communications with Regulatory Authorities 89
12.4. Regulatory Audits 90
12.5. Ownership of Regulatory Documentation, Registrational Filings and Regulatory Approvals; Transfer of Registrational Filings and Regulatory Approvals 91
12.6. Medical and Customer Inquiries 91
12.7. Safety Agreement 91
12.8. Product Recalls 92

13. MISCELLANEOUS 92
13.1. Force Majeure 92
13.2. Agency 93
13.3. Choice of Law 93
13.4. Notices 93
13.5. Severability 95
13.6. Entire Agreement 95
13.7. Modifications; No Waiver 95
13.8. Cumulative Remedies 95
13.9. Assignment; Binding Effect 96
13.10. Change in Control of Progenics; Acquisition 96
13.11. Counterparts 97
13.12. Executive Mediation 97
13.13. No Consequential Damages 98
13.15. Representation by Counsel 98
13.16. Further Assurances 98
13.17. Jurisdiction; Venue; Service 99
13.18. Specific Enforcement 99
13.19. Export Control 99
13.20. Performance by Third Party Contractors and Affiliates 100
13.21. No Benefit to Third Parties 100
13.22. Effect of Termination of the UR Labs-Progenics Agreement 100

13.23. Effect of Termination of the [*] Agreement 102

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

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SCHEDULES

Schedule 1.32
Chemical drawing of Compound

Schedule 1.135
Salix COGs

Schedule 1.139
Salix Competitors

Schedule 4.1
Initial Development Outline

Schedule 4.6(d)
Major supply and other contracts

Schedule 5.1(a)
Initial Commercialization Outline

Schedule [*]
[*]

Schedule [*]
[*]

Schedule 9.2(a)(i)
Licensed Patent Rights

Schedule 9.2(a)(ii)
Progenics Third Party Agreements

Schedule 9.2(b)(i)
Wyeth Collaboration Patent Rights

Schedule 9.2(b)(ii)
Wyeth Collaboration Joint Patent Rights

Schedule 9.2(c)(i)
Exceptions to ownership of Patent Rights

Schedule 9.2(c)(ii)
Exceptions to ownership of interest in Joint Patent Rights
Schedule 9.2(d)
Exceptions as to inventors

Schedule 9.2(e)
Exceptions as to prior art

Schedule 9.2(f)
Exceptions as to interest in Progenics Know-How

Schedule 9.2(i)
Exceptions as to freedom to operate

Schedule 9.2(j)(i)
Exceptions as to validity and enforceability of Progenics Patent Rights

Schedule 9.2(j)(ii)
Exceptions as to misappropriation

Schedule 9.2(j)(iii)
Exceptions as to claims of invalidity or unenforceability of Licensed Patent Rights

Schedule 9.2(m)
Disclosures in respect of RELISTOR marks

Schedule 9.2(o)
Adverse Information

Schedule 9.2(p)
Studies

Schedule 9.2(r)(i)
Regulatory Approvals

Schedule 9.2(s)
Promotional Materials

RELATED AGREEMENTS
[*]
[*]

2010 Agreement Related to Progenics’s MNTX In-License, among the Expanded Parties and the University of Chicago and ARCH Development Corporation

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

This LICENSE AGREEMENT (this “Agreement”) is made and entered into as of 3 February 2011 (the “Effective Date”), by and between Salix Pharmaceuticals, Inc., a corporation existing under the laws of California and having a place of business at 1700 Perimeter Park Drive, Morrisville, NC 27560 (“Salix”), and Progenics Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591 (“Progenics”), Progenics Pharmaceuticals Nevada, Inc., a corporation organized and existing under the laws of the State of Nevada and having a principal place of
business at 777 Old Saw Mill River Road, Tarrytown, NY 10591, USA and a wholly-owned subsidiary of Progenics ("ProNev"), and Excelsior Life Sciences Ireland Limited, a corporation organized and existing under the laws of Ireland and having a principal place of business at 25/28 North Wall Quay, Dublin 1 Ireland and a wholly-owned subsidiary of Progenics ("Excelsior," and together with Progenics and ProNev, the "Progenics Parties"). Salix and Progenics may each be referred to herein individually as a "Party" and, collectively, as the "Parties." Salix and the Progenics Parties may each be referred to herein individually as an "Expanded Party" and, collectively, as the "Expanded Parties."

BACKGROUND

A. Salix is in the business of discovering, developing, manufacturing and marketing human pharmaceutical products.

B. Progenics is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products. Progenics has developed [*]-methylnaltrexone ("[*]-MNTX") for the treatment of opioid-induced constipation associated with advanced illness and is developing [*]-MNTX for other indications and in other formulations.

C. The Progenics Parties own or have rights under certain patents, patent applications, other valuable technology and know-how relating to [*]-MNTX and other methylnaltrexone molecules.

D. Progenics and ProNev entered into a License and Co-Development Agreement with Wyeth, acting through Wyeth Pharmaceuticals Division, Wyeth Whitehall Pharmaceuticals, Inc. and Wyeth Ayerst Lederle, Inc. (collectively, "Wyeth"), dated as of 23 December 2005 (the "Wyeth Agreement"), under which Progenics granted Wyeth a worldwide license to develop and commercialize [*]-MNTX.

E. The parties to the Wyeth Agreement entered into a Partial Termination and License Agreement, dated 16 October 2008 (the "Partial Termination Agreement"), confirming the termination with respect to Japan of the rights granted to Wyeth under the Wyeth Agreement.

F. Progenics entered into a License Agreement with Ono Pharmaceutical Co., Ltd. ("Ono"), dated as of 16 October 2008 (the "Ono Agreement"), under which Progenics granted Ono a license to develop and commercialize the subcutaneous formulation of [*]-MNTX for the Japanese market and an option to develop and commercialize additional formulations of [*]-MNTX.

G. Wyeth and certain of its affiliates and Progenics, ProNev and their affiliate Excelsior entered into a Termination and Transition Agreement, effective 1 October 2009, as amended (the "Termination Agreement"), providing for the termination of the Wyeth Agreement and the Partial Termination Agreement.

H. Salix and Progenics wish to collaborate regarding the further development and commercialization of methylnaltrexone worldwide except, unless and until Japan is included in the Territory hereunder, for Japan, and Progenics wishes to grant to Salix, and Salix wishes to receive from Progenics, a license to so develop and commercialize methylnaltrexone.

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 Expanded Parties hereby agree as follows:

1. DEFINITIONS

Capitalized terms used in this Agreement, including its Exhibits and/or Schedules, and not otherwise defined herein shall have the following meanings:

1.1. “1985 Agreement” means the Option and License Agreement entered into by UR Labs and the University of Chicago and dated as of 8 May 1985, as amended.

1.2. “[*]" has the meaning set forth in Section [*].

1.3. “[*]" has the meaning set forth in Section [*].

1.4. “[*]" has the meaning set forth in Section [*].

1.5. “[*]" means, in respect of the ["] or the ["], that:
(a) the ["] required for ["] does not contain any ["]; and, in addition,
(b) ["] is required by the ["].

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1.6. "Acquisition," with respect to a Party, means a merger, acquisition (whether of all of the stock or all or substantially all of the assets of a Person or any operating or business division of a Person) or similar transaction by or with the Party, other than a Change in Control of the Party.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

6

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1.7. “Action Party” has the meaning set forth in Section 7.3(d).

1.8. "Adverse Events" has the meaning set forth in Section 9.2(o).

1.9. Affiliate means, in respect of any Person, any other Person that, directly controls or is controlled by, or is under common control with the first Person. For purposes of this definition, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means (a) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (b) ownership, directly or indirectly, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the voting securities, or other voting ownership interests, in the case of any limited liability company or other type of legal entity.

1.10. “Agreement” has the meaning set forth in the first paragraph hereof.

1.11. "API" means active pharmaceutical ingredient.

1.12. "Applicable Law" means applicable national, federal, state, provincial, local or other laws, statutes, rules, regulations and guidances, including rules, regulations, guidances, guidelines or other requirements of Regulatory Authorities or other governmental authorities, as in effect from time to time in any jurisdiction.

1.13. "Applicable Net Sales Percentage" has the meaning set forth in Section 6.5(a).

1.14. “Board of Directors” has the meaning set forth in the definition of “Change in Control.”

1.15. “Business Day” means a day other than a Saturday or a Sunday on which banks in New York, New York are open for the conduct of regular banking business.

1.16. “Calendar Year” means each successive period of twelve (12) months commencing on January 1 and ending on December 31.


1.18. “cGLP” means current good laboratory practices as stated in Applicable Law, including Directive 2004/10/EC and 21 C.F.R. Part 58 et seq., each as amended from time to time and all FDA and Council of the Organization for Economic Cooperation and Development (OECD) guidelines related thereto.

1.19. “cGMP” means current good manufacturing practices as stated in Applicable Law, including 21 C.F.R. Part 210 and 211 and Directive 2003/94/EEC, each as amended from time to time and all FDA, European Commission and ICH guidelines related thereto.

7

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1.20. “Change in Control”, with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

(i) any “person” or “group” (as such terms are defined below) (a) is or becomes the “beneficial owner” (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (“Voting Stock”) of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or (b) has the power, directly or indirectly, to elect a majority of the members of the Party’s board of directors or similar governing body (“Board of Directors”);

or

(ii) such Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing at least a majority of
the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction; or

(iii) such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets; or

(iv) the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change in Control, (a) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act, (b) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act, and (c) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.21. “Chronic Pain Product” means a Product for use in the Human Field for the treatment of opioid-induced constipation arising from the treatment of chronic pain associated with one or more non-cancer diseases or conditions.

1.22. “[*]” has the meaning set forth in Section [*].

1.23. “Claim” means any claim, action, cause of action, chose in action, or suit (in contract or tort or otherwise), litigation, arbitration, investigation, opposition, hearing, complaint, demand, notice or proceeding to, from, by or before any arbitrator, court, administrative organization, or other governmental authority or other Person.

1.24. “Clinical Data” means all information relating to a drug product made, collected or otherwise generated in the performance of or in connection with any clinical trials (including any Phase 4 Clinical Trials), including any data, reports and results relating thereto.

1.25. “CMC” means Chemistry, Manufacturing and Controls information as required to be submitted under Section 505 of the FD&C Act and 21 C.F.R. 214.

1.26. “Collaboration” means the Development, Commercialization and other activities of Salix and Progenics under this Agreement in respect of Products in the Field in or for the Territory.

1.27. “Commercialization” means, in respect of a particular compound or product and a particular country, all activities related to the commercial exploitation of the compound or product in the country, including the making, having made, supply, use, importation, exportation, marketing, promotion, distribution, pre-launch, launch, offering for sale or sale of the compound or product in the country. When used as a verb, “Commercialize” or “Commercializing” means to engage in Commercialization.

1.28. “Commercialization Milestone Payments” has the meaning set forth in Section 6.3.

1.29. “Commercialization Plan” means a comprehensive plan prepared by Salix (as amended from time to time in accordance with this Agreement) that specifies the efforts Salix, its Affiliates and Sublicensees intend to use in respect of Commercialization of Products in the Field in the Territory, which plan shall be consistent with the Initial Commercialization Outline and with Salix’s obligations under Section 5.1 and shall include (with reasonable detail) a description of, and [*] and [*] for, all Product-related [*] activities (including activities [*] and other arrangements affecting the Commercialization of Products), including [*] activities, the [*] in each Major Market Country, Product-related [*] in each Major Market Country, Product-related [*] activities to be performed by [*] in furtherance of Commercialization of Products in the Field in the Territory, and the general [*] in each Major Market Country.

1.30. “Commercially Reasonable Efforts” means efforts and resources normally used by the Party required to use such efforts and resources for a product, proposed product or technology owned by it or to which it has rights, which is of similar commercial potential at a similar stage in its development or product life to the product in question, (a) taking into account issues of: [*].

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

1.31. “Committee” and “Committees” have the meaning set forth in Section 3.1.

1.32. “Compound” means methylnaltrexone (MNTX), which is chemically defined as [*]. A chemical drawing of the Compound is attached as Schedule 1.32.
1.33. “Confidential Information” means all information disclosed by one Expanded Party to another Expanded Party (other than solely by virtue of such information being disclosed between the Progenics Parties), whether prior to the Effective Date or during the Term, that either is identified as confidential or is information that is of a nature that is customarily regarded as confidential within the pharmaceutical industry, whether disclosed in electronic, tangible, oral or visual form. The terms and existence of this Agreement shall constitute Confidential Information of each Expanded Party, the restrictions on disclosure of which imposed hereunder shall be subject to Section 8.4.

1.34. “Control” means, with respect to any item of Know-How, Regulatory Documentation, Patent Rights, or trademark or other intellectual property right, possession of the right, whether directly or indirectly, whether existing as of the Effective Date or thereafter acquired, and whether by ownership, license or otherwise (other than by operation of any license and other grants hereunder), to assign or grant a license, sublicense or other right to or under such Know-How, Regulatory Documentation, Patent Rights, or trademark or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.35. “Controlling Affiliate” of a Person means an Affiliate that controls (as such term is used in the definition of Affiliate) such Person.

1.36. “Controlling Third Party” has the meaning set forth in the definition of Progenics Know-How.

1.37. “CRO” has the meaning set forth in Section 9.2(n)(iii).

1.38. “Cure Period” has the meaning set forth in Section 10.2(a).

1.39. “Debtor Party” has the meaning set forth in the Section 10.11.

1.40. “Designated Countries” means (a) the Major Market Countries, (b) any country in the Territory in which [*] or [*] have, [*], [*] and [*], and (c) all other countries in the Territory except [*] and [*].

1.41. “Development” means, in respect of a particular compound or pharmaceutical product and a particular country, all activities related to the development of the compound or product and obtaining Regulatory Approval for the compound or product in the country, including all activities related to research, development, preclinical testing, stability testing, toxicology, formulation, product line-extensions, clinical trials, regulatory affairs, statistical analysis, report writing, manufacturing process and scale up, qualification and validation activities, product life-cycle management, quality assurance/quality control development and regulatory filing creation and submission related to obtaining Regulatory Approval for the compound or product in the country. When used as a verb, “Develop” or “Developing” means to engage in Development.

1.42. “Development Milestone Payments” has the meaning set forth in Section 6.2.

1.43. “Development Plan” has the meaning set forth in Section 4.1.

1.44. “Disclosing Party” has the meaning set forth in Section 8.2.

1.45. “Dispute” has the meaning set forth in Section 13.12(a).

1.46. “Drug Price Approval” means, with respect to any drug product in any country, the achievement of all applicable pricing and reimbursement approvals with respect to such drug product in such country.

1.47. “Effective Date” has the meaning set forth in the first paragraph hereof.

1.48. “EMEA” means the European Medicines Association, and any successor agency thereto.

1.49. “Excelsior” has the meaning set forth in the first paragraph hereof.

1.50. “Executive Mediation” has the meaning set forth in Section 13.12(a).

1.51. “Expanded Party” has the meaning set forth in the first paragraph hereof.


1.53. “FDA” means the United States Food and Drug Administration or any successor agency thereto.

1.54. “Field” means the Human Field and the Non-Human Animal Field, together.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.
1.55. “First Commercial Sale” means, with respect to a particular Product and a particular country in the Territory, the first commercial sale of such Product to a Third Party in such country after such Product has been granted Regulatory Marketing Approval by a Regulatory Authority in the Territory. By way of example and for the avoidance of doubt, the First Commercial Sale of a [*] shall be the first commercial sale of such Product to a Third Party in such country after such [*] has been granted Regulatory Marketing Approval by a Regulatory Authority in the Territory for an [*].

1.56. “FTE Rate” means the hourly rate of [*] dollars ($[*]) per hour for certain activities that Salix requests Progenics to perform under the Collaboration. This hourly rate shall apply to Progenics activities through [*], and will be adjusted at the beginning of each subsequent Calendar Year from the prior year amount by the change in the United States Department of Labor Bureau of Labor Statistics Consumer Price Index-All Urban Consumers during the prior year.

1.57. “GAAP” means U.S. generally accepted accounting principles consistently applied.

1.58. “[*] Patent Rights” means those Patent Rights licensed by [*] [*] to Progenics pursuant to a Third Party Agreement between [*] and Progenics dated [*], as and to the extent such Patent Rights subsist and claim inventions made on or prior to the Effective Date and as and to the extent Controlled by Progenics, Progenics’s Affiliates, Salix or Salix’s Affiliates as of the Effective Date or at any time during the Term.

1.59. “Human Field” means all uses in humans, including the diagnosis, treatment or prevention of diseases or conditions in humans.

1.60. “Indemnified Party” has the meaning set forth in Section 11.3.

1.61. “Indemnifying Party” has the meaning set forth in Section 11.3.

1.62. “IND” means an investigational new drug application, clinical study application, clinical trial exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformity with the requirements of such Regulatory Authority.

1.63. “Initial Commercialization Outline” has the meaning set forth in Section 5.1.

1.64. “Initial Development Outline” has the meaning set forth in Section 4.1.

1.65. “Invoiced Sales” has the meaning set forth in the definition of Net Sales.

1.66. “Japan” means the country of Japan (Nihon/Nippon Koku).

1.67. “JDC” has the meaning set forth in Section 3.1(a).

1.68. “Joint Know-How” means any Know-How made or created in the course of the Collaboration jointly by employees or agents of Progenics or any of its Affiliates or licensees (to Confidential treatment requested; certain information omitted and filed separately with the SEC.

1.69. “Joint Patent Rights” means any Patent Rights related to any invention, development or discovery made or created in the course of the Collaboration jointly by employees or agents of Progenics or any of its Affiliates or licensees (to the extent such Patent Rights involving such a licensee is Controlled by Progenics) and employees or agents of Salix or any of its Affiliates or Sublicensees (to the extent such Patent Rights involving such a Sublicensee is Controlled by Salix), as determined in accordance with Section 7.1(a).


1.71. “JSC” has the meaning set forth in Section 3.1(a).

1.72. “Know-How” means any confidential unpatented or unpatentable invention, development, discovery, technology, cell line, biological material, compound, probe, sequence, technical information, method, biological material, Clinical Data, or other confidential information or material.
1.73. “Liability” has the meaning set forth in Section 11.1.

1.74. “License Notice” has the meaning set forth in Section 2.13(a).

1.75. “Licensed Activity(ies)” means, collectively, the Development and Commercialization of any Product in the Field in or for the Territory, the practice of any Progenics Technology or Joint Technology pursuant to the licenses granted by Progenics to Salix hereunder or by Salix to its Affiliates or Sublicensees pursuant hereto, or the exercise of any other right granted by Progenics to Salix under this Agreement or by Salix to its Affiliates or Sublicensees pursuant hereto, in each case to the extent permitted under this Agreement.

1.76. “Licensed Know-How” means (a) the Progenics Know-How and (b) Progenics’s interest in the Wyeth Collaboration Joint Know-How, the Wyeth Collaboration Know-How, the Ono Collaboration Joint Know-How, the Ono Collaboration Know-How, and Know-How included in the Wyeth Additional Licensed Rights.


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1.79. “Major Market Country” means any of [*] and [*]. In the event that, and commencing at such time as, the [*] set forth in this Agreement are [*], then [*] shall also be a “Major Market Country” for purposes of this definition.

1.80. “Manufacture” or “Manufacturing” means, in respect of a particular compound or pharmaceutical product, those manufacturing-related activities that support Development and Commercialization activities for such compound or product, including the synthesis, formulating, processing, scale-up, validation, qualification and audit of manufacturing facilities, bulk production, packaging, Product Labeling, fill/finish work, storage and release of such compound or product and related quality assurance/quality control and technical support activities.

1.81. “[*] Agreement” means the Exclusive License Agreement, dated [*] [*], between [*], [*] and Progenics.

1.82. “[*] Patent Rights” means those Patent Rights licensed to Progenics under the [*], as and to the extent such Patent Rights subsist and claim inventions made on or prior to the Effective Date and as and to the extent Controlled by Progenics, Progenics’s Affiliates, Salix or Salix’s Affiliates as of the Effective Date or at any time during the Term.

1.83. “NDA” means a New Drug Application that is filed with the FDA to formally propose that the FDA approve a new drug for sale and marketing in the United States, or an equivalent application or submission.

1.84. “Net Sales” means, for any period, the gross amount invoiced by Salix and its Affiliates for sales of Products to Third Parties (other than Sublicensees) (the “Invoiced Sales”), less deductions for

(a) normal and customary trade, quantity and cash discounts and sales returns and allowances, including (i) those granted on account of price adjustments, billing errors, rejected goods, damaged goods and returns, (ii) reimbursements, rebates, chargebacks, incentives and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations and health care insurance carriers, and (iii) coupons, co-pay cards and similar price reductions and discounts provided to customers;

(b) freight, postage, shipping and insurance expenses to the extent that such items are included in the Invoiced Sales;

(c) customs and excise duties and other duties related to the sales to the extent that such items are included in the Invoiced Sales;

(d) rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority such as, by way of illustration and not in limitation of the Parties’ rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program;

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

14

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(e) sales and other taxes and duties actually paid by Salix and its Affiliates and Sublicensees and directly related to the sale or delivery of the relevant Product (but not including taxes assessed against the income derived from such sale);
(i) in respect of sales outside the United States, deductions in the applicable jurisdiction that are substantially similar to deductions otherwise set forth in clauses (a) through (e), above, but because of local Applicable Law, practices and customs may not conform in terminology to the deductions set forth in the said clauses (a) through (e);

(g) product placement and similar fees paid to pharmacies only in connection with the initial launch of a Product and within [*] [*] [*] of the commencement of such launch; and

(h) any such invoiced amounts that are not collected by Salix or its Affiliates, provided that, to the extent that any uncollected invoiced amount relates to a group of products, the deduction taken for such uncollected amount shall only take into account the share of such uncollected amount fairly allocable to Products;

in each case, as accounted for in accordance with United States generally accepted accounting principles, consistently applied. Any of the deductions listed above that involves a payment by Salix or its Affiliates shall be taken as a deduction in the Quarter in which the payment is accrued by such entity, and if such accrual is reversed a corresponding credit will be made to Net Sales in the Quarter in which the reversal is made. Deductions pursuant to subsection (h) above shall be taken in the Quarter in which such sales are no longer recorded as a receivable. For purposes of the determination of Net Sales, a Product shall be deemed to be sold when invoiced and a “sale” shall not include transfers or dispositions for charitable, promotional, pre-clinical, clinical, regulatory or governmental purposes to the extent no amount is received by Salix or its Affiliates in connection therewith. Without derogation to the foregoing, a “sale” shall include a transfer or other disposition for consideration other than cash, in which case such consideration shall be valued at the fair market value thereof.

For purposes of calculating Net Sales, sales between or among Salix and its Affiliates and Sublicensees shall be excluded from the computation of Net Sales, but sales by Salix and its Affiliates to Third Parties other than Sublicensees shall be included in the computation of Net Sales. For the avoidance of doubt, the preceding sentence shall not apply for purposes of the determination of Sublicense Revenue.

If Salix or its Affiliates should, in a given country during a given accounting period, sell a Product that contains one or more active ingredients in addition to the Compound (which may be

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

either combined in a single formulation or bundled with separate formulations but sold as one product), Net Sales for such combination product shall be calculated by [*]. If, on a country-by-country basis, either the relevant Product, on the one hand, or such other active ingredient or ingredients in the combination product, on the other hand, is, or both of the foregoing are, not sold separately in said country, Net Sales for the purpose of determining royalties of the relevant Product shall be determined by the respective chief financial officers of the Parties in good faith and in a manner consistent with the intent of this Agreement, provided that any matters in dispute with respect thereto shall be reasonably determined by the chief financial officer of [*] in a manner consistent with the intent of this Agreement unless an Expanded Party invokes the procedures set forth in Section 13.12 hereof with respect to such matter.

During the Term, Salix shall not “bundle” a Product for sale together with one or more other products or offer a Product for sale as a “loss leader” to encourage the sale of one or more other product(s) without first reaching an agreement with Progenics, to be negotiated between Progenics and Salix in good faith, in respect of the appropriate allocation, in accordance with Applicable Law, of the gross amount invoiced for such group or bundle of products between the Product and other products in the bundle or group.

No sales of Products that give rise to, or are made pursuant to arrangements involving, Sublicense Revenue that is shared between Salix and Progenics pursuant to Section 6.4(a) shall constitute or be included in Net Sales.

1.85. “New Progenics OIC Product” has the meaning set forth in Section 2.13(a).

1.86. “Non-Debtor Party” has the meaning set forth in Section 10.11.

1.87. “Non-Human Animal Field” means all uses in non-human animals, including the diagnosis, treatment or prevention of diseases or conditions in non-human animals.

1.88. “Notice of Breach” has the meaning set forth in Section 10.2(a).

1.89. “Ono” has the meaning set forth in the Background.

1.90. “Ono Additional Patent Rights” means those Patent Rights under which Ono grants a license to Progenics pursuant to Section 2.6.2 of the Ono Agreement.

1.91. “Ono Agreement” has the meaning set forth in the Background.
1.92. “Ono Collaboration Joint Know-How” means the “Joint Know-How” as such term is defined in the Ono Agreement, as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term, which relates to the Compound or a Product or to the use of the Compound or a Product.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

1.93. “Ono Collaboration Joint Patent Rights” means the “Joint Patent Rights” as such term is defined in the Ono Agreement, as and to the extent such rights subsist and as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term, which relate to the Compound or a Product or to the use of the Compound or a Product.

1.94. “Ono Collaboration Know-How” means the “Ono Collaboration Know-How” as such term is defined in the Ono Agreement, as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term, which relates to the Compound or a Product or to the use of the Compound or a Product.

1.95. “Ono Collaboration Patent Rights” means the “Ono Collaboration Patent Rights” as such term is defined in the Ono Agreement, as and to the extent such rights subsist and as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term, which relate to the Compound or a Product or to the use of the Compound or a Product.

1.96. “Ono Independent Patent Rights” means the “Ono Independent Patent Rights” as such term is defined in the Ono Agreement.

1.97. “Oral Product” means any Product that is formulated to be administered orally for use in the Human Field.

1.98. “[*]” has the meaning set forth in Section [*].

1.99. “Other Product” has the meaning set forth in Section 1.168.

1.100. “Outside Contractor” means any Person contracted by Salix or Progenics or an Affiliate or Sublicensee thereof to provide products or services relating to the Collaboration, including contract manufacturing services, clinical services or regulatory services that contribute to the performance of its responsibilities under the Development Plan or that result in any work product or other information that Progenics or Salix or such Affiliate or Sublicensee could include or might reasonably be expected to include in any document or report, including, a Registrational Filing, submitted to a Regulatory Authority or subject to review by a Regulatory Authority.

1.101. “Partial Termination Agreement” has the meaning set forth in the Background.

1.102. “Party” and “Parties” have the meaning set forth in the first paragraph hereof.

1.103. “Patent Rights” means (a) all national, regional and international patent applications, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, and all international equivalents thereof, (b) all national, regional and international patents, including utility models, petty patents and design patents and certificates of invention, (c) any and all extensions or restorations of patents

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1.104. “Patent Term Extension” shall mean any extension of Patent Rights that may be granted by any patent office or regulatory office, including supplemental protection certificates (“SPCs”).

1.105. “Person” means any individual or legal entity.

1.106. “Phase 4 Clinical Trial” means, in respect of a pharmaceutical product, product support clinical trials of the product not for the purpose of obtaining Regulatory Marketing Approval of the product, whether such clinical trials are commenced before or after receipt of Regulatory Marketing Approval of the product.

1.107. “Product” means a pharmaceutical product containing the Compound, whether alone or in combination with other APIs or other substances and whether formulated to be administered subcutaneously, intravenously, orally or otherwise. A Product shall be considered...
separate from another Product if, in order to obtain Regulatory Marketing Approval for such second Product, the applicant is required to submit Clinical Data not submitted or required to be submitted in order to obtain Regulatory Marketing Approval for the first Product.

1.108. “Product Information” has the meaning set forth in Section 8.1(a).

1.109. “Product Labeling” means, with respect to a particular pharmaceutical product and a particular country, (a) the full prescribing information for the product approved by the applicable Regulatory Authorities in such country, including any required patient information; and (b) all labels and other written, printed or graphic matter physically upon a container, wrapper or any package insert utilized with or for the product in such country.

1.110. “Product Trademarks” means the Trademarks, including all product packaging and other trade dress, and all copyrights relating thereto and therein, used, held for use or intended for use on or in connection with the Development and Commercialization of Products.

1.111. “Progenics” has the meaning set forth in the first paragraph hereof.

1.112. “Progenics Indemnified Party” has the meaning set forth in Section 11.1.

1.113. “Progenics Know-How” means Know-How as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term which relates to the Compound or a Product or to the Manufacture, use, sale, Development or Commercialization of the Compound or a Product. For the purposes hereof, Progenics Know-How does not include Wyeth Collaboration Know-How, Wyeth Collaboration Joint Know-How, Ono Collaboration Know-How, Ono Collaboration Joint Know-How, Salix Collaboration Know-How, Progenics’s interest in Joint Know-How, or Know-How Controlled by a Third Party that becomes an Affiliate of Progenics pursuant to a transaction or series of related transactions as a result of which such Third Party is able to elect a majority of the members of the board of directors of Progenics (or its successor company) or any of its Controlling Affiliates (a “Controlling Third Party”) to the extent such Controlling Third Party’s Know-How was Controlled by such Controlling Third Party (and not by Progenics) prior to the completion of such transaction or series of related transactions.

1.114. “Progenics Party” and “Progenics Parties” have the meaning set forth in the first paragraph hereof.

1.115. “Progenics Patent Rights” means any Patent Right as and to the extent subsisting and as and to the extent Controlled by Progenics or its Affiliates as of the Effective Date or at any time during the Term having issued claims that, or pending claims that if issued, would be infringed by an unlicensed Third Party’s Manufacture, use, sale, importation, Development or Commercialization of the Compound or any Product. For the purposes hereof, the Progenics Patent Rights include the [*] Patent Rights, the [*] Patent Rights and the [*] Patent Rights, and shall continue to include such Patent Rights even if the underlying Third Party Agreement by which Progenics obtains any such Patent Rights is assigned to Salix or to a Salix Affiliate. For the avoidance of doubt, the calculation of the Royalty Period shall not be affected by such an assignment of any such Third Party Agreement. For the purposes hereof, “Progenics Patent Rights” does not include Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Patent Rights, Ono Collaboration Joint Patent Rights, Progenics’s interest in Joint Patent Rights or Patent Rights Controlled by a Controlling Third Party to the extent such Controlling Third Party’s Patent Rights were Controlled by such Controlling Third Party (and not by Progenics) prior to the completion of the transaction or series of related transactions through which a Third Party became such Controlling Third Party. Progenics Patent Rights in the Territory as of the Effective Date are identified on Schedule 9.2(a)(i).


1.117. “Progenics Third Party Agreement” means any agreement in effect as of the Effective Date (a) under which any Progenics Party or any of its Affiliates is granted any license or otherwise has any rights or interests under or in respect of any Licensed Technology or (b) that relates to the Manufacture, Development, or Commercialization of the Compound or any Product in the Territory, including the agreements listed in Schedule 9.2(a)(ii).

1.118. “Promotional Materials” means, with respect to a particular pharmaceutical product, all [*] materials with respect to the product and all [*] or [*] matter, including [*] and [*] and [*] and [*] (for example, [*] and other such items) intended for use or used in connection with any promotion of the product, except Product Labeling.

1.119. “ProNev” has the meaning set forth in the first paragraph hereof.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.
1.120. “Quarter” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

1.121. “Quarterly Activity Report” has the meaning set forth in Section 6.6(b).

1.122. [*].

1.123. “Recall” means, with respect to any pharmaceutical product, a “recall” or a “product withdrawal” or a “stock recovery” or any similar term as utilized by any Regulatory Authority under such Regulatory Authority’s procedures regarding the recall of pharmaceutical products, as the same may be amended from time to time, and shall include any post-sale warning or mailing of information regarding such product, including any warnings or mailings described in the Regulatory Authority’s product recall procedures.

1.124. “Receiving Party” has the meaning set forth in Section 8.2.

1.125. “Registrational Filing” means an application submitted to a Regulatory Authority seeking a Regulatory Marketing Approval.

1.126. “Regulatory Approval” means, in respect of a particular country, the technical, medical and scientific licenses, registrations, authorizations and approvals of any Regulatory Authority necessary for the Development, clinical testing, Manufacture, distribution, marketing, promotion, offering for sale, use, import, export, sale or other Commercialization of a drug product in such country, including INDs, NDAs, Biologic License Applications, Registrational Filings, supplements and amendments, pre- and post- approvals, Drug Price Approval, drug naming approvals, Product Labeling approvals, and drug master files.

1.127. “Regulatory Authority” means, with respect to a particular country, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Agency for the Evaluation of Medicinal Products), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity involved in the granting of a Regulatory Approval for such country.

1.128. “Regulatory Documentation” means, in respect of a particular drug product, (a) the trial master file and all regulatory files relating to the Development, Regulatory Approval, Manufacture or Commercialization of the product, including any licenses (to the extent transferable), minutes of meetings and telephone conferences with any Regulatory Authorities, validation data, preclinical and clinical studies and tests related to the product (including all audit reports of clinical studies and all other Clinical Data), all applications (and amendments thereto) for Regulatory Approvals, annual reports and safety reports associated therewith, and all correspondence with Regulatory Authorities regarding the marketing status of the product; and (b) all records maintained under cGMP or other Applicable Law, including record keeping or reporting requirements of Regulatory Authorities, all correspondence and communications with Regulatory Authorities in connection with the product, including those relating to any Product Labeling or Promotional Materials, adverse event files, complaint files or manufacturing records.

1.129. “Regulatory Marketing Approval” means, in respect of a particular country, a Regulatory Approval authorizing the marketing of a drug product in such country for any indication. For the sake of clarity, Regulatory Marketing Approval (a) shall be deemed to have occurred when (i) the Regulatory Authority sends a notification of such Regulatory Marketing Approval to the applicant seeking Regulatory Marketing Approval or, (ii) if Applicable Law provides for authorization for the marketing of a drug product by an action or event other than a notification, then when such action or event has been taken or occurred, and (b) shall not require that Drug Price Approval or any other Regulatory Approval has occurred.

1.130. “Related Agreements” has the meaning set forth in Section 13.6.

1.131. “RELISTOR Marks” has the meaning set forth in Section 9.2(m).

1.132. “Royalty Period” means, with respect to any particular Product in any particular country, the period of time beginning with the [*] and extending until the later of (a) the expiration of the last to expire of any Valid Claim included in any [*] which, in any such case, would be infringed by an unlicensed Third Party’s Manufacture, use, sale, importation, Development or Commercialization of such Product in the Field in such country; (b) the date on which there is no marketing exclusivity right with respect to the Product [*]; and (c) the fifteenth (15th) anniversary of the First Commercial Sale [*]; provided, however, that notwithstanding the foregoing, the period set forth in this clause (c) with respect to any particular Product in any particular country shall terminate effective as of the first day of any Quarter in which either
(i) (A) one or more Persons other than Salix or Salix’s Affiliates or Sublicensees sell one or more Unauthorized Generic Products in respect of such Product in such country, and (B) the unit sales of such Unauthorized Generic Product(s) in such country during such Quarter amount in the aggregate to more than [*] percent ([*]%) of the Unauthorized Generic Product Market in such country for the relevant Product (excluding, for purposes of this clause (i) only, clause (b) from the definition of “Unauthorized Generic Product Market”); or

(ii) (A) one or more Persons other than Salix or Salix’s Affiliates or Sublicensees sell one or more Unauthorized Generic Products in such country that would be included in the determination of the Unauthorized Generic Product Market for the relevant Product in such country, and (B) the unit sales of such Unauthorized Generic Product(s) in such country during such Quarter amount in the aggregate to more than [*] percent ([*]%) of the Unauthorized Generic Product Market in such country for the relevant Product; or

but shall resume, in the case where termination was triggered pursuant to clause (i), if Progenics demonstrates to the reasonable satisfaction of Salix, using independent data from IMS or Wolters Kluwer or such similar organization reporting pharmaceutical sales information as the Parties may agree, that the unit sales of such Unauthorized Generic Product(s) in respect of such Product in such country have fallen below [*] percent ([*]%) of the Unauthorized Generic Product Market in such country for the relevant Product for at least [*] [*] consecutive [*] or, in the case where termination was triggered pursuant to clause (ii), if Progenics demonstrates to the reasonable satisfaction of Salix, using independent data from IMS or Wolters Kluwer or such similar organization reporting pharmaceutical sales information as the Parties may agree, that the unit sales of such Unauthorized Generic Product(s) in respect of such Product in such country have fallen below [*] percent ([*]%) of the Unauthorized Generic Product Market in such country for the relevant Product for at least [*] [*] consecutive [*]. If the period set forth in this clause (c) resumes pursuant to the proviso clause in the preceding sentence, then such resumption shall occur effective as of the date (either during or after such [*] [*] period) on which Salix receives notice from Progenics that the requirements for resumption as set forth in such proviso clause have been satisfied.

By way of example, if during a Quarter in country X:

[*].

1.133. “Safety Agreement” has the meaning set forth in Section 12.7.

1.134. “Salix” has the meaning set forth in the first paragraph hereof.

1.135. “Salix COGs” has the meaning set forth in Schedule 1.135.

1.136. “Salix Collaboration Know-How” means any Know-How relating to the Compound or any Product, as and to the extent Controlled at any time during the Term by Salix or its Affiliates (as determined in accordance with Section 7.1(a)), that is made or created in the course of and arising out of the Collaboration solely by employees or agents of Salix or any of its Affiliates or Sublicensees.

1.137. “Salix Collaboration Patent Rights” means any Patent Right, as and to the extent subsisting and as and to the extent Controlled at any time during the Term by Salix or its Affiliates, that claims inventions made solely by employees or agents of Salix or any of its Affiliates or Sublicensees (as determined in accordance with Section 7.1(a)) in the course of and arising out of the Collaboration that, if issued, would be infringed by an unlicensed Third Party’s Manufacture, use, sale, importation, Development or Commercialization of the Compound or any Product.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.


1.139. “Salix Competitor” means any of those companies set forth in Schedule 1.139, and their successors.

1.140. “Salix Indemnified Party” has the meaning set forth in Section 11.2.

1.142. “Salix Non-Defaulting Termination” has the meaning set forth in Section 13.22(b).

1.143. “SEC” has the meaning set forth in Section 8.4.

1.144. “[ ]” has the meaning set forth in Section [ ].

1.145. “SPC” has the meaning set forth in the definition of Patent Term Extension.

1.146. “Specified Product” has the meaning set forth in Section 1.168.

1.147. “Subject Agreements” means the [ ] Agreement, the [ ] Agreement and related agreements, the [ ] Agreement, and the [ ] Agreement.

1.148. “Subject Country” has the meaning set forth in Section 9.2(n)(iv).

1.149. “Subject Documentation” has the meaning set forth in Section 9.2(n)(i).

1.150. “Subject Law” has the meaning set forth in Section 9.2(n)(iv).

1.151. “Sublicense” means, directly or indirectly, to sublicense, grant any other right with respect to, or agree not to assert, any right licensed to Salix under this Agreement. When used as a noun, “Sublicense” means any agreement to Sublicense.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

23

1.152. “Sublicense Revenue” means all payments directly or indirectly by or on behalf of a Sublicensee to Salix or its Affiliates relating to, or resulting from, in either case directly or indirectly, an arrangement respecting any one or more of a Sublicense or Compound or Product or sales thereof, including (a) all upfront and other payments payable to Salix upon execution of a Sublicense with a Sublicensee in respect of Salix’s rights hereunder; (b) all development, regulatory, commercialization or other milestone payments for milestones under any such Sublicense; (c) all license maintenance fees under any such Sublicense; (d) all payments to Salix for the supply of Products; (e) all payments to Salix under any such Sublicense for the reimbursement of research and development costs incurred by Salix; (f) the fair market value of any equity securities issued in respect of any such Sublicense to Salix that exceeds any amount paid by Salix for such securities; (g) the amount by which any amount paid by a Sublicensee to Salix for equity securities issued to such Sublicensee in respect of any such Sublicense exceeds the fair market value of such equity securities; (h) all royalties, profit share payments and other payments based on the sales of Products; and (i) the fair market value of any other form of consideration paid to Salix by a Sublicensee for a Sublicense granted by Salix pursuant to this Agreement, but excluding in all cases Salix COGs to procure or Manufacture Products for which payments under clause (d) above are made to Salix and Salix’s actual cost to perform activities in and specifically for the sublicensed territory for which payments under clause (e) above are made to Salix. The amount of Sublicense Revenue for any Quarter shall be reduced by any amount of Sublicense Revenue previously received by Salix that Salix is required to return or refund to the payor thereof during such Quarter.

1.153. “Sublicense Revenue Report” has the meaning set forth in Section 6.6(b).

1.154. “Sublicensee” means any Third Party who is granted a Sublicense.

1.155. “Sued Party” has the meaning set forth in Section 7.4(d).

1.156. “Term” has the meaning set forth in Section 10.1.

1.157. “Termination Agreement” has the meaning set forth in the Background.

1.158. “Territory” means the entire world, excluding, subject to the provisions of Section 2.12, Japan.

1.159. “Third Party” means any Person other than Salix, the Progenics Parties or their respective Affiliates.

1.160. “Third Party IP Rights” has the meaning set forth in Section 7.4(b).

1.161. “Third Party License” has the meaning set forth in Section 6.5(d).

1.162. “Title 11” shall have the meaning set forth in Section 10.11.

1.163. “Trademark” means any trademark, service mark, trade name, trade dress, brand name, product shape, logo, slogan, design, design rights, or any other similar designation of source or origin, whether or not registered, and all statutory and common law rights therein and registrations and applications therefor, together with all goodwill symbolized by any of the foregoing.
1.164. “Trademark Countries” has the meaning set forth in Section 9.2(m)(ii).

1.165. “Transition Agreement” has the meaning set forth in Section 5.2(a).

1.166. “[*]” has the meaning set forth in Section [*].

1.167. “Unauthorized Generic Product” means, with respect to any Product, on a Product-by-Product basis, a pharmaceutical product (other than the Product itself) sold by an unlicensed Third Party that contains the Compound and gains Regulatory Marketing Approval for one of the same indications as such Product without de novo evidence of safety and efficacy, such as through an abbreviated new drug application as defined in 21 U.S.C. 355(j) or an application submitted pursuant to 21 U.S.C. 355(b)(2) (or their equivalent outside the United States).

1.168. “Unauthorized Generic Product Market” means, for any Quarter with respect to any Product in any country in the Territory (the “Specified Product”), [*]. Unauthorized Generic Product sales shall be determined using independent market data (where available) published by IMS, Wolters Kluwer or such similar organization reporting pharmaceutical sales information as the Parties may agree.

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

1.170. “University of Chicago” has the meaning set forth in Section 2.4(a).

1.171. “UR Labs” has the meaning set forth in Section 13.22.

1.172. “UR Labs-Progenics Agreement” has the meaning set forth in Section 13.22.

1.173. “Valid Claim” means, with respect to a particular Product and country, a claim of a patent application or an issued and unexpired patent that has not lapsed, been canceled or become abandoned or been held unpatentable, revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal (except, in both cases, to the United States Supreme Court or any similar court of final appeal that hears matters at its discretion in a jurisdiction other than the United States), and that has not been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. If a claim of a pending patent application has not issued as a claim of an issued patent within [*] ([*]) years after the earliest priority date for such claim, then such claim shall cease to be a Valid Claim unless and until such claim becomes an issued claim of an issued patent.

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25
2. LICENSE GRANTS AND RELATED MATTERS

2.1. License from Progenics to Salix. Subject to the terms and conditions of this Agreement, the Progenics Parties hereby grant to Salix, and Salix hereby accepts in respect of the Licensed Technology and the Progenics Parties’ interest in the Joint Technology:

(a) the exclusive license, even as to the Progenics Parties and their Affiliates, with the right to grant Sublicenses in accordance with Section 2.2, (i) to Develop the Compound and Products in the Territory for use and Commercialization in the Field in the Territory and (ii) to Commercialize Products in the Field in the Territory;

(b) a non-exclusive license, with the right to grant Sublicenses in accordance with Section 2.2, to Manufacture or have Manufactured in the Territory (i) Products for use or Commercialization by Salix and its Sublicensees under the license granted under Section 2.1(a) and (ii) Compound for incorporation into such Products.

Salix acknowledges that with respect to any Progenics Technology and any of the Progenics Parties’ rights in the Wyeth Collaboration Joint Patent Rights, the Wyeth Collaboration Joint Know-How, the Wyeth Collaboration Patent Rights, the Wyeth Collaboration Know-How, the Ono Collaboration Joint Patent Rights, the Ono Collaboration Joint Know-How, the Ono Collaboration Patent Rights, the Ono Collaboration Know-How, the Wyeth Additional Licensed Rights, and the Ono Additional Patent Rights that are Controlled by the Progenics Parties pursuant to Progenics Third Party Agreements, the license granted in this Section 2.1 is subject to the rights of the Third Party licensors under such Progenics Third Party Agreements.

Subject to the terms and conditions of this Agreement, Progenics retains the non-exclusive, non-transferable, non-licensable right under the Progenics Technology and Joint Technology solely to make, have made, import, export and use the Compound and Develop the Compound and Products in the Field in the Territory.

2.2. Sublicenses.

(a) The licenses granted to Salix in Section 2.1 shall include the right to grant Sublicenses through multiple tiers of Sublicensees (i) in the Human Field in the Territory other than the United States and (ii) in the Non-Human Animal Field in the Territory. In order to facilitate the operation of the provisions of Section 6.4, Salix agrees that it will not “bundle” a Product for Sublicensing with one or more other products that are not Products or offer a Product for Sublicensing to encourage the licensing or sublicensing by the Sublicensee of one or more products that are not Products without first reaching an agreement with Progenics, to be negotiated between Progenics and Salix in good faith, in respect of the appropriate allocation, in accordance with Applicable Law, the definition of “Sublicense Revenue,” and Section 6.4, of the gross amount to be received by Salix under any such arrangement between the Product and other products in the bundle or group.

(b) Salix shall, to the extent practical, inform Progenics reasonably in advance of the execution of any Sublicense that Salix expects to grant under this Agreement in respect of a Major Market Country or [*] or [*] and shall promptly (and, in the case of material items, within [*] ([*]) Business Days) provide to Progenics (i) notice of any Sublicense granted by Salix under this Agreement setting forth in reasonable detail the nature of such Sublicense and the identity of the Sublicensee and (ii) unredacted English-language copies of any agreement with a Third Party granting such Sublicense.

(c) Each Sublicense entered into by Salix shall contain (i) confidentiality, exclusivity, reporting and access to data and information obligations comparable to those set forth herein as and to the extent relevant to the exercise by Progenics of its rights hereunder, and (ii) provisions adequate to ensure that (A) neither of the Parties will be precluded during or after the Term from Manufacturing, Developing and Commercializing the Compound or Products as contemplated hereby pursuant to the Licensed Technology and the licenses granted pursuant hereto as a result of any invention, development or discovery, as and to the extent Controlled by the Sublicensor or its Affiliates, that is made or created in the course of or arising out of Manufacturing, Development and Commercialization activities of the Sublicensee or any of its Affiliates or Sublicensees under the relevant Sublicense, (B) the Progenics Parties shall have the benefit of all indemnification rights, if any, provided to Salix under such Sublicense, (C) the amount of Sublicense Revenue in respect of such Sublicense paid to Progenics pursuant to Section 6.4 shall at no time be less than the amount, if any, Progenics or an Affiliate is required to pay as royalties in respect of sales of Products pursuant to such Sublicense to the University of Chicago under the 1985 Agreement and to [*]’s heirs under the [*] Agreement (as such agreements exist on the Effective Date), and (D) Progenics will be provided or have access to net sales information in respect of sales of Products pursuant to such Sublicense.
2.5. License from Salix to Progenics. Salix hereby grants to Progenics an exclusive, perpetual, irrevocable, royalty-free, fully paid-up license under the Salix Collaboration Patent Rights and the Salix Collaboration Know-How, and an exclusive, perpetual, irrevocable, royalty-free, fully paid-up license under Salix’s interest in the Joint Patent Rights and Salix’s interest in the Joint Know-How, in each case with a right to sublicense, to research, make, have made, use, Develop, sell, offer to sell or use, have sold, market, promote, import, export, or otherwise Commercialize the Compound or any Products outside the Field or outside the Territory, without any compensation or royalty relating thereto. Progenics shall timely notify Salix of any sublicenses. An agreement with any sublicensee shall provide that such sublicense is consistent with and subject to the material terms and conditions of this Agreement, including without limitation the material obligations of Progenics hereunder.

2.6. Enforcement of Non-Assertion of Rights Covenants. Each Progenics Party shall cooperate with Salix and take such actions as Salix may reasonably request, and Salix shall reimburse each Progenics Party’s reasonable costs resulting from actions so requested, as may be necessary to permit Salix to exercise, for the benefit of Salix and its Affiliates and Sublicensees, the Progenics Parties’ rights (a) under the Termination Agreement to prevent Wyeth from asserting any Wyeth Independent Patent Rights against the Progenics Parties or any of their licensees and (b) under the Ono Agreement to prevent Ono from asserting any Ono Independent Patent Rights against the Progenics Parties or any of their licensees. For the avoidance of doubt, this Section 2.6 shall require the Progenics Parties to consent to be joined, with the Progenics Parties’ reasonable costs to be reimbursed by Salix, as a party to any action required to enforce the rights identified in the preceding sentence, but shall not obligate any Progenics Party to indemnify or defend Salix in respect of any such action.

(d) Salix hereby guarantees the performance of its Sublicensees and shall remain responsible to Progenics for full compliance with the terms of this Agreement, including all diligence, payment and reporting obligations. No Sublicense granted by Salix hereunder shall relieve Salix of any of its obligations under this Agreement.

(e) The Parties agree that appointment by Salix of any bona fide pharmaceutical wholesalers or providers of pharmaceutical distribution services shall not constitute a sublicense for purposes of this Section 2.2.

2.3. Direct Licenses to Affiliates. Salix may at any time request and authorize Progenics to grant licenses in respect of the rights licensed to Salix in Section 2.1 (including the

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28

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right to Sublicense as set forth in Section 2.2) directly to wholly owned Affiliates of Salix by giving notice designating to whom a direct license is to be granted. Upon receipt of any such notice, Progenics shall enter into and sign a separate direct license agreement with such designated Affiliate of Salix. All such direct license agreements shall be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by Applicable Law; provided, however, that Progenics shall have no obligation to enter into any such direct license agreement if the effect of entering into such agreement (and continuing as a Party to this Agreement) would be to increase the level of obligations owed by or risks assumed by Progenics, or decrease the consideration owed to Progenics, relative to the obligations owed by, risks assumed by, or consideration owed to Progenics under this Agreement or otherwise adversely affect Progenics. In countries where validity of the direct license agreement requires governmental approval or registration, such direct license agreement shall not become binding between the parties thereto until such approval or registration is granted, which approval or registration shall be obtained by Salix. All costs of making a direct license, including Progenics’s reasonable attorneys fees, under this Section 2.3 shall be borne by Salix. Salix shall be responsible to Progenics for the performance of its Affiliates under such direct licenses.

2.4. Certain Matters Relating to the University of Chicago.

(a) The Parties hereby acknowledge that, pursuant to that certain [*] dated as of [*] by and among the University of Chicago, on behalf of itself and its affiliate ARCH Development Corporation (the “University of Chicago”), and [*] shall (i) [*] and (ii) if [*].

(b) The Parties hereby acknowledge that [*]. The Parties further acknowledge that, pursuant to Section [*] of the [*] and Section [*] of the [*].
2.7. Non-Assertion of Progenics’s Rights; Non-Exclusive License Grant; Non-Assertion by Salix.

(a) Non-Assertion of Progenics’s Rights. Progenics shall not, and shall cause its Affiliates not to, bring any action asserting that the exercise by Salix, its Affiliates or Sublicensees of the rights granted by Progenics to Salix under this Agreement infringes or would infringe any Patent Rights Controlled by Progenics or its Affiliates.

(b) Non-Exclusive License from Salix to Progenics. In the event that the exercise by Progenics, its Affiliates, licensees (including Ono), or sublicensees of the rights granted by Salix in Section 2.5 would infringe any Patent Rights Controlled by Salix or its Affiliates, and which Patent Rights are not covered by the grant in Section 2.5, Salix hereby grants to Progenics, its Affiliates, licensees and sublicensees to the extent Salix is legally able to do so, a non-exclusive, sublicensable, royalty-free license outside the Territory under such Patent Rights solely to the extent necessary for Progenics, its Affiliates, licensees and sublicensees to exploit the rights granted to Progenics and its Affiliates under Section 2.5.

(c) Non-Assertion by Salix. Salix shall not assert any Salix Independent Patent Rights against Progenics, its Affiliates or its licensees or sublicensees relating to the Development, Commercialization or other exploitation of the Compound or any product containing the Compound outside the Territory or outside the Field.

2.8. Fully Paid-Up, Royalty Free License. After expiration of the Royalty Period for any Product in a particular country, the license granted to Salix under Section 2.1 with respect to such Product in such country shall be a fully paid-up, perpetual, non-exclusive, irrevocable, royalty-free license.

2.9. Know-How Disclosure and Transfer.

(a) By Progenics. Commencing immediately after the Effective Date, Progenics shall as promptly as reasonably practicable disclose the then-existing Licensed Know-How in its Control to Salix. During the Term, Progenics shall promptly disclose to Salix all Licensed Know-How and Joint Know-How, in each case that is developed by Progenics or otherwise comes into Progenics’s Control. Disclosure of Know-How by Progenics as provided in this Section 2.9(a) shall be accomplished through: (i) the transfer of [*] and [*]; and (ii) the delivery of [*] and [*]. In addition, Progenics shall use Commercially Reasonable Efforts to cause Wyeth and Ono to provide, for delivery to Salix, relevant [*] and [*]. The provisions of this Section 2.9 are in addition to, and not by way of limitation of, the provisions of the Transition Agreement.

(b) By Salix. During the Term, Salix shall promptly disclose to Progenics any Joint Know-How and Salix Collaboration Know-How.

2.10. Costs of Assistance. Each Progenics Party shall perform the activities it is required to perform under Sections 2.6 and 2.9(a), Article 3, Sections 4.5 and 4.6, Section 5.2(c) and (d) and Articles 7 and 12, except as otherwise specifically provided therein, at no charge to Salix. If Salix requests that a Progenics Party perform any other activities in connection with the Collaboration or the Commercialization and Development of the Compound or any Product, then Salix shall reimburse the applicable Progenics Party for any and all costs the Progenics Party incurs, including out-of-pocket costs (including travel) and personnel costs at the FTE Rate. Salix shall reimburse the applicable Progenics Party for such costs within [*] (‘[*]’ days of Salix’s receipt of an invoice therefor accompanied by reasonable documentation. Salix shall have no obligation to reimburse any Progenics Party for any costs that may be incurred by the Progenics Parties or their Affiliates in respect of any activity, whether or not relating to the Collaboration, that is not specifically requested by Salix in writing.

2.11. No Implied Rights. Except as expressly provided in this Agreement, neither Party shall be deemed to have granted the other Party any license or other right with respect to any intellectual property of such Party.

2.12. Japan. Provided that Salix is at such time in compliance in all material respects with its obligations under this Agreement, in the event that at any time the Ono Agreement should terminate or be modified with the result that rights in respect of the Development, Commercialization or Manufacture of Products in Japan licensed or otherwise granted by Progenics to Ono pursuant to the Ono Agreement revert to or otherwise come to be Controlled, directly or indirectly and in any manner whatsoever, by Progenics or its Affiliates, then the terms of this Agreement shall automatically, without further action by either Party and without any further payment by or on behalf of Salix, be, and they are hereby, amended to expand and extend the license grants, territory and other rights of Salix set forth in this Agreement to cover and include the license grants, territory and other rights so reverting to or otherwise coming to be Controlled, directly or indirectly, by Progenics or its Affiliates. In connection with any acquisition by Salix of rights in respect of Japan pursuant to this Section 2.12, Progenics shall use its good faith efforts to ensure the transfer and conveyance to Salix of all such rights in Regulatory Approvals, trademarks, trade names and similar intellectual property rights, rights under Third Party agreements relating to Products or their Development, Commercialization or Manufacture, and Clinical Data, Know-How and other information relating to Products, in each case relating to Japan, which Progenics may Control or have the right to transfer or assign or with respect to which Progenics may reasonably be able to obtain Control or the right to transfer or assign.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.
2.13. Other Progenics Products.

(a) New Progenics Opioid-Induced Constipation Product. Progenics agrees that, in the event it or any of its Affiliates desires to grant a license or similar right to a Third Party in respect of any product or compound (other than the Compound or Products) that is Developed, or that Progenics or any of its Affiliates intends to Develop or Commercialize or permit to be Developed or Commercialized, in respect of the diagnosis, treatment or prevention of opioid-induced constipation (a "New Progenics OIC Product"), Salix shall have a right of first negotiation with respect to such license, as follows:

(i) Progenics shall not, and shall cause its Affiliates not to, enter into any agreement or other legally binding arrangement with any Third Party in respect of the grant of a license or other right by Progenics or any of its Affiliates to permit the Development or Commercialization of a New Progenics OIC Product without first having complied with the provisions of this Section 2.13.

(ii) In the event Progenics or any of its Affiliates should propose to grant any such license or other right, Progenics shall notify Salix of the proposed grant (the "License Notice"). Salix may exercise its right of first negotiation in respect of such proposed grant by means of notice given to Progenics within [*] [*] days of the date of the License Notice.

(iii) In the event Salix provides timely notice of its exercise of its right of first negotiation, then for a period of [*] [*] days beginning on the date of the License Notice, the Parties shall negotiate in good faith in respect of the terms upon which the proposed license might be granted by Progenics to Salix. During such [*] [*] day period, Progenics shall negotiate exclusively with Salix and shall not pursue negotiations with, nor provide information regarding the licensing opportunity to, any other Person.

(iv) If (A) Salix does not provide timely notice of its exercise of its right of first negotiation or (B) the Parties are unable to conclude an agreement in respect of such license during the [*] [*] day period specified in Section 2.13(a)(iii) and, in the case of this clause (B), Salix does not notify Progenics that it wishes to continue negotiations with Progenics, Progenics shall then be free to pursue and enter into agreements with Third Parties and Salix shall have no further rights in respect of such New Progenics OIC Product.

(v) If the Parties do negotiate pursuant to Section 2.13(a)(iii) but are unable to conclude an agreement in respect of such license during the [*] [*] day period specified in Section 2.13(a)(iii) and Salix notifies Progenics that it wishes to continue negotiations with Progenics, Progenics shall then be free to pursue and enter into agreements with Third Parties and Salix shall have no further rights in respect of such New Progenics OIC Product.

(b) Other New Progenics Products. Progenics agrees that, if at any time prior to a Change in Control of Salix, Progenics or any of its Affiliates desires to grant a license or similar right to a Third Party in respect of any product or compound (other than the Compound or Products) that is not a New Progenics OIC Product, it shall provide Salix with notice and information in respect of such product or compound reasonably in advance of granting such license or similar right to a Third Party and, at Salix’s request, shall provide Salix with an opportunity to propose and discuss a potential licensing or collaboration arrangement between Progenics and Salix in respect of such product or compound. Nothing in this clause (b) shall obligate Progenics to enter into any agreement with Salix in respect of any product or compound addressed hereby or condition or delay Progenics’s right to pursue discussions with any other Person in respect of a license or similar right in respect of any product or compound as to which it may have provided a notice to Salix hereunder.

3. GOVERNANCE OF COLLABORATION

3.1. Joint Committees.

(a) Creation. Within [*] [*] days following the Effective Date, the Parties shall establish a Joint Steering Committee ("JSC") to oversee, review and coordinate the Development, Manufacture and Commercialization of Products in the Territory and a Joint Development Committee ("JDC") to oversee, review and coordinate the Development of Products in the Territory (each of the JSC and JDC, a "Committee", and collectively, the "Committees"). The Committees shall serve solely as a forum for the regular exchange of information between the Parties and shall have no authority to bind, or limit the rights of, either Party.
(b) Functions of JSC. Without limiting Section 3.1(a) or any other functions the Parties agree to delegate to the JSC, the JSC shall:

(i) consider [*];

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

(ii) review [*] and [*];

(iii) review and approve [*] and [*], and seek to [*];

(iv) discuss and approve [*] and [*];

(v) review [*];

(vi) discuss and analyze any [*] or [*];

(vii) decide whether [*];

(viii) establish [*] or [*];

(ix) discuss and consider from time to time as appropriate [*]; and

(x) otherwise facilitate [*] between [*].

(c) Functions of JDC. Without limiting Section 3.1(a) or any other functions the Parties agree to delegate to the JDC, the JDC shall:

(i) establish [*];

(ii) review [*];

(iii) review and discuss [*];

(iv) review and approve [*];

(v) review [*];

(vi) establish [*];

(vii) if the JSC determines it is advisable to [*], establish [*];

(viii) facilitate the exchange of [*];

(ix) support [*]; and

(x) provide [*].

3.2. Membership. Each of the JSC and JDC shall be comprised of [*] ("[*]") representatives from each of Salix and Progenics, selected by such Party. Each of Salix and Progenics may replace either or both of its representatives on such Committees at any time by providing prior notice to the other Party. Other representatives of Salix or Progenics may attend.

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3.3. Committee Meetings. Each Committee shall meet (a) quarterly until [*] ("[*]" after the Effective Date and thereafter [*] and (b) as otherwise determined by the chairperson. Such meetings shall be joint meetings of the Committees if so requested by the chairperson, and shall be conducted in person or by videoconference or teleconference. In-person meetings shall [*]. A quorum of the Committee shall exist whenever there is present at or participating in a meeting at least one representative appointed by each Party. Each Party shall bear its own personnel and
travel costs and expenses relating to Committee meetings. Each Committee shall follow such other administrative procedures as it may adopt for the efficient conduct of its meetings and other matters.

3.4. Committee Officers; Minutes.

(a) Salix shall select one of its representatives on each Committee to be the chairperson of such Committee. The chairperson shall call meetings of the Committee no less frequently than contemplated by Schedule 3.3, prepare and circulate an agenda for each meeting reasonably in advance (have due regard to any relevant circumstances) of such meeting, and chair all meetings of the Committee. The chairperson may, in his or her absence, delegate responsibility for chairing meetings of the Committee to the other Salix representative on such Committee.

(b) Progenics shall select a secretary to prepare and circulate the meeting agendas and minutes. Such minutes shall be distributed in draft form not later than [*] [*] days following each meeting and shall be deemed accepted and effective unless Salix has objected to the same within [*] [*] days of its receipt of such minutes. Any such objection shall be noted in the minutes. Final minutes shall be promptly distributed to the Parties.

3.5. Decision-Making.

(a) For the avoidance of doubt, neither Committee shall have the power to amend the terms of this Agreement, which amendment may occur only in compliance with the procedures set forth in Section 13.7.

(b) The members of each Committee shall endeavor to reach a consensus on all decisions within its jurisdiction. All official actions, decisions or rulings of each Committee must be made by a consensus of the members of the Committee or in a writing signed by at least one Committee representative of each Party.

(c) If the members of either Committee cannot reach consensus with respect to any action, decision or ruling within [*] [*] days (or such shorter time as may be reasonable under the circumstances) following the day that such Committee first considers such matter, then the issue shall be finally and definitively resolved by the chairperson of such Committee; provided, however, that in the event that the matter for which consensus is not reached relates to an action or proposed amendment of the Commercialization Plan or the Development Plan that would have the effect of making the Commercialization Plan inconsistent with the Initial Commercialization Outline or the Development Plan inconsistent with the Initial Development Outline, as applicable, then the issue shall not be finally and definitively resolved by the chairperson but instead shall be finally and definitively resolved according to the procedures set forth in Section 13.12 hereof.

3.6. Sunset Provision. The Parties acknowledge that the utility and roles of the Committees may evolve over the course of the Term and that it is appropriate that such evolution be addressed by modifications to the role and operation of the Committees contemplated in Sections 3.1 through 3.5. For such purpose, either Party may, at any time following the [*] [*] days of the Effective Date, propose by notice to the other Party that some or all of the operations of the Committee(s) be terminated or modified or the frequency of its meetings be reduced. Upon the giving of any such notice, the Parties shall discuss and act upon it in good faith and shall, in respect thereof, make such amendments to this Article 3 as may be necessary to reflect their agreement.

3.7. Oversight by Senior Executives. In addition to and separate from the Committees provided for in Sections 3.1 through 3.6, each of Progenics and Salix shall designate a senior executive officer to oversee matters relating to the Collaboration on behalf of such Party, to facilitate communications between the Parties (including discussion and planning relating to [*] [*] of [*] to address any matters as to which the JSC and JDC consultative process has proved unsatisfactory, to be available to consult with his/her counterpart at the other Party, and generally to manage the Collaboration so as to most effectively achieve its intent and purposes. Such officers shall be, for Progenics: [*], and for Salix: [*].

4. DEVELOPMENT

4.1. Development Plan. An outline of the Development activities to be performed by Salix under this Agreement is set forth in Schedule 4.1 (the "Initial Development Outline"). Within [*] [*] days following the Effective Date, Salix shall prepare a detailed development plan (the "Development Plan") for the continued Development of Products for the Territory. Such Development Plan shall be consistent with the Initial Development Outline, including all timelines set forth therein, and shall set forth the objectives and planned tasks for the Development of Products for the Territory. Progenics shall have the right to review and provide comments to Salix with respect to such Development Plan. Salix shall consider Progenics’s comments in good faith. Salix shall notify Progenics of any material changes to the Development Plan prior to implementation of such changes and shall consider in good faith Progenics’s comments with respect thereto. Notwithstanding the preceding sentence, Salix shall not make any change to the Development Plan that would have the effect of making the Development Plan inconsistent with the Initial Development Outline except following consultation with Progenics through the Committees and subject to Section 3.5(c).
4.2. Development Responsibilities of Salix.

(a) Costs. Except as contemplated by Section 4.6(c), Salix shall pay one hundred percent (100%) of the costs to Develop Products for the Territory.

(b) Responsibilities. Salix shall be solely responsible for, and shall:

(i) use Commercially Reasonable Efforts to Develop the Compound and Products in accordance with the Development Plan, including the performance of the work under the Development Plan in accordance with the estimated timelines set forth therein;

(ii) undertake all required correspondence and any official communications (except where Progenics may be required by Applicable Law or Regulatory Authority to communicate) regarding Products with Regulatory Authorities in the Territory;

(iii) determine, in Salix’s sole discretion, whether or the manner in which to perform any Phase 4 Clinical Trials for any Product, including any Phase 4 Clinical Trials that may be required by Regulatory Authorities in the Territory, and thereafter conduct and manage any such Phase 4 Clinical Trials.

(c) Development Coordination.

(i) Progenics shall conduct such Development tasks as Salix may request it to perform as part of the Development of Products hereunder, subject to such reasonable compensation and other terms as the Parties may agree. For the avoidance of doubt, the provisions of this Section 4.2(c)(i) do not limit or qualify the provisions of Sections 2.10 and 3.3, and no compensation or reimbursement of expenses shall be payable by Salix to Progenics in connection with Progenics’s participation in the Committees.

(ii) Except as contemplated by Section 4.2(c)(i), Progenics shall not conduct, nor shall it permit any of its Affiliates or, except to the extent required by the provisions of the Ono Agreement as they exist on the Effective Date or as amended in accordance with the provisions of this Agreement, licensees or sublicensees (other than Salix) to conduct, any Development with respect to Products except in accordance with a plan that has been approved by the JSC.

(iii) Each Party shall use, and shall cause its Affiliates and, in the case of Progenics, subject to the provisions of the Ono Agreement as they exist on the Effective Date or as amended in accordance with the provisions of this Agreement, licensees and Sublicensees (other than the other Party) to use, reasonable efforts consistent with those prevailing in the pharmaceutical industry to conduct all clinical trials, non-clinical safety studies and all other Development activities relating to the Compound or Products in such a manner as not to affect adversely the regulatory and commercial potential of Products.

(d) Efforts. Salix’s obligations under Section 4.2(b) to use Commercially Reasonable Efforts in Development of Products will be satisfied if Salix uses Commercially Reasonable Efforts in the Human Field in the Major Market Countries. Salix shall not be in breach of its obligation under Section 4.2(b) for failing to use Commercially Reasonable Efforts in the Non-Human Animal Field, in countries other than the Major Market Countries, or in any country other than the United States in respect of which Salix despite its good faith efforts is unable to enter into a Sublicense as a result of the minimum Sublicense Revenue requirements set forth in clause (ii)(C) of Section 2.2(c). Furthermore, Salix shall be relieved of its obligation to use Commercially Reasonable Efforts in any particular country with respect to a particular Product if a Third Party Controls Patent Rights as to which, in the written reasoned opinion of Salix’s outside patent counsel (which written opinion shall be reasonably acceptable to Progenics), there is a reasonable risk that a court would find the making, using or selling of such Product in such country to constitute an infringement and Salix or its Affiliates or Sublicensee(s) are unable to obtain a license under such Patent Rights on commercially reasonable terms or configure the Product so as to avoid infringement through the use of Commercially Reasonable Efforts.

(e) Unforeseen Events. The Parties recognize that the Development Plan and the objectives to be set forth therein are based upon numerous assumptions which are not in the control of the Parties. In view of the numerous assumptions underlying the Development Plan, the proposed timeframe for achieving the objectives and events described in the Development Plan will be regularly reviewed by the JDC in light of unforeseen matters. In the event that despite the use of Commercially Reasonable Efforts by the Parties, [""], or other issues beyond the control of the Parties arise that prevent either Party from fulfilling the objectives of the Development Plan within the timeframe set forth in the Development Plan, the JDC will discuss any appropriate revisions to the Development Plan, which revisions the other Party shall not unreasonably oppose, provided that the Party can demonstrate its use of Commercially Reasonable Efforts to Develop the Products.
4.3. Records. Salix and its Affiliates shall maintain, and shall use Commercially Reasonable Efforts to cause (a) their Outside Contractors to maintain and (b) Salix’s Sublicensees to cause such Sublicensees’ respective Outside Contractors to maintain, accurate and complete records of all activities related to the Development of Products, consistent with the responsibilities of Salix under this Agreement, and all results of any trials, studies and other investigations conducted under this Agreement by or on behalf of Salix, its Affiliates, Sublicensees and Outside Contractors, as applicable.

4.4. Reports on Development.

(a) For so long as Salix continues to Develop a Product under this Agreement, it shall in respect of such Product provide the JDC with reports containing
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

38

relevant information in reasonable detail regarding [•] and [•], [•], and [•] related to Registrational Filings and Clinical Trials of such Product conducted or overseen by Salix and its Affiliates and Sublicensees. Such reports shall be provided by Salix to the JDC as and when such reports are produced or made available to Salix for its internal use.

(b) In addition, through its representatives on the JSC, each Party shall make reports to the JSC, as and at such time as such reports are produced by or made available to such Party for its internal use and otherwise on a periodic basis, updating the JSC as to the status and results of Development efforts of such Party and its licensees and Sublicensees (other than, in the case of Progenics, Salix and, in the case of Salix, Progenics) with respect to Products.

4.5. Transfer of Data. Without limiting the provisions of Sections 2.9(a) or 12.5(b), as soon as reasonably practicable, but in any event within [•] ([•]) days, following the Effective Date, Progenics shall, at its expense, provide Salix with access to, and (to the extent requested by Salix) copies of, all [•] and [•] relating to the Compound and Products to the extent the same is in the possession or Control of Progenics or its Affiliates. In addition, Progenics shall use Commercially Reasonable Efforts to cause Wyeth and Ono to provide, for delivery to Salix, relevant [•] and [•] which Wyeth and Ono are obligated, under the Wyeth Agreement, the Termination Agreement, and the Ono Agreement, respectively, to provide to Progenics. The provisions of this Section 4.5 are in addition to, and not by way of limitation of, the provisions of the Transition Agreement.


(a) Subject to Ono’s rights under the Ono Agreement and the Initial Development Outline, all ongoing Development work in respect of the Compound or Products that is being conducted by the Progenics Parties or their Affiliates or licensees as of the Effective Date, including any pre-clinical or clinical studies and Clinical Studies (as such term is defined in Section 9.2(p)) identified on Schedule 9.2(p), shall either, as Salix may direct by notice to the Progenics Parties, be continued, terminated or transferred and transitioned to Salix.

(b) Subject to the provisions of Section 4.8(c), all ongoing Development work continued by the Progenics Parties as aforesaid and any termination or transfer and transition of ongoing Development work effected pursuant to Section 4.6(a) shall be at [•] sole cost and expense at the relevant [•] or the [•], as applicable.

(c) In respect of any ongoing Development work continued by the Progenics Parties as to which the Progenics Parties continue to have the right to receive reimbursement from Wyeth pursuant to the Termination Agreement, the Progenics Parties shall remain responsible for all costs and expenses of such Development work up to the amount of reimbursement that Wyeth is obligated to pay to the Progenics Parties in respect thereof under the terms of the Termination Agreement. Salix shall be responsible, in accordance with Section 4.6(b), for any and all amounts in excess of such amounts that are reimbursable by Wyeth. In the event that the Progenics Parties should be unable to collect from Wyeth, because of Wyeth’s bankruptcy or insolvency, any amount that Wyeth is required to reimburse to the Progenics Parties under the Termination Agreement for Development work that has been conducted by the Progenics Parties as contemplated by the first sentence of this Section 4.6(c), then Salix shall pay such amount to the Progenics Parties and shall, by virtue of such payment, be subrogated to any rights that the Progenics Parties may have against Wyeth in respect of the amount so paid.

(d) Each Progenics Party shall reasonably cooperate with Salix to effect the transfer and termination of any ongoing Development work that Salix directs is to be transferred and transitioned to it. Without limitation, each Progenics Party shall use its reasonable efforts to assign and delegate to Salix or its Affiliates, as Salix may direct, all of the rights and obligations of the Progenics Party or its Affiliates or licensees, as the case may be, under such Progenics Third Party Agreements (other than the Subject Agreements) as Salix may determine are relevant to the conduct of
ongoing Development work to be transferred and transitioned to it. The Progenics Parties and Salix shall use their respective reasonable efforts to obtain the consent of any relevant Third Party to the assignment and delegation of any such Progenics Third Party Agreement. In connection with obtaining any such consents, Salix shall cooperate with the Progenics Parties in obtaining from the relevant Third Party a release of the relevant Progenics Parties from liability under the relevant Progenics Third Party Agreement with respect to matters arising after the relevant assignment effective date, and, notwithstanding and in addition to the foregoing, shall, at Salix’s expense, cause the relevant Progenics Parties to be released from liability under the Progenics Third Party Agreements identified on Schedule 4.6(d) with respect to matters arising after or related to the relevant assignment effective date. To the extent any such Progenics Third Party Agreement is not assignable without the consent of a Third Party and the consent of such Third Party cannot be obtained following the reasonable efforts contemplated hereby, the performance obligations of the Progenics Parties or their Affiliates under such Progenics Third Party Agreement shall, unless not permitted by such Progenics Third Party Agreement, be deemed to be subcontracted to Salix until such Progenics Third Party Agreement can be effectively assigned and delegated. If any such consent cannot be timely obtained, (i) the Progenics Parties shall waive any exclusivity provision contained in the relevant Progenics Third Party Agreement to allow Salix to enter into its own agreement with the relevant Third Party and (ii) the Progenics Parties and Salix shall cooperate in any reasonable arrangement designed to provide for Salix the benefits and obligations intended to be assigned or delegated to and assumed by it in respect of such Progenics Third Party Agreement, including the right to enforce such Progenics Third Party Agreement for its own account. In furtherance of the foregoing, in respect of any Progenics Third Party Agreement that cannot be effectively assigned or delegated as contemplated hereby, the Progenics Parties hereby consent to the use by any Third Party which is a party to such Progenics Third Party Agreement of confidential information, technology and/or Know-How developed or held by such Third Party under the Progenics Third Party Agreement for the benefit of Salix, subject to applicable confidentiality and use restrictions. Notwithstanding any of the foregoing provisions of this Section 4.6(d), the Progenics Parties shall not be obligated to take or to permit to be taken any action which would, in the reasonable judgment of the Progenics Parties, be likely to result in a breach of any Progenics Third Party Agreement.

(e) Any transfer or transition of ongoing Development work from Progenics or its Affiliates or licensees to Salix pursuant to this Section 4.6 shall not affect the liability of the transferring party for any matters arising prior to the effective date of such transfer, and Salix shall have no liability in respect of any such matter. Conversely, any such transfer or transition shall result in Salix, as between it and the transferring party, being liable for all matters arising in respect of such Development work on or after the effective date of such transfer, provided, however, that, as between Salix and the transferring party, the transferring party shall remain solely liable for any matters arising before or after such transfer in respect of Development work transferred by the transferring party to Salix to the extent any such matter is a result of any act or omission on the part of the transferring party, its Affiliates, licensees, sublicensees or its or their directors, officers, employees or agents.

(f) The provisions of this Section 4.6 are in addition to, and not by way of limitation of, the provisions of the Transition Agreement.

5. COMMERCIALIZATION

5.1. Salix’s Commercialization Responsibilities and Efforts.

(a) Commercialization Plan. An outline of the Commercialization activities to be performed by Salix under this Agreement is set forth in Schedule 5.1(a) (the “Initial Commercialization Outline”). Within [*] ([*]) days following the Effective Date, Salix shall prepare the Commercialization Plan for the continued Commercialization of Products for the Territory. Such Commercialization Plan shall be consistent with the Initial Commercialization Outline, including all timelines set forth therein, and shall set forth the objectives and planned tasks for the Commercialization of Products for the Territory. Progenics shall have the right to review and provide comments to Salix with respect to such Commercialization Plan. Salix shall consider Progenics’s comments in good faith. Salix shall notify Progenics of any material changes to the Commercialization Plan prior to implementation of such changes and shall consider in good faith Progenics’s comments with respect thereto. Notwithstanding the preceding sentence, Salix shall not make any change to the Commercialization Plan that would have the effect of making the Commercialization Plan inconsistent with the Initial Commercialization Outline except following consultation with Progenics through the Committees and subject to Section 3.5(c). Costs. Salix shall pay one hundred percent (100%) of the costs to Commercialize Products in the Territory.

(b) Responsibilities. Salix shall be solely responsible for the Commercialization of the Products in the Territory and shall use Commercially Reasonable Efforts to pre-launch, launch, promote, market, distribute, sell in finished pharmaceutical form, and otherwise Commercialize Products in the Territory in accordance with the

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5.2. Plan. Salix shall be solely responsible for distribution and pricing of Products in the Territory, either itself or through its Sublicensees, and shall itself or through its Sublicensees book all sales of Products in the Territory.

(c) Efforts. Salix’s obligations under this Section 5.1 to use Commercially Reasonable Efforts will be satisfied if Salix uses Commercially Reasonable Efforts in the Human Field in Major Market Countries. Commercially Reasonable Efforts expended by a Sublicensee in a given
country shall satisfy Salix’s efforts obligations in that country. Salix shall not be in breach of its obligation under this Section 5.1 for failing to use Commercially Reasonable Efforts in the Non-Human Animal Field, in countries other than the Major Market Countries, or in any country other than the United States in respect of which Salix despite its good faith efforts is unable to enter into a Sublicense as a result of the minimum Sublicense Revenue requirements set forth in clause (ii)(C) of Section 2.2(c). Furthermore, Salix shall be relieved of its obligation to use Commercially Reasonable Efforts with respect to a Product in any particular country if a Third Party Controls Patent Rights as to which, in the written reasoned opinion of Salix’s outside patent counsel (which written opinion shall be reasonably acceptable to Progenics), there is a reasonable risk that a court would find the making, using or selling of such Product in such country to constitute an infringement and Salix or its Affiliates or Sublicensee(s) are unable to obtain a license under such Patent Rights on commercially reasonable terms or configure the Product so as to avoid infringement through the use of Commercially Reasonable Efforts.

5.2. Transition; Supply.

(a) Transition Agreement. Simultaneously herewith, the Expanded Parties are entering into a Transition Arrangements Agreement, of even date herewith (the “Transition Agreement”).

(b) Supply. Except as otherwise contemplated by the Transition Agreement, Salix shall be solely responsible at its expense for the Manufacture and supply of one hundred percent (100%) of the Compound and finished Products for Development and Commercialization both as bulk API and as finished and packaged products.

(c) Manufacturing and Transfer of Manufacturing Know-How. Progenics will disclose to Salix, Salix’s Affiliates, and/or Salix’s Third Party contract manufacturer all relevant Progenics Know-How and all Know-How included in the Wyeth Collaboration Know-How, Wyeth Collaboration Joint Know-How, Ono Collaboration Know-How and Ono Collaboration Joint Know-How relating to the Manufacture of the Products. Progenics shall use its Commercially Reasonable Efforts to cause Wyeth to provide Salix with that cooperation, inventory, technology, know-how and documentation set forth in Section 10.4.1(d) of the Wyeth Agreement. Such Know-How disclosure shall include the transfer of data and information stored on the computer systems of Progenics for and in respect of Regulatory Marketing Approval for Products.

(d) Assignment of Supply and Manufacturing License Agreements. At Salix’s written request in connection with the transfer of responsibility for Manufacture under Section 5.2(c), Progenics shall use Commercially Reasonable Efforts to promptly assign and transfer to Salix any existing supply agreements related to the supply of the Compound or the Products. Furthermore, to the extent necessary to permit Salix to manufacture the Compound and Products as contemplated by this Agreement, Progenics shall use Commercially Reasonable Efforts to sublicense to Salix any license agreement under which Progenics licenses any intellectual rights from any Third Party related to the Manufacture of the Compound or the Products. If the terms of any of the agreements referred to in the previous two sentences require the consent of the other party thereto to effect its assignment, then upon Salix’s request for an assignment, until Progenics is able to obtain such consent and effect such assignment, Progenics will exercise its rights under such agreements for the benefit of Salix and as reasonably requested by Salix. In the event of any assignment to Salix under this Section 5.2(d), Salix shall assume full responsibility for satisfying all obligations of Progenics under any assigned agreement to the extent arising after such assignment and assumption. Notwithstanding any of the foregoing provisions of this Section 5.2(d), Progenics shall not be obligated to take or permit to be taken any action which would, in the reasonable judgment of Progenics, be likely to result in a breach of any such supply agreements.

5.3. Marketing Materials and Corporate Branding. Subject to Section 7.5, Salix shall be solely responsible at its expense for all pre-marketing and marketing efforts and for creating all packaging and Promotional Materials for the Products in the Field in the Territory. Salix shall own all copyrights in such Promotional Materials. Subject to Progenics’s reasonable approval of the form and presentation thereof, the corporate name and logo of Progenics shall appear on all Product packaging, package inserts and Promotional Materials Manufactured, distributed or sold by Salix, its Affiliates and Sublicensees hereunder or pursuant hereto, subject, in each case, to compliance with Applicable Law and regulatory requirements.

5.4. Sharing of Information. Salix shall provide the JSC with a copy of Salix’s Commercialization Plan for any Product and any updates thereof, including information regarding [*] and [*] of the Product, [*] and [*]. Such updates shall be provided by Salix to the JDC as and when such reports are produced by or made available to Salix for its internal use. Salix shall report to the JSC at each meeting thereof and at such other times as appropriate on the progress of its implementation of the Commercialization Plan. All commercial information so disclosed by Salix shall be Salix’s Confidential Information for the purposes of Section 8.2.

5.5. Unauthorized Sales.

(a) Unauthorized Sales by Salix. Salix (i) shall, and shall cause its Affiliates and Sublicensees to, distribute, market, promote, offer for sale and sell Products only in the Field in the Territory and (ii) shall not, shall not permit its Affiliates to, and shall make reasonable efforts to cause its Sublicensees not to, distribute, market, promote, offer for sale or sell Products (A) to any Person in fields of use and countries other than those as specified in the preceding clause (i) or (B) to any Person in the fields of use and countries as specified in the preceding clause (i) that Salix, its Affiliates or Sublicensees, as applicable,
knows (y) is likely to distribute, market, promote, offer for sale or sell Products in fields of use and countries other than those as specified in the preceding clause (i) or assist another Person to do so, or (z) has directly or indirectly distributed, marketed, promoted, offered for sale or sold Products in fields of use and countries other than those as specified in the preceding clause (i) or assisted another Person to do so. If Salix or its Affiliates receives any orders for Products for fields of use and countries other than those specified in clause (i) of the first sentence of this Section 5.5(a), it shall promptly refer such orders to Progenics, and Salix shall make reasonable efforts to cause any Sublicensee that receives such an order to refer such order to Progenics. In addition, neither Salix nor its Affiliates shall sell or otherwise provide, directly or indirectly, Products to any Sublicensee or distributor in excess of amounts reasonably required to meet local demand in the country or other territory in respect of which the Sublicensee or distributor is authorized to distribute, market, promote, offer for sale or sell Products, and Salix shall make reasonable efforts to prevent its Sublicensees from doing the same.

(b) Unauthorized Sales by Progenics. Progenics shall, and shall cause its Affiliates to, distribute, market, promote, offer for sale and sell Products only outside the Territory or for use outside the Field. Progenics shall not, and shall not permit its Affiliates to, distribute, market, promote, offer for sale or sell Products (i) to any Person other than outside the Territory or for use outside the Field or (ii) to any Person that Progenics or its Affiliates, as applicable, knows (A) is likely to distribute, market, promote, offer for sale or sell Products for use in the Field or assist another Person to do so, or (B) has directly or indirectly distributed, marketed, promoted, offered for sale or sold Products for use in the Field or assisted another Person to do so. If Progenics or its Affiliates receives any orders for Products for use in the Field, it shall promptly refer such orders to Salix. In addition, neither Progenics nor its Affiliates shall sell or otherwise provide, directly or indirectly, Products to any licensee or distributor in excess of amounts reasonably required to meet local demand in the country or other territory in respect of which the licensee or distributor is authorized to distribute, market, promote, offer for sale or sell Products.

(c) Certain Limitations. The provisions of this Section 5.5 shall apply only to the extent permitted by Applicable Law. To the extent any provision of this Section 5.5 shall be found in any jurisdiction to be in violation of public policy or illegal or unenforceable in law or equity, the provisions of Section 13.5 shall apply.

6. PAYMENTS BY SALIX TO PROGENICS

6.1. Upfront License Fee Payment. Salix shall pay to Progenics upon the execution of this Agreement sixty million dollars ($60,000,000) as a one-time, nonrefundable and noncreditable license fee in partial consideration for the licenses granted under Section 2.1 hereof. Such amount shall be paid within five (5) Business Days after receipt by Salix of an invoice from Progenics.


(a) In partial consideration for the licenses granted to Salix under Section 2.1 hereof, Salix shall pay to Progenics upon the satisfaction of the specified conditions the following one-time, nonrefundable, and noncreditable payments ("Development Milestone Payments") within five (5) Business Days of receipt by Salix of an invoice for the payment of the applicable Development Milestone Payment as set forth in this Section 6.2. Each Development Milestone Payment is payable one time only, regardless of the number of Products or indications for which the condition is satisfied. For the avoidance of doubt, the maximum aggregate value of all Development Milestone Payments is ninety million dollars ($90,000,000).

   Condition

   Payment

   [*]

   $ [*], [*]

   [*]

   $ [*], [*]
6.3. Commercialization Milestone Payments. In partial consideration for the licenses granted to Salix under Section 2.1 hereof, Salix shall pay to Progenics upon the satisfaction of the specified conditions the following one-time, nonrefundable, and noncreditable payments (“Commercialization Milestone Payments”) within [*] ("[*]") Business Days of receipt by Salix of an invoice for the payment of the applicable Commercialization Milestone Payment. Each Commercialization Milestone Payment is payable one time only, regardless of the number of times the condition is satisfied. For the avoidance of doubt, the maximum aggregate value of all Commercialization Milestone Payments is two hundred million dollars ($200,000,000), and up to all six (6) payments could be made with respect to a single Calendar Year.

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1 For the avoidance of doubt and by way of example, the Commercialization Milestone Payment for the [*].

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6.4. Ex-U.S. Sublicenses and Sales.

(a) When Salix enters into arrangements with one or more Sublicensees relating to any area outside the United States, Salix shall pay Progenics sixty percent (60%) of all Sublicense Revenues pursuant to any such arrangements.

(b) All payments under this Section 6.4 shall be payable within [*] ("[*]") days after receipt of the applicable Sublicense Revenue by Salix.

(c) For the avoidance of doubt, Section 6.4(a) shall not apply to any sales or other Commercialization of Products by Salix or its Affiliates, whether inside or outside the United States.

6.5. Royalty Payments.

(a) Royalties. In partial consideration for the licenses granted to Salix under Section 2.1, Salix shall pay to Progenics royalties in the amount of the applicable Net Sales percentage (as set forth below) (the “Applicable Net Sales Percentage”) of the Net Sales made during the Royalty Period by Salix and its Affiliates, whether inside or outside the United States, as follows:

| Combined Net Sales of All Products by Salix and its Affiliates | Applicable Net Sales | Percentage |
(b) Royalty Period.

(i) The royalties payable under Section 6.5(a) shall be payable by Salix only during the Royalty Period in respect of the relevant Product and country.

(ii) Following the expiration of the Royalty Period in respect of a Product in a country in the Territory, the license grants to Salix in Section 2.1 in respect of such Product shall, in accordance with Section 2.8, become fully paid-up, perpetual and irrevocable with respect to such Product and such country and accordingly the Net Sales of the relevant Product in such country shall be excluded from the royalty calculations for purposes of Section 6.5(a) and from calculations of thresholds for Commercialization Milestone Payments for purposes of Section 6.3.

(c) Adjustment of Royalties. If at any time the Royalty Period is continuing solely because of clause (c) of the definition thereof for a particular Product in a particular country, then the dollar amount of royalties payable in respect of Net Sales of such Product in such country thereafter during the Royalty Period pursuant to Section 6.5(a) shall be reduced by [*] percent ([*]%) from the amount which would have been so payable under this Agreement in the absence of this clause (c).

(d) Progenics Third Party Agreements; Third Party Licenses.

(i) Except as otherwise provided in or contemplated by Section 4.6, Progenics shall, as between the Parties, be solely responsible for all obligations under each Progenics Third Party Agreement unless and until such Progenics Third Party Agreement is assigned to Salix pursuant to Section 4.6(d) or 9.4(d). In the event that a Progenics Party or any of its Affiliates fails to pay any amount that it is obligated to pay in respect of a Progenics Third Party Agreement pursuant to the preceding sentence and Salix makes such payment on behalf of such Progenics Party, then Salix shall be entitled to credit such amount against any amount owed by Salix to Progenics under this Agreement. Except as otherwise provided herein, Salix shall, as between the Parties, be solely responsible in respect of all Progenics Third Party Agreements assigned to Salix pursuant to Sections 4.6(d) and 9.4(d) for any and all obligations arising under such Progenics Third Party Agreements from and after the date of assignment. In the event that Salix or any of its Affiliates fails to pay any amount that it is obligated to pay in respect of a Progenics Third Party Agreement pursuant to the preceding sentence and Progenics or one of its Affiliates makes such payment on behalf of Salix or such Affiliate, then Salix shall promptly reimburse Progenics for the amount paid.

(ii) If, during the Term, Salix or its Affiliates, whether pursuant to Section 7.4(b) or otherwise, enters into an agreement with a Third Party to license Patent Rights as to which, [*], there is [*] (a “Third Party License”), then Salix may deduct up to [*] percent ([*]%) of the royalties or other payments payable pursuant to such Third Party License actually paid by Salix or its Affiliates to such Third Party pursuant to the Third Party License from the royalties otherwise due from Salix to Progenics in respect of Net Sales of the relevant Product(s) under Section 6.5(a) as adjusted pursuant to Section 6.5(c), up to a maximum amount in respect of the relevant Net Sales for any Quarter that would result in Progenics’s effective royalty rate in respect of such Net Sales in such Quarter under Section 6.5(a) as adjusted pursuant to Section 6.5(c) for such Product(s) being reduced by not more than [*] ([*]) percentage points, with any balance then remaining to be carried over to amounts owed by Salix to Progenics pursuant to Section 6.5(a) as adjusted pursuant to Section 6.5(c) in respect of such subsequent Quarters, up to a maximum amount for each Quarter that would result in Progenics’s

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effective royalty rate in respect of each such Quarter under Section 6.5(a) for such Product(s) as adjusted pursuant to Section 6.5(c) being reduced by not more than [*] [*%] percentage points. By way of example, if the royalty rate applicable in respect of the relevant Quarter was [*] percent ([*]%), then the maximum amount in respect of amounts paid by Salix to the Third Party in respect of the Third Party License that could be deducted from royalties on relevant Net Sales otherwise owed by Salix to Progenics for such Quarter would be an amount that would reduce Progenics’s effective royalty rate for the Quarter for the relevant Product(s) to [*] percent ([*]%).

(e) Disclaimers. Each Party acknowledges and agrees that nothing in this Agreement (including, without limitation, any exhibits or attachments hereto) shall be construed as representing an estimate or projection of either (i) the number of Products that will or may be successfully Developed or Commercialized or (ii) anticipated sales or the actual value of any Product. SALIX MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZING ANY PRODUCT OR, IF COMMERCIALIZED, THAT ANY SUCH PRODUCT WILL ACHIEVE ANY PARTICULAR SALES LEVEL, OR THAT, EXCEPT AS EXPRESSLY AGREED IN THIS AGREEMENT, IT WILL DEVOTE ANY LEVEL OF DILIGENCE OR RESOURCES TO COMMERCIALIZING ANY SUCH PRODUCT.

6.6. Reports, Payments and Related Matters.

(a) Cumulative Royalties. The obligation to pay royalties under this Agreement shall be imposed only once with respect to any sale of any Product, regardless of the number of patents that may cover the Product.

(b) Reports and Payments. Within [*] [*] days after the first day of each Quarter following the First Commercial Sale of a Product in the Territory, Salix shall submit to Progenics a written report with respect to the preceding Quarter (the "Quarterly Activity Report") stating: (i) the gross sales and Net Sales of Products sold by Salix and its Affiliates and any Sublicensee during the Quarter just ended for each country in which sales were made, making reference to the specific deductions taken in accordance with the definition of Net Sales; (ii) the date of any First Commercial Sale of any Product in a country in the Territory during the Quarter just ended; (iii) the currency exchange rates used in determining gross sales, Net Sales and amounts payable under Section 6.5; and (iv) a calculation of the amounts due to Progenics pursuant to Section 6.5 in respect of the Quarter just ended. All royalty payments due under Section 6.5 shall be due and payable within [*] [*] Business Days following the distribution of each Quarterly Activity Report. Salix shall submit to Progenics with each payment under Section 6.4 a written report with respect to such payment (a “Sublicense Revenue Report") describing in detail the Sublicense Revenue to which such payment relates and providing such other information specified above for inclusion in a Quarterly Activity Report as may be relevant thereto. The obligation of Salix to provide Quarterly Activity Reports and Sublicense Revenue Reports under this Section 6.6(b) shall cease to apply once Salix has no further obligation to make payments of, respectively, royalties under Section 6.5 or payments under Section 6.4.

(c) Taxes and Withholding. All payments under this Agreement will be made without any deduction or withholding for or on account of any tax, duties, levies, or other charges unless such deduction or withholding is required by Applicable Law to be assessed against Progenics. If Salix is so required to make any deduction or withholding from payments due to Progenics, Salix will (i) promptly notify Progenics of such requirement, (ii) pay to the relevant authorities on Progenics’s behalf the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against Progenics, and (iii) promptly forward to Progenics an official receipt (or certified copy) or other documentation reasonably acceptable to Progenics evidencing such payment to such authorities.

(d) Currency. All payments under this Agreement shall be made in dollars. As applicable, Sublicense Revenue, Net Sales and any royalty deductions shall be translated into dollars at the exchange rate used by Salix for public financial accounting purposes in accordance with GAAP.

(e) Record Keeping. Salix shall keep, and shall cause its Affiliates to keep, books and accounts of record in connection with Sublicense Revenue and the sale of Products in accordance with GAAP and in sufficient detail to permit accurate determination of all figures necessary for verification of Sublicense Revenue to be shared by Salix with Progenics under Section 6.4(a) and royalties to be paid under Section 6.5. Salix and its Affiliates shall maintain such records for a period of at least [*] [*] years after the end of the Quarter in which they were generated, provided, however, that if any records are in dispute and Salix has received notice from Progenics of the records which are in dispute, Salix shall keep such records until the dispute is resolved.

(f) Audits.

(i) Examination of Books and Records. Upon [*] [*] days’ prior notice from Progenics, Salix shall permit an independent certified public accounting firm, of nationally recognized standing selected by Progenics and reasonably acceptable to Salix, to examine, at Progenics’s sole expense, the relevant books and records of Salix and its Affiliates, and shall take reasonable efforts to cause its Sublicensees to permit Progenics to examine the relevant books and records of Sublicensees, in each case as may be reasonably necessary to verify the amounts reported by Salix in accordance with Section 6.6(b) and the sharing of Sublicense Revenue under Section 6.4(a) and payment of royalties under Section 6.5 and its compliance with its other Development and Commercialization obligations hereunder. An examination by Progenics under
shall be limited to the pertinent books and records for any [*] ending not more than [*] ([*]) months before the date of the request. The accounting firm shall be provided access to such books and records at Salix’s and other relevant facility(ies) where such books and records are normally kept and such examination shall be conducted during normal business hours. Salix may require the accounting firm to sign a standard non-disclosure agreement before providing the accounting firm with access to relevant facilities or records. Upon completion of the audit, the accounting firm shall, subject to Section 6.6(g), provide both Salix and Progenics with a written report disclosing any discrepancies in the reports submitted by Salix or the Sublicense Revenue shared or the royalties paid, and, in each case, the specific details concerning any discrepancies.

(ii) Underpayments/Overpayments. If such accounting firm concludes that additional portions of Sublicense Revenue were due to Progenics under Section 6.4(a) or additional royalties were due to Progenics under Section 6.5(a), Salix shall pay to Progenics the additional Sublicense Revenue or royalties, as the case may be, within [*] ([*]) days of the date Salix receives such accountant’s written report, plus interest, which shall be calculated at the average of the prime rate reported by JPMorgan Chase, New York City, each month during the period beginning on the day the unpaid amount was due until the unpaid amount is paid in full, plus [*] percent ([*]%) per annum. If such underpayment exceeds the greater of [*] dollars ($[*]) and [*] percent ([*]%) of the aggregate share of Sublicense Revenue and royalties that were to be paid by Salix to Progenics for the audited period, Salix also shall reimburse Progenics for the out-of-pocket expenses incurred in conducting the audit. Progenics shall not reveal to such accounting firm the conditions under which the audit expenses are to be reimbursed hereunder. If such accounting firm concludes that Salix overpaid Sublicense Revenue or royalties to Progenics, Progenics will refund such overpayments to Salix within [*] ([*]) days of the date Progenics receives such accountant’s report. [*] interest shall be due to Salix on any such overpayment.

(g) Confidentiality. All progress reports and financial information of Salix subject to review under this Article 6 shall be deemed to be Salix’s Confidential Information subject to the provisions of Article 8 hereof, and Progenics shall not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than reviewing progress made or verifying payments to be made by Salix to Progenics under this Agreement; provided, however, that such Confidential Information may be disclosed by Progenics to Third Parties only to the extent necessary to enforce Progenics’s rights under this Agreement.

6.7. Diagnostic or Veterinary Products. Notwithstanding anything to the contrary in this Article 6, sales of Products for diagnostic (including screening or monitoring) or veterinary use shall not be considered Net Sales for purposes of Section 6.3 or 6.5 or Sublicense Revenues for purposes of Section 6.4. In the event that Salix Develops or seeks to Sublicense Development of any Product for any such use, then the Expanded Parties shall negotiate in good faith to agree upon, as a condition to Salix’s right to Commercialize (whether itself or through a Sublicensee) such Product, appropriate compensation to be paid by Salix to Progenics in connection with the Commercialization of such Product.

7. INTELLECTUAL PROPERTY.


(a) Inventorship/Authorship. For purposes of this Agreement, (i) inventorship of any invention and any Patent Right claiming such invention shall be determined in accordance with the rules and guidelines regarding inventorship as established under United States patent law (including case law and regulations associated therewith); and (ii) authorship of any work subject to copyright protection shall be determined in accordance with U.S. copyright law. Without limiting the foregoing, each Expanded Party shall own all right, title and interest in and to all Patent Rights, Know-How, or copyright materials created solely by or on behalf of such Party.

(b) Ownership of Joint Technology and Joint Copyrights. As between the Progenics Parties, on the one hand, and Salix, on the other hand, each shall own an equal, undivided interest in any Joint Technology and any copyright materials authored jointly by employees or agents of Progenics or any of its Affiliates and employees or agents of Salix or any of its Affiliates.

(c) Exploitation of Joint Technology and Joint Copyrights. Except as expressly provided in this Agreement neither Party shall exploit any Joint Technology inside or outside the Territory without the prior written approval of the other Party. Neither Party shall exploit any copyright materials authored jointly by employees or agents of Progenics or any of its Affiliates and employees or agents of Salix or any of its Affiliates without the prior written approval of the other Party except in connection with the Manufacturing, Development or Commercialization of the Compound and Products in the Territory as contemplated hereby.


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and Ono Collaboration Joint Patent Rights) in all countries in the Territory where such Patent Rights are currently pending and, respecting the [*]. In respect to any Progenics Patent Rights as to which Progenics does not have the right to control prosecution and maintenance of such Patent Rights, Progenics (i) shall ensure that Salix is promptly provided with all such information as Progenics may receive in respect of the prosecution and maintenance of such Patent Rights and with a full opportunity to participate in any consultations that may take place between Progenics and any Third Party holding the right to pursue prosecution and maintenance of such Patent Rights and (ii) shall exercise such rights as it does have in respect of the prosecution and maintenance of such Patent Rights in accordance with Salix’s directions. The Parties shall cause their respective patent counsel to communicate no less frequently than [*] per [*] regarding the prosecution and maintenance of the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights and Ono Collaboration Joint Patent Rights. Without limiting the generality of the foregoing, Salix shall provide to Progenics copies of all communications sent to and received from any patent office pertaining to Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights or Ono Collaboration Joint Patent Rights, including [*]. Whenever possible, Progenics shall be given at least [*] [*] Business Days prior to the earlier of the expiration of any shortened statutory period for response or anticipated filing to review and comment upon the text of any such communication. Salix shall also keep Progenics advised on the maintenance of any patents included within the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights and Ono Collaboration Joint Patent Rights and provide Progenics with reasonable opportunity to comment on maintenance. In the event that the Parties’ respective patent counsel, after good faith discussions, cannot agree with respect to any decision to be made with respect to the preparation, filing, prosecution and maintenance of the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights or Ono Collaboration Joint Patent Rights (including decisions relating to [*]), Salix shall make such decision.

(b) Ono Collaboration Patent Rights. Progenics shall provide to Salix, promptly following its receipt of the same from Ono pursuant to Section 7.2.3 of the Ono Agreement, copies of all communications (and English translations or English summaries thereof, as provided by Ono) sent to and received from patent offices pertaining to the prosecution of Ono Collaboration Patent Rights. Salix shall have the right to review and comment upon the text of any such communication and Progenics shall for that purpose solicit any comments that Salix may have and include them as part of its comments to Ono. Salix shall have the right to have its patent counsel participate in any communications between Progenics’s patent counsel and Ono’s patent counsel that may occur pursuant to, or in conformance with, Section 7.2.3 of the Ono Agreement. Progenics shall provide Salix with notice of any communications between its patent counsel and Ono’s patent counsel that may be contemplated pursuant to Section 7.2.3 of the Ono Agreement. Such notice shall be provided by Progenics promptly following its becoming aware of any such proposed communication and in a manner appropriate to provide Salix with a reasonable opportunity

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(c) Joint Patent Rights. The Parties shall discuss in good faith, and thereupon implement, a mutually agreeable patent strategy with respect to all Joint Technology that may be patentable, and shall cause their respective patent counsel to communicate no less frequently than [*] per [*] regarding the prosecution and maintenance of the Joint Patent Rights in the Territory and outside the Territory. With respect to all Joint Technology for which the Parties agree patent prosecution should be sought, the Parties shall cooperate in the preparation, filing and prosecution of patent applications (including provoking, instituting or defending interference, opposition, revocation, reexamination and similar proceedings related to the Joint Patent Rights), and shall discuss and agree on the content and form of relevant patent applications and any other relevant matters before such applications are made. Each Party shall consider in good faith any comments from the other Party regarding steps to be taken to strengthen any Joint Patent Right. Salix shall serve as the lead Party to prosecute and maintain all applications covering Joint Patent Rights in the Territory.

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53

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(d) Salix Collaboration Technology. Salix shall be solely responsible for the prosecution of the Salix Collaboration Patent Rights and the maintenance of any patents included within the Salix Collaboration Patent Rights at Salix’s expense. Salix shall provide to Progenics copies of all communications sent to and received from patent offices pertaining to the prosecution of the Salix Collaboration Patent Rights including, but not limited to, [*]. Furthermore, the Parties shall cause their respective patent counsel to communicate no less frequently than once per Quarter regarding the prosecution of the Salix Collaboration Patent Rights. In the event that the Parties, after good faith discussions, cannot agree with respect to any decision to be made regarding the preparation, filing, prosecution and maintenance of the Salix Collaboration Patent Rights (including decisions relating to interference, opposition, revocation, reexamination and similar proceedings related to the Salix Collaboration Patent Rights), at Salix’s expense, unless otherwise agreed by the Parties. In the event that the Parties, after good faith discussions, cannot agree with respect to any decision to be made with respect to any draft submission, including any forms such as Form FDA 3542, Form FDA 3542a or any equivalent thereof, for Progenics’s review and comment. Salix shall consider in good faith any comments made by Progenics pursuant to this Section 7.2(e). In the event that the Parties’ respective patent counsel, after good faith discussions, cannot agree with respect to any decision to be made with respect to such draft submission, then Salix shall make such decision. In all cases, each Party shall provide reasonable assistance to the other Party, at Salix’s expense, with respect to Joint Patent Rights in the Territory. At least [*] [*] Business Days prior to expiration of the time period under 21 C.F.R. 314.53 for submitting patent information pertaining to Progenics Patent Rights or Joint Patent Rights with respect to any Product, Salix shall submit to Progenics any such draft submission, including any forms such as Form FDA 3542, Form FDA 3542a or any equivalent thereof, for Progenics’s review and comment. Salix shall consider in good faith any comments made by Progenics pursuant to this Section 7.2(e). In the event that the Parties’ respective patent counsel, after good faith discussions, cannot agree with respect to any decision to be made with respect to such draft submission, then Salix shall make such decision.

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54

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(f) Cooperation. Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 7.2, including the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Patent Rights as provided for in this Section 7.2.

(g) Application for Patent Term Extension. The Parties shall cooperate in obtaining Patent Term Extensions. At least [*] [*] Business Days prior to the expiration of any statutory or other regulatory time period in the Territory for submitting an application for patent term extension pertaining
to any of the patent rights included in the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Patent Rights, Ono Collaboration Joint Patent Rights, Ono Independent Patent Rights, Joint Patent Rights, Salix Collaboration Patent Rights or Salix Independent Patent Rights, including applications for interim extension and SPC in the U.S. or in any foreign country in the Territory, Salix shall submit to Progenics a draft application theretofor for Progenics’s review and comment. Salix shall also promptly provide to Progenics copies of all correspondence received from any patent office or regulatory office concerning such application for extension, and Progenics shall have at least [*] ([*]) Business Days to review and comment on all correspondence sent to any patent office or regulatory office pertaining to such application. Salix shall consider in good faith any comments made by Progenics pursuant to this Section 7.2(g). In the event that the Parties cannot agree with respect to any decision to be made under this Section 7.2(g), including the patent to apply for extension, then Salix shall make such decision. As necessary to give effect to the provisions of this Section 7.2(g) and the allocation of rights and responsibilities between Salix and Progenics set forth herein, Progenics shall exercise its rights under Section 7.2.5 of the Ono Agreement as directed by Salix.

(h) Patent Markings. Salix and Progenics shall discuss whether Products shall be marked with the appropriate numbers of patents owned solely or jointly by the Parties.

(i) Progenics Right to File, Prosecute and Maintain. Notwithstanding anything to the contrary in Section 7.2(a), (b) and (c), in the event that Salix decides not to file, prosecute, maintain or otherwise decides to abandon any Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Patent Rights or the Joint Patent Rights, then Progenics, in its sole discretion and at its own expense, shall have the right to file, prosecute and maintain such Patent Right. Whenever possible, Salix shall be given at least [*] ([*]) Business Days prior to the earlier of the expiration of any shortened statutory period for response, maintenance, or anticipated filing to review and comment upon the text of any such communication. In the event that the Parties’ respective patent counsel, after good faith discussions, cannot agree with respect to any decision to be made with respect to the preparation, filing, prosecution and maintenance of such Patent Right (including decisions relating to [*]), Progenics shall make such decision.


(b) Enforcement of Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Patent Rights and Joint Patent Rights. Except as otherwise provided in this Section 7.3(b), Salix shall, as between Progenics and Salix to the extent Progenics has the right to enforce the Progenics Patent Rights, have the first right but not the obligation, at its own expense, to take action (or cause or permit to be taken action) to obtain a discontinuance of infringement or bring suit against a Third Party infringer in the Territory of any Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Joint Patent Rights or Joint Patent Rights. Such right shall remain in effect until [*] ([*]) days after the date of notice given under Section 7.3(a). Salix, at its own expense, may join Progenics as a party plaintiff to any action or suit resulting from Salix’s exercise of such rights. Progenics may participate, and be represented by independent counsel, in such litigation at its own expense. Salix shall not consent to the entry of any judgment or enter into any settlement with respect to such an action or suit without the prior written consent of Progenics (not to be unreasonably withheld, conditioned, or delayed) if such judgment or settlement includes a finding or agreement that any Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Joint Patent Rights or Joint Patent Rights are invalid, unenforceable, or not infringed, grants a Third Party license, or would enjoin or grant other equitable relief against Progenics. Salix shall bear all the expenses (except for the expense of Progenics’s independent counsel) of any such action or suit brought by Salix under this first right claiming infringement of any Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Joint Patent Rights or Joint Patent Rights. If, after the expiration of the [*] ([*]) day period, Salix has not obtained a discontinuance of the infringement of the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Joint Patent Rights or Joint Patent Rights, as applicable, or filed suit against any such Third Party infringer of such rights, or provided Progenics with information and arguments demonstrating to Progenics’s reasonable satisfaction that there is insufficient basis for the allegation of such infringement of the Progenics Patent Rights, Wyeth Collaboration Patent

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56

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In respect to any Progenics Patent Rights as to which Progenics does not have the right to control enforcement of such Patent Rights, Progenics (i) shall ensure that Salix is promptly provided with all such information as Progenics may receive in respect of the enforcement of such Patent Rights and with a full opportunity to participate in any consultations that may take place between Progenics and any Third Party holding the right to pursue enforcement of such Patent Rights and (ii) shall exercise such rights as it does have in respect of the enforcement of such Patent Rights in accordance with Salix’s directions.

(c) Enforcement of Ono Collaboration Patent Rights. Progenics shall exercise its rights under Section 7.2.7(c) of the Ono Agreement as directed (and only as directed) by Salix; provided, however, that any action taken by Progenics to obtain a discontinuance of infringement or bring suit against an infringer of Ono Collaboration Patent Rights pursuant to Section 7.2.7(c) shall be at Salix’s expense. Progenics shall permit any counsel that it may retain to represent it as permitted by the provisions of Section 7.2.7(c) of the Ono Agreement to be directed by Salix. Neither Party shall incur any liability directly to the other Party as a consequence of such action or suit or any unfavorable decision resulting therefrom, including any decision holding any Ono Collaboration Patent Right invalid or unenforceable. However, to the extent Salix exercises its rights under this Section 7.3(c) to direct Progenics to bring an action or suit and to direct and control the prosecution of such action or suit, Salix shall indemnify and hold Progenics harmless from any liability to a Third Party (including Ono) as a consequence of such action or suit or any unfavorable decision resulting therefrom. Any recovery obtained by either Party as a result of any such action or suit against a Third Party infringer shall be allocated first to reimburse each Party for all litigation costs in connection with such action or suit paid by that Party and then any remaining amount shall be allocated as follows:

(i) If [*] brought the infringement action or suit, any remaining portion of such recovery shall be allocated between the Parties [*] under this Agreement, as determined in good faith by the Parties; or

(ii) If [*] brought the infringement suit, [*] shall receive an amount equal to [*] percent ([*]%) of any remaining portion of such recovery and [*] shall receive the other [*] percent ([*]%).

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

57
7.4. Infringement and Third Party Licenses.

(a) Infringement of Third Party Patents - Course of Action. If the performance of the Licensed Activities by Salix or any of its Affiliates is alleged by a Third Party to infringe a Third Party’s patent or other intellectual property right, the Party becoming aware of such infringement shall promptly notify the third party. Additionally, if either Party determines that, based upon the review of a Third Party’s patent or patent application or other intellectual property rights, it may be desirable to obtain a license from such Third Party with respect thereto so as to avoid any potential suit between either Party and such Third Party, such Party shall promptly notify the other Party of such determination and initiate discussions to determine whether such license is desirable.

(b) Salix Option to Negotiate. Subject to Section 7.4(c), in the event that Salix determines that, in order for Salix or its Affiliates or Sublicensees to engage in the Licensed Activities, it is necessary or desirable for Salix to obtain a license under one or more patents or patent applications or other intellectual property rights owned or controlled by a Third Party (collectively, “Third Party IP Rights”), Salix shall have the first right, but not the obligation, to negotiate and enter into an agreement with such Third Party, whereby Salix is granted a license under such Third Party IP Rights permitting Salix and its Affiliates and Sublicensees, as relevant, to practice such Third Party IP Rights in connection with the Licensed Activities and the performance of any of its obligations or the exercise of any of its rights under this Agreement. If after the earlier to occur of (*) (*) months following Progenics’s notice to Salix of the need for a license in respect of Third Party IP Rights in order for Salix or its Affiliates or Sublicensees to engage in the Licensed Activities and [*] (**) days following receipt by Salix or Progenics of a written threat of imminent litigation alleging that the conduct by Salix or its Affiliates or Sublicensees of the Licensed Activities infringes Third Party IP Rights, Salix has not then entered into a license agreement with the relevant Third Party whereby Salix is granted a license under such Third Party’s Third Party IP Rights, then Progenics shall have the right, but not the obligation, to negotiate and enter into, at its expense, an agreement with such Third Party, whereby Progenics is granted a license, with the right to sublicense, under such Third Party IP Rights. Any such license into which Progenics
may enter pursuant to the preceding sentence shall constitute a Progenics Third Party Agreement.

(c) Ono Third Party License. Progenics shall provide Salix with notice of any notification that it may receive from Ono pursuant to Section 7.2.8(a) of the Ono Agreement or any determination that Progenics itself may make that it may be desirable to obtain a license as contemplated by said section. Such notice shall be provided by Progenics promptly following its receipt of any such notification or its making of any such determination and in a manner appropriate to provide Salix with a reasonable opportunity to participate in any discussions by Progenics and Ono in respect thereof as contemplated by Section 7.2.8(a) of the Ono Agreement. Salix shall have the right, either directly or through Progenics, as Progenics and Ono may agree, to participate in any discussions that may be conducted pursuant to Section 7.2.8(c). Progenics shall not provide its written consent to any agreement into which Ono may propose to enter under Section 7.2.8(b) of the Ono Agreement without first having obtained Salix’s consent thereto, such consent not to be unreasonably withheld or delayed.

(d) Third Party Infringement Suit. If a Third Party sues Salix or any of Salix’s Affiliates or Sublicensees (each Person so sued being referred to herein as a “Sued Party”), alleging that the Licensed Activities of Salix or any of Salix’s Affiliates or Sublicensees during the Term of and pursuant to this Agreement infringe or will infringe such Third Party’s patent, then, upon Salix’s request and in connection with the Sued Party’s defense of any such Third Party infringement suit, Progenics shall provide reasonable assistance to the Sued Party for such defense. Such assistance shall include, but not be limited to, Progenics’ reasonable participation in any discussions by Progenics and Ono in respect thereof as contemplated by Section 7.2.8(a) of the Ono Agreement.

(e) Patent Certifications. Each Party shall immediately give notice to the other Party of any certification filed by a Third Party pursuant to 21 U.S.C. § 355(b)(2)(A) or § 355(j)(2)(A)(vii) (or any amendment or successor statute thereto) of which it becomes aware claiming that any Patent Right of either Party related to this Agreement has expired or is invalid, unenforceable or not infringed.

7.5. Trademarks.

(a) Product Trademarks. Salix shall be solely responsible for selecting, and shall own, all Product Trademarks used, held for use or intended for use on or in connection with the Manufacturing, Development and/or Commercialization of the Compound and Products in the Territory under this Agreement.

(b) Transfer of RELISTOR Trademark. Pursuant to and in accordance with the terms of the Transition Agreement, Progenics shall, simultaneously with the transfer of relevant Commercialization activities in respect of Products to Salix, cause Wyeth and Wyeth’s Affiliates, as applicable, to assign, convey, transfer and deliver to Salix all right, title and interest in and to the Trademark RELISTOR as well as all other Assigned US IP and Assigned Ex-US IP (as such terms are defined under the Termination Agreement) and all registrations and applications in respect of any of the foregoing in the Territory, in each case together with all goodwill associated therewith, except for all right, title and interest in and to [*] in the [*] and the [*], which Progenics shall, simultaneously with the transfer of relevant Commercialization activities in respect of Products to Salix, [*].

(c) Certain Restrictions. Until termination of this Agreement for any reason other than expiration at the end of the Term as provided in Section 10.1, Progenics shall not use, register or seek to register, or permit its Affiliates to use, register or seek to register, anywhere in the Territory, any Trademark that is confusingly similar to any Trademark owned or used by Salix or its Affiliates or Sublicensees in connection with the Commercialization of any Product in the Territory.

8. CONFIDENTIALITY.

8.1. Product Information.

(a) The Progenics Parties recognize that by reason of, inter alia, Salix’s status as an exclusive licensee pursuant to the grants under Section 2.1, Salix has an interest in the Progenics Parties’ retention in confidence of certain information of the Progenics Parties. Accordingly, during the Term, the Progenics Parties shall, and shall cause their Affiliates and their respective officers, directors, employees, and agents to, keep confidential, and not publish or otherwise disclose, and not use directly or indirectly for any purpose other than to fulfill the Progenics Parties’ obligations, or exercise the Progenics Parties’ rights, hereunder or under any Subject Agreement or Related Agreement, any data or information owned or possessed by the Progenics Parties or any of their Affiliates that relates to the Compound or any Product for use in the Field, or the Manufacturing, Development or Commercialization of any of the foregoing (the “Product Information”); except to the extent (i) the Progenics Parties’ Product Information is in the public domain through no fault of the Progenics Parties or their Affiliates or any of their respective officers,
agreement, such information shall, subject to the other terms and conditions of this Article 8, also constitute Confidential Information of the disclosing Progenics Party with respect to the use and disclosure of such data or information by Salix (and the Progenics Party shall be deemed to be the Disclosing Party with respect to such Product Information). In the event this Agreement is terminated, this Section 8.1(b) shall have no continuing force or effect with respect to the use or disclosure of such information, but Product Information disclosed by Salix to the Progenics Parties hereunder shall continue to be Confidential Information of Salix, subject to the terms of Sections 8.2, 8.3, and 8.5 for purposes of the surviving provisions of this Agreement.

(b) Salix recognizes that, in the event the licenses granted to Salix by Progenics are terminated pursuant to Section 10.5, the Progenics Parties will have an interest in Salix’s retention in confidence of certain information of Salix’s. Accordingly, following such termination pursuant to Section 10.5, Salix shall, and shall cause its Affiliates and their respective officers, directors, employees, and agents to, keep confidential, and not publish or otherwise disclose, and not use directly or indirectly for any purpose other than to fulfill Salix’s obligations, or exercise Salix’s rights, hereunder any Salix Product Information (as Product Information is defined in Section 8.1(a)); except to the extent (i) the Salix Product Information is in the public domain through no fault of Salix or its Affiliates or any of their respective officers, directors, employees, or agents (including pursuant to disclosure as contemplated by Section 9.2(l)(i) mutatis mutandis); (ii) such disclosure or use is expressly permitted under Section 8.3, or (iii) such disclosure or use is at such time otherwise expressly permitted by the terms of this Agreement. For purposes of Section 8.3, following termination of the licenses from Progenics to Salix pursuant to Section 10.5, the Progenics Parties shall be deemed to be the Disclosing Party with respect to Salix’s Product Information under Section 8.3 and Salix shall be deemed to be the Receiving Party with respect thereto. For further clarification, (i) without limiting this Section 8.1(b), to the extent the Progenics Parties’ Product Information is disclosed by the Progenics Parties to Salix pursuant to this Agreement, such information shall, subject to the other terms and conditions of this Article 8, also constitute Confidential Information of the disclosing Progenics Party with respect to the use and disclosure of such data or information by Salix and (the Progenics Parties shall be deemed to be the Disclosing Party with respect to such Product Information). In the event this Agreement is terminated, this Section 8.1(b) shall have no continuing force or effect with respect to the use or disclosure of such information, but Product Information disclosed by Salix to the Progenics Parties hereunder shall continue to be Confidential Information of Salix, subject to the terms of Sections 8.2, 8.3, and 8.5 for purposes of the surviving provisions of this Agreement.

8.2. Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Expanded Parties agree that, for the Term and for five (5) years thereafter, each Expanded Party (the “Receiving Party”) receiving any Confidential Information of another Expanded Party (the “Disclosing Party”) under this Agreement shall keep such Confidential Information confidential and shall not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement, except for Confidential Information that the Receiving Party can establish:

(i) was already known by the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party and the Receiving Party has documentary evidence to that effect; provided, however, that the foregoing exception shall not apply in respect of Regulatory Documentation and information included therein transferred to Salix pursuant to the provisions hereof or the Transition Agreement;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, other than through any act or omission of the Receiving Party or any of its Affiliates;

(iv) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or

(v) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party and the Receiving Party has documentary evidence to that effect; provided, however, that the foregoing exception shall not apply in respect of Regulatory Documentation and information included therein transferred to Salix pursuant to the provisions hereof or the Transition Agreement.
Information that is otherwise Confidential Information and consists of a combination of information shall not be deemed to be in the public domain if individual elements of such information are in the public domain, unless the specific combination of those elements is also in the public domain.

8.3. Authorized Disclosure.

(a) Disclosure. Notwithstanding the provisions of Sections 8.1 and 8.2, a Receiving Party may disclose Confidential Information belonging to the Disclosing Party and a Progenics Party may disclose Product Information to the extent such disclosure is reasonably necessary to:

(i) file or prosecute patent applications as contemplated by this Agreement,

(ii) prosecute or defend litigation,

(iii)(A) exercise its rights under this Agreement, including conducting clinical trials, (B) exercise its rights or perform its obligations under, in the case of Progenics, the Subject Agreements as the same exist on the date hereof, and in the case of both Salix and Progenics, the Related Agreements, provided in each such disclosure is covered by terms of confidentiality similar to those set forth herein, or (C) engage in [*], including [*] or [*], provided in each case such disclosure is covered by terms of confidentiality similar to those set forth herein, and

(iv) comply with Applicable Law.

(b) Notice of Disclosure. In the event a Receiving Party shall deem it reasonably necessary to disclose Confidential Information belonging to the Disclosing Party pursuant to this Section 8.3, the Receiving Party shall to the extent possible give reasonable advance notice of such disclosure to the Disclosing Party and take reasonable measures to ensure confidential treatment of such Confidential Information.

8.4. SEC Filings and Other Disclosures. Any Expanded Party may disclose the existence and terms of this Agreement, Product Information and other material information relating to this Agreement and the matters contemplated hereby (a) to the extent required, in the reasonable opinion of such Expanded Party’s legal counsel, to comply with Applicable Law, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission (“SEC”), and (b) in connection with a [*], provided that prior to such disclosure each such [*] shall be in writing to be bound by obligations of confidentiality and non-use no less restrictive in scope than those set forth in this Article 8. Notwithstanding the foregoing, before making a disclosure contemplated by clause (a) above, the Expanded Parties will consult with one another on material to be redacted in making any such disclosure. If an Expanded Party makes a disclosure contemplated by clause (a) above, such Expanded Party agrees, at its own expense, to seek such confidential treatment of portions of such disclosure, as may be reasonably requested by any other Expanded Party.

8.5. Public Announcements; Publications.

(a) Coordination. The Expanded Parties agree on the importance of coordinating their public announcements respecting this Agreement and the subject matter hereof (other than academic, scientific or medical publications that are subject to the publication provision set forth below). The Expanded Parties shall, from time to time, and at the request of any other Expanded Party, discuss and agree on the general information content relating to this Agreement (including relating to the Development or Commercialization of the Product) which may be publicly disclosed (including by means of any printed publication or oral presentation).

(b) Press Releases. Promptly following the execution of this Agreement, the Parties shall simultaneously release their agreed-upon announcement regarding the signing of this Agreement. Thereafter, any press release or similar public announcement relating to this Agreement or the transactions and activities contemplated hereby (including relating to Development or Commercialization events in respect of Products) shall, unless otherwise agreed by the Parties, be made in the form of a joint release with form and content agreed by the Parties, provided that the foregoing shall not prohibit a Party from making any such press release or similar public announcement independently of the other Party to the extent such Party determines it must make such press release or similar public announcement in order to comply with Applicable Law and cannot in compliance with Applicable Law make such press release in the form suggested by the other Party, in which event, however, the Party proposing to make an independent press release shall use reasonable efforts to provide a draft of such press release to the other Party sufficiently in advance of release to permit the other Party to comment thereon. Except as contemplated by this Section 8.5(b) or permitted by Section 8.4, no Expanded Party shall, nor shall it permit its Affiliates to, issue any press release or similar public announcement relating to this Agreement or the transactions and activities contemplated hereby (including relating to Development or Commercialization events in respect of Products).

(c) Publications. During the Term, each Expanded Party will submit to the other Expanded Parties (including specifically to its in-house patent counsel) for prior
9. REPRESENTATIONS AND WARRANTIES.


(a) Each of the Progenics Parties hereby represents, warrants, and covenants to Salix, and Salix hereby represents, warrants, and covenants to the Progenics Parties, as follows:

(i) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;

(ii) 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;

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

(iv) the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof do not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (A) a loan agreement, guaranty, financing agreement, agreement relating to one or more Patent Rights or other agreement or instrument binding or affecting it or its property; (B) the provisions of its charter or operative documents or bylaws; or (C) any law, regulation, order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; and

(v) it shall at all times comply with all material laws and regulations applicable to its activities under this Agreement.

(b) The representations and warranties contained in this Section 9.1 shall survive the execution and delivery of this Agreement.

9.2. Additional Representations and Warranties of Progenics. In addition to the representations and warranties made by Progenics elsewhere in this Agreement, Progenics hereby represents, warrants and covenants to Salix as follows. For purposes of this Section 9.2, (1) “Knowledge” means, in respect of Progenics, the actual knowledge, with no duty of or having made any specific inquiry or investigation, of any of the following:

[*] and (2) [*].

(a) Licensed Patent Rights; Progenics Third Party Agreements.

(i) To Progenics’s Knowledge, Schedule 9.2(a)(i) identifies all Licensed Patent Rights as of the Effective Date in the Designated Countries, in each case along with the following information with respect to each identified Patent Right, as applicable: (A) [*], (B) [*], (C) [*], (D) [*], (E) [*], (F) [*], (G) [*], and (H) [*]. For the avoidance of doubt, to Progenics’s Knowledge Schedule 9.2(a)(i) includes all Patent Rights Controlled by Progenics as of the Effective Date in the Designated Countries that claim: (i) the [*], (ii) the [*], or (iii) the [*].

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(review and approval all proposed academic, scientific and medical publications and public presentations relating to the Development or Commercialization of any Product for review in connection with preservation of Progenics Patent Rights, Wyeth Collaboration Joint Patent Rights, Wyeth Collaboration Patent Rights, Ono Collaboration Joint Patent Rights, Ono Collaboration Patent Rights, Joint Patent Rights, and Salix Collaboration Patent Rights and to determine whether any disclosure of any other Expanded Party’s Confidential Information should be modified or deleted. Written copies of such proposed publications and presentations shall be submitted to the non-publishing Expanded Parties no later than [*] days before submission for publication or presentation, and each non-publishing Expanded Party shall provide its comments with respect to such publications and presentations within [*] days of its receipt of such written copy. The review period may be extended for an additional [*] days in the event any non-publishing Expanded Party can demonstrate reasonable need for such extension, including, but not limited to, the preparation and filing of patent applications. By mutual agreement, this period may be further extended. Each Expanded Party will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other persons in any publications relating to the Development or Commercialization of any Product. During the Term, each Expanded Party shall provide to the other Expanded Parties (including specifically to its in-house patent counsel) for its information any academic, scientific and medical publications relating to the Compound or any Product of which such Expanded Party is aware.)
(ii) Schedule 9.2(a)(ii) identifies each material Progenics Third Party Agreement as well as each Progenics Third Party Agreement of which Progenics is aware. Progenics has delivered to Salix copies of all Progenics Third Party Agreements listed on Schedule 9.2(a)(ii). Such copies are true, correct and complete and include all amendments, waivers or modifications in respect of each such Progenics Third Party Agreement.


(i) To Progenics’s Knowledge, Schedule 9.2(b)(i) identifies all Wyeth Collaboration Patent Rights, in each case in existence as of the Effective Date in the Designated Countries, and in each case along with the following information with respect to each identified Patent Right, as applicable: (A) [*], (B) [*], (C) [*], (D) [*], (E) [*], (F) [*], (G) [*], and (H) [*].

(ii) To Progenics’s Knowledge, Schedule 9.2(b)(ii) identifies all Wyeth Collaboration Joint Patent Rights, in each case in existence as of the Effective Date in the Designated Countries, and in each case along with the following information with respect to each identified Patent Right, as applicable: (A) [*], (B) [*], (C) [*], (D) [*], (E) [*], (F) [*], (G) [*], and (H) [*].

(iii) To Progenics’s Knowledge, there are no Ono Collaboration Patent Rights in existence as of the Effective Date in any Designated Country.

(iv) To Progenics’s Knowledge, there are no Ono Collaboration Joint Patent Rights in existence as of the Effective Date in any Designated Country.

(c) Rights in Licensed Patent Rights.

(i) Except as disclosed on Schedule 9.2(c)(i) and only as to Patent Rights on Schedule 9.2(a)(i) where Progenics is listed as the sole owner: (a) Progenics is the sole and exclusive owner of the entire right, title and interest to such Patent Rights; and (b) none of such Patent Rights is subject to any encumbrance, lien or claim of ownership by any Third Party.

(ii) Except as disclosed on Schedule 9.2(c)(ii) and only as to Patent Rights on Schedule 9.2(a)(i) where Progenics is listed as a joint owner: (a) Progenics is the sole and exclusive owner of Progenics’s right, title and interest to such jointly owned Patent Rights; and (b) none of Progenics’s interest in such jointly owned Patent Rights is subject to any encumbrance, lien or claim of ownership by any Third Party.

(iii) Except for that interest retained by Wyeth pursuant to the Wyeth Agreement and the Termination Agreement, Progenics is the sole and exclusive licensee in the Designated Countries of the entire right, title and interest to the Wyeth Collaboration Patent Rights and Wyeth Collaboration Joint Patent Rights in accordance with the terms of the Wyeth Agreement and the Termination Agreement, and Progenics’s interest as licensee of such Patent Rights is not subject to any encumbrance, lien or claim of ownership by any Third Party. Progenics owns an equal, undivided interest in the Wyeth Collaboration Joint Patent Rights and Progenics’s interest is not subject to any encumbrance, lien or claim of ownership by any Third Party.

(d) Prosecution of Patent Rights. As of the Effective Date, the Licensed Patent Rights are being procured from the respective patent offices in the Designated Countries in accordance with Applicable Law. As of the Effective Date, each such Patent Right is and at all times has been in compliance with all legal requirements applicable thereto, and all filings, payments, and other actions required to be made or taken to maintain such Patent Rights in full force and effect have been made or still can be made by the applicable deadline; and no application for any such Patent Right has been abandoned or allowed to lapse. Except as disclosed on Schedule 9.2(d), as of the Effective Date and to Progenics’s Knowledge, there are no inventors, as determined in accordance with applicable patent laws, with respect to the technology claimed in any such Licensed Patent Right other than the inventors named in Schedule 9.2(a)(i).

(e) Pending Patent Applications. As of the Effective Date and to Progenics’s Knowledge, in respect of any pending United States patent applications included in the Licensed Patent Rights which are solely owned by Progenics, the Wyeth Collaboration Patent Rights, or the Wyeth Collaboration Joint Patent Rights, except as disclosed on Schedule 9.2(e), Progenics or the Person prosecuting such Patent Right has presented, to the extent such presentation is required given the stage of prosecution of the relevant Patent Right, all relevant prior art of which it and the inventors are aware to the relevant patent examiner at the United States Patent and Trademark Office.
(f) Rights in Progenics Know-How. Except as limited by Progenics Third Party Agreements listed on Schedule 9.2(a)(ii), Progenics has full and unrestricted rights to use in the Designated Countries for all purposes the Progenics Know-How in its possession or currently used by it. Progenics is entitled to grant the licenses granted hereunder in respect of the Progenics Know-How. Except as disclosed in Schedule 9.2(f), Progenics Know-How solely owned by Progenics and Progenics’s interest in Know-How jointly owned by Progenics is not subject to any encumbrance, lien or claim of ownership by any Third Party.


(i) Subject to the Wyeth Agreement and the Termination Agreement, to Progenics’s Knowledge: (i) Progenics has full and unrestricted rights to use in the Designated Countries for all purposes the Wyeth Collaboration Know-How and Wyeth Collaboration Joint Know-How, (ii) Progenics is entitled to grant the licenses granted hereunder in respect of such Know-How, and (iii) Progenics’s interest as licensee of such Know-How is not subject to any encumbrance, lien or claim of ownership by any Third Party.

(ii) Subject to the Ono Agreement, to Progenics’s Knowledge: (i) Progenics has full and unrestricted rights to use in the Designated Countries for all purposes the Ono Collaboration Know-How and Ono Collaboration Joint Know-How, (ii) Progenics is entitled to grant the licenses granted hereunder in respect of such Know-How, and (iii) Progenics’s interest as licensee of such Know-How is not subject to any encumbrance, lien or claim of ownership by any Third Party.

(h) Absence of Infringement. To Progenics’s Knowledge, in the Designated Countries there is no actual, alleged or threatened infringement of the Licensed Patent Rights or actual, alleged or threatened misuse or wrongful appropriation of Licensed Know-How or Regulatory Documentation, in each case by any Person.

(i) Freedom to Operate.

(i) Except as disclosed in Schedule 9.2(i), to Progenics’s Knowledge, the Manufacture, Development and Commercialization in the Designated Countries, of Products currently sold or in active Development, in the current formulation, do not require a license from any Third Party other than as provided under this Agreement. For the avoidance of doubt, the Products currently sold or in active development in one or more of the Designated Countries are the syringe/vial Product, the pre-filled syringe Product, the multi-dose pen Product and the oral SLS immediate release Product. Neither Progenics nor any of its Affiliates has received written notice from any Third Party of any issued and enforceable Patent Right of such Third Party that would be infringed by the Manufacture, Development or Commercialization of the Compound or Products in the Designated Countries.

(ii) Except as disclosed in Schedule 9.2(i), no claim or litigation has been brought or threatened by any Person alleging that the Regulatory Documentation, the Progenics Technology or, to Progenics’s Knowledge, any other Licensed Technology, or alleging that the disclosing, copying, making, assigning, licensing or other utilizing of the Regulatory Documentation, the Progenics Technology or, to Progenics’s Knowledge, any other Licensed Technology, violates, infringes or otherwise conflicts or interferes with any intellectual property or proprietary right of any Person.

(j) Validity and Enforceability.

(i) Except as disclosed in Schedule 9.2(j)(i), the issued Progenics Patent Rights in the Designated Countries solely owned by Progenics and covering the Manufacture, Development and Commercialization of Products currently sold or in active Development (as referenced in Section 9.2(i)(i)) are subsisting and, to Progenics’s Knowledge, are not invalid or unenforceable, in whole or in part. To the Knowledge of Progenics, the issued Wyeth Collaboration Patent Rights and Wyeth Joint Patent Rights in the Designated Countries, covering the Manufacture, Development and Commercialization of Products currently sold or in active Development (as referenced in Section 9.2(i)(i)) are subsisting and are not invalid or unenforceable.

(ii) Except as disclosed in Schedule 9.2(j)(ii), the conception, development and reduction to practice of the inventions claimed in the Licensed Patent Rights in the Designated Countries solely owned by Progenics have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person. To the Knowledge of Progenics, the conception, development and reduction to practice of the inventions claimed in the Licensed Patent Rights in the Designate Countries not solely owned by Progenics have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person.

(iii) Except as disclosed in Schedule 9.2(j)(iii), no claim or litigation, including any interference, opposition, cancellation or other proceeding, has been brought or, to Progenics’s Knowledge, threatened by any Person alleging that the Licensed Patent Rights in the Designated Countries solely owned by Progenics are invalid or unenforceable. To the Knowledge of Progenics, no claim or litigation, including any interference, opposition,
cancellation or other proceeding, has been brought or threatened by any Person alleging that the Licensed Patent Rights in the Designated Countries not solely owned by Progenics are invalid or unenforceable.

(k) No Previous Assignments. Except as provided under the Wyeth Agreement and the Ono Agreement, Progenics has not previously assigned, transferred, licensed, conveyed or otherwise encumbered its right or title to or interest in the Licensed Technology or Regulatory Documentation (including by granting any covenants not to sue with respect thereto).

(l) Confidentiality of Licensed Know-How.

Through the Effective Date, Progenics has used commercially reasonable measures to keep Progenics Know-How and Wyeth Collaboration Joint Know-How confidential, subject to those disclosures that Progenics has determined in its reasonable business judgment to make itself. As of the Effective Date, there is no Ono Collaboration Joint Know-How.

(iii) To Progenics’s Knowledge, Wyeth has used reasonable measures to keep Wyeth Collaboration Know-How and Wyeth Collaboration Joint Know-How confidential.

(m) RELISTOR Marks.

(i) To the Knowledge of Progenics, Schedule 9.2(m) sets forth a true and complete list of all registrations, and applications therefor, for the RELISTOR Trademark owned by Wyeth or one of its Affiliates as of the Effective Date. The word mark RELISTOR and all registrations and applications for registration therefor owned of record by Wyeth as of the date hereof in the Territory are herein referred to as the “RELISTOR Marks.”

(ii) Except as set forth in Schedule 9.2(m), to the Knowledge of Progenics, (A) Wyeth or one of its Affiliates is the sole and exclusive owner of the RELISTOR Marks in the Designated Countries in which Progenics or its licensees have registered any of the RELISTOR Marks (the “Trademark Countries”), free and clear of all claims, liens, encumbrances, options and licenses other than Wyeth’s obligation under the Termination Agreement to assign the RELISTOR Marks to Progenics or Salix, as Progenics’s designee, and (B) Wyeth or one of its Affiliates is the record owner of all the registrations and applications set forth on Schedule 9.2(m) for the RELISTOR Marks in the Trademark Countries, and all such registrations and applications are in full force and effect, are valid and enforceable, have not lapsed, expired or been forfeited, cancelled or abandoned, and all maintenance and renewal fees, as applicable, due as of the Effective Date in respect thereof have been timely paid.

(iii) Except as set forth in Schedule 9.2(m), none of Progenics and its Affiliates and, to the Knowledge of Progenics, Wyeth and its Affiliates has granted any license or sublicense in, or waived any rights with respect to, any of the RELISTOR Marks.

(iv) Except as set forth in Schedule 9.2(m), to the Knowledge of Progenics, no claims are pending or have been threatened to Progenics or any of its Affiliates, or, to the Knowledge of Progenics, Wyeth or any of its Affiliates challenging the ownership, use, right to use, registrability, priority, scope, validity, or enforceability of any of the RELISTOR Marks in the Trademark Countries, and to the Knowledge of Progenics, there exist no facts or circumstances which could reasonably provide a basis for any such claim or assertion materially adversely affecting the ownership, use, continuing right to use, registrability, priority, scope, validity or enforceability of any of the RELISTOR Marks.

(v) Except as set forth in Schedule 9.2(m), to the Knowledge of Progenics, there are no legal or governmental proceedings that relate to any of the RELISTOR Marks in the Trademark Countries.

(vi) Except as set forth in Schedule 9.2(m), (A) to the Knowledge of Progenics, the RELISTOR Marks do not infringe, dilute, violate or otherwise conflict with the intellectual property rights of any other Person in the any Trademark Country, (B) none of Progenics or its Affiliates or, to the Knowledge of Progenics, Wyeth or its Affiliates has received any notice of any such claim or assertion violation or infringement, and (C) no proceedings or claims been instituted or asserted in writing against Progenics or its Affiliates or, to the Knowledge of Progenics, Wyeth or its Affiliates alleging any such infringement, dilution, violation or conflict and, to the Knowledge of Progenics, there exist no facts or circumstances which could reasonably provide a basis for any such claim or assertion.

(vii) Except as set forth in Schedule 9.2(m), to the Knowledge of Progenics, none of the RELISTOR Marks is subject to any outstanding injunction, judgment, order, decree, ruling, charge, settlement or other disposition of any dispute.

(viii) Except as set forth in Schedule 9.2(m), to the Knowledge of Progenics, no other Person is engaging in any activity that infringes, dilutes, violates or conflicts with Progenics’s or any of its Affiliates’ or Wyeth’s or any of its Affiliates’ intellectual property rights in the RELISTOR Marks in any Trademark Country.

(n) Regulatory Documentation.
(i) In respect of the Compound and Products, Progenics or, to Progenics’s Knowledge, Wyeth, has prepared, maintained and retained in all material respects all Regulatory Documentation prepared by or for Progenics or Wyeth for filing in each Subject Country (the “Subject Documentation”) that is required to be maintained or reported pursuant to and in accordance with cGCP, cGLP and all other material Applicable Law and all such information is true, complete and correct in all material respects.

(ii) Subject to the terms of the Wyeth Termination Agreement, Progenics, to Progenics’s Knowledge, owns all right, title, and interest in and to all Subject Documentation free and clear of any liens, claims, and encumbrances of any Person.

(iii) To Progenics’s Knowledge, none of the Subject Documentation (other than Subject Documentation prepared by or for Wyeth) has been obtained by Progenics pursuant to any license or other agreement with any Third Party, other than contract research organizations (“CROs”) and other subcontractors of Progenics or Wyeth.

72

(iv) All Subject Documentation prepared by or for Progenics, and to Progenics’s Knowledge, all Subject Documentation prepared by or for Wyeth, is and has been filed, updated, and maintained in all material respects in accordance with Applicable Law in effect in each country in which Progenics or its licensees have sought Regulatory Marketing Approval for a Product (the “Subject Law”; such countries, the “Subject Countries”), and, except as set forth on Schedule 9.2(r)(i), Progenics has not received any notice, nor been the subject of, any action on the part of any Regulatory Authority in respect of the Subject Documentation that would reasonably be expected to have a material adverse effect on the Development or Commercialization of Products.

(o) Adverse Information. To Progenics’s Knowledge, information provided by Progenics [*] fairly describes all Adverse Events of which Progenics has Knowledge in respect of the Products. “Adverse Events” means (a) any finding from tests in laboratory animals or in vitro that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity or carcinogenicity and (b) any undesirable, untoward or noxious event or experience associated with the clinical, commercial or other use or occurring following administration, of a product in humans, occurring at any dose, whether expected or unexpected and whether or not considered related to or caused by a product, including such an event or experience as occurs in the course of the use of a product in professional practice, in a clinical trial, from overdose, whether accidental or intentional, from abuse, from withdrawal or from a failure of expected pharmacological or biological therapeutic action of a product, and including those events or experiences that are required to be reported to the FDA under 21 C.F.R. Sections 312.32 or 314.80 or to Regulatory Authorities under corresponding Applicable Law outside the United States.

(p) Studies. Progenics or its Affiliates and licensees have conducted or are conducting those Clinical Studies with respect to the Compound and those Clinical Studies with respect to Products set forth on Schedule 9.2(p). Progenics has conducted, and has caused its contractors and consultants to conduct, the aforesaid studies (other than those covered by the next succeeding sentence) and any and all other preclinical and Clinical Studies related to the Products conducted by any such Person in accordance in all material respects with applicable cGCP, cGLP and all other Subject Law. To Progenics’s Knowledge, Progenics’s licensees have conducted, and have caused their contractors and consultants to conduct, the aforesaid studies conducted by any such Person and any and all other preclinical and Clinical Studies related to the Products conducted by any such Person in accordance in all material respects with applicable cGCP, cGLP and all other Subject Law. Progenics is not aware of any actions, investigations or proceedings threatened or taken by any Regulatory Authority to suspend or terminate any ongoing Clinical Studies for Products, and none of Progenics or its Affiliates or, to Progenics’s Knowledge, its licensees, has received any notice, charge, subpoena or other request for information, which has not been complied

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

73

with or withdrawn, by a Regulatory Authority in the Subject Countries asserting any material breach of the conditions for approval of any ongoing clinical trials relating to Products. All Clinical Data resulting from the Clinical Studies set forth on Schedule 9.2(p) and any other Clinical Studies conducted by Progenics or its licensees in respect of the Compound or Products has been collected or acquired, maintained and used in compliance with Subject Law and the transfer of all such Clinical Data to Salix, or the making available of the same to Salix, as contemplated hereby will comply with all requirements of Subject Law. For the purposes of this Section 9.2(p), “Clinical Studies” means clinical investigations as defined in 21 C.F.R. 312.3(b) and clinical trials governed by Directive 2001/20/EC.

(q) No Third Party Rights. Except as to rights of reference granted in favor of Third Parties to Regulatory Approvals under a Progenics Third Party Agreement listed on Schedule 9.2(a)(i), neither Progenics nor any of its Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any rights granted to Salix under this Agreement.

(r) Certain Regulatory Matters.
(vi) To Progenics’s Knowledge, all Products in their finished form sold prior to the Effective Date in the Subject Countries were manufactured in all material respects in accordance with then current cGMP and in compliance with the applicable specifications of the Products as defined in the Regulatory Marketing Approvals in the Subject Countries.

(v) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been disqualified, excluded, debarred or voluntarily excluded by the FDA or any other relevant Regulatory Authority in the Subject Countries for any purpose, or has been debarred or voluntarily excluded by the FDA or any other relevant Regulatory Authority in the Subject Countries for any purpose, or has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(vi) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been disqualified, excluded, debarred or voluntarily excluded by the FDA or any other relevant Regulatory Authority in the Subject Countries for any purpose, or has been debarred or voluntarily excluded by the FDA or any other relevant Regulatory Authority in the Subject Countries for any purpose, or has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(vii) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(viii) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(ix) None of Progenics’s or its Affiliates’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(x) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xi) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xii) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xiii) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xiv) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xv) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xvi) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xvii) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xviii) None of Progenics’s or its Affiliates’s Knowledge, or to Progenics’s Knowledge, any of its licensees, nor, to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.

(xix) None of Progenics’s or any of its licensees’s Knowledge, or to Progenics’s Knowledge, any of its employees or any agent or consultant, has been subject to any comparable exclusionary or debarment orders or orders of any other Regulatory Authority in the Subject Countries.
(e) Promotional Materials. Schedule 9.2(e) sets forth a true, accurate and complete list of all material Promotional Materials held by Progenics that Progenics and, to Progenics’ Knowledge, its Affiliates and licensees, have utilized in connection with the Commercialization of Products in the [*] [*] days prior to the Effective Date.

(t) Products.

(i) Each Product sold by Progenics or its Affiliates or, to Progenics’s Knowledge, licensees through the Effective Date (A) has been Manufactured and sold in compliance with Applicable Law and (B) has been fit for the ordinary purposes for which it is intended to be used, in all material respects.

(ii) No Product has been withdrawn, suspended or discontinued by Progenics or, to Progenics’s Knowledge, any of its licensees as a result of any action by any Regulatory Authority.

(u) Government Funding. To the extent that any of the Progenics Patent Rights, Wyeth Collaboration Patent Rights, Wyeth Collaboration Joint Patent Rights, Ono Collaboration Patent Rights or Ono Collaboration Joint Patent Rights arose from work funded in whole or in part by United States federal funding, to Progenics’s Knowledge, all requirements necessary to (i) vest the entire right, title and interest in Progenics or, to Progenics’s Knowledge, Progenics’s licensee of such Patent Rights, subject to the rights of the United States, and (ii) to Progenics’s Knowledge, grant the licenses granted to Progenics under Patent Rights licensed to Progenics, have been satisfied.

(v) Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions contemplated hereby, or the performance by Progenics of its obligations hereunder will trigger any termination right, option, right of first refusal, or other rights in any of the Licensed Technology or conflict with Progenics’s or any of its Affiliates’ rights in and to the Licensed Technology or the ownership, use, right to use, validity, priority, duration, scope, enforceability, or effectiveness of any of such rights, in whole or in part.

(w) Disclosure. No representation or warranty of Progenics contained in this Agreement or the Related Agreements, and none of the statements or information contained in any other document, certificate, schedule, exhibit, annex, list or other writing furnished by Progenics or its Affiliates to Salix, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statement contained herein or therein not misleading.

9.3. Survival.

(a) Except as provided in Section 9.3(b), the representations and warranties contained in Section 9.2 shall survive the execution and delivery of this Agreement.

(b) The representations and warranties contained in Section [*] shall survive only until [*] [*] months after the Effective Date, provided, however, in the event Salix provides notice of a Dispute prior to the end of such period, the relevant representation and warranty shall remain in effect for purposes of such Dispute until such Dispute is resolved pursuant to Section 13.12.

9.4. Progenics Party Covenants.

(a) Necessary Agreements. Each Progenics Party will maintain and keep in full force and effect all agreements reasonably necessary to perform its obligations, and grant the rights granted to Salix, hereunder.

(b) Encumbrances. No Progenics Party will, without the prior written consent of Salix, encumber any portion of the Licensed Technology or Regulatory Documentation with liens, charges or encumbrances, or grant any right or title in respect of the Licensed Technology or Regulatory Documentation, that is inconsistent with the rights and licenses granted to Salix under this Agreement or that would adversely affect Salix’s ability to Manufacture, Develop, Commercialize or otherwise exploit Compound and Products as contemplated hereby. No Progenics Party shall (i) commit any acts or permit the occurrence of any omissions by it that would cause the breach or termination of any Progenics Third Party Agreement or (ii) amend or otherwise modify any Progenics Third Party Agreement, in each case, such as to diminish or otherwise adversely affect the rights granted to Salix hereunder.

(c) Conflicts. No Progenics Party will, or permit any of its Affiliates to, enter into any agreement or obligation that would materially adversely affect such Progenics Party’s ability to grant the licenses to Salix set forth in this Agreement.

(d) Assignment of Contracts. The Progenics Parties hereby agree, at Salix’s request, to cooperate in good faith with Salix in effecting the assignment to Salix of the Progenics Parties’ rights under any Third Party contract or agreement to which any Progenics Party is a party in respect of the Manufacture, Development (subject to Section
4.6), Commercialization or other exploitation of the Compound or Products, other than the Subject Agreements, that the Progenics Parties and Salix mutually determine should be assigned to Salix in order to permit or facilitate the Manufacture, Development, Commercialization or other exploitation by Salix or its Sublicensees of the Compound or Products as contemplated hereby. Without limiting the foregoing, the Progenics Parties shall assist Salix in reaching any necessary accommodation or agreement with any Third Party that is a party to any such contract or agreement so as to permit the effective assignment of the Progenics Parties’ rights as contemplated by the preceding sentence. It is acknowledged and agreed that the Progenics Parties may condition any such assignment upon the assumption by Salix of the Progenics Parties’ related obligations (or other satisfactory arrangement for the satisfaction by Salix of such obligations) to a Third Party that is a party to a contract or agreement to be assigned by Progenics to Salix pursuant to this Section 9.4(d), and the Progenics Parties and Salix agree to negotiate in good faith with respect to any such arrangements. The provisions of this Section 9.4(d) are in addition to, and not by way of limitation of, the provisions of Section 4.6.

(e) Proprietary Rights. Each Progenics Party shall obtain or has already obtained from, or required to be in place with respect to, each of its Affiliates and licensees of the Compound or Products and its and their employees and agents who are performing tests or studies under this Agreement or otherwise participating in the Development or Commercialization of the Compound or Products or who otherwise have access to any Salix Confidential Information appropriate covenants of confidentiality. Each Progenics Party shall also take, or has already taken, all such steps as are customary and reasonable in the pharmaceutical industry to secure from such employees and agents the rights to any inventions, information or other product that result from such tests or studies that relate to the Compound or Products.

(f) Certain Agreements. Each Progenics Party shall exercise its rights under the Subject Agreements, including in respect of its obligations under Section 2.9(a), (i) in a manner as consistent as possible with the Progenics Party’s obligations under this Agreement and, (ii) in respect of any exercise of any such right that could adversely affect Salix’s rights under this Agreement or the Manufacture, the Development or Commercialization of the Compound or Product in the Territory, in accordance with any reasonable direction provided by Salix. Without the prior written consent of Salix, no Progenics Party shall voluntarily (i) amend or modify, or consent to any action that may be taken under a Subject Agreement, or (ii) terminate or engage in any act or omission that constitutes or would constitute, with or without the giving of notice or the passage of time, an event that would permit (A) the [*] to [*], (B) [*] to [*] or (C) [*] to [*], the effect of which, in the case of (A), (B) or (C), would materially adversely affect Salix’s rights under this Agreement. Each Progenics Party shall promptly notify Salix of any such event or of the receipt by the Progenics Party of any notice of breach or termination of the [*]. Each Progenics Party shall take all reasonable actions necessary to maintain and enforce the Progenics Party’s rights under the [*] in a manner consistent with the terms of this Agreement. Without limiting the foregoing provisions of this Section 9.4(f), no Progenics Party shall [*] the [*] in order for [*] to have the [*] without first obtaining Salix’s written consent thereto, which consent Salix acknowledges and agrees may not be withheld in any circumstances other than those in which Progenics is permitted by the terms of the [*] to withhold its consent.

10. TERM AND TERMINATION

10.1. Term. This Agreement shall take effect as of the Effective Date and, unless earlier terminated pursuant to Section 10.2, 10.3, 10.4 or 10.5, shall expire when Salix has no further obligation to make payments of Sublicense Revenues under Section 6.4 or to pay royalties under Section 6.5(a) (the “Term”).

10.2. Termination for Cause.

(a) Breach. If any of the Progenics Parties, on the one hand, or Salix, on the other hand, breaches any of its material obligations under this Agreement and has not remedied such breach within [*] ([“]” days (or, in the case of a payment breach, [*] ([“]”] days) (the “Cure Period”) after receipt of notice thereof from, in the case of a breach by any Progenics Party, Salix or, in the case of a breach by Salix, the Progenics Parties (the “Notice of Breach”), then, respectively, Salix or the Progenics Parties may terminate this Agreement in its entirety but not in part immediately upon expiration of such Cure Period; provided that such notice of Breach shall specifically identify the provisions under this Agreement that respectively, Salix or the Progenics Parties believe to have been breached and state the intent of, respectively, Salix or the Progenics Parties to terminate this Agreement upon expiration of the Cure Period. Without limiting the foregoing, the failure of either Salix or the Progenics Parties to pay any amount in excess of [*] dollars ($[*]) owed to the other within the Cure Period shall constitute a breach of a material obligation under this Agreement, provided that, if such non-payment is subject to a bona fide good faith dispute between the Expanded Parties involved in such payment as to whether such payment is due, the [*] ([“]”) day Cure Period shall be tolled pending resolution of such dispute so long as the Expanded Party alleged to have breached the payment condition is reasonably diligent in pursuing such resolution, and further provided that if such amount is part of a larger payment due, only the Cure Period for the amount in dispute shall be tolled.
10.3. Termination for Insolvency or Bankruptcy. Either Party may terminate this Agreement in its entirety but not in part effective on notice to the other Party (a) upon the liquidation, dissolution, winding up, insolvency, bankruptcy, or filing of any petition therefor, assignment for the benefit of its creditors, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other Party where such petition, assignment or similar proceeding is not dismissed or vacated within [*] [[*]] calendar days, (b) if the other Party shall propose a written agreement of composition or extension of its debts outside the ordinary course of its business or (c) if the other Party shall admit in writing its inability generally to pay its debts as they fall due in the general course.

10.4. Termination by Salix At Its Discretion. At any time on or after the first anniversary of the Effective Date, Salix may terminate this Agreement, in whole but not in part, for any reason or no reason, upon [*] [*] days’ prior notice to Progenics. Notwithstanding the foregoing, Progenics shall have a one-time right, exercisable by notice to Salix given not less than [*] [*] days prior to the date the Agreement would otherwise terminate, to postpone such termination for an additional [*] [*] -day period from the date such termination would otherwise have become effective in the event that Progenics, despite its good faith and diligent efforts, has not succeeded in transitioning Development and Commercialization of the Products to Progenics or its licensee. Salix shall continue to fulfill its obligations under this Agreement during such [*] [*] or [*] [*] -day period.

10.5. Termination of Licenses; Accrued Obligations.

(a) Termination of Licenses. Upon termination of this Agreement for any reason (other than expiration at the end of the Term as provided in Section 10.1), subject to Sections 2.8 and 6.5(b)(ii), all licenses granted to Salix by Progenics under this Agreement shall terminate, and Salix shall have no further right in or to the Licensed Technology, except that, in the case of a termination of a Product by Salix under Section 10.2(b), only the licenses respecting the terminated Product granted to Salix by Progenics under this Agreement shall terminate.

(b) Accrued Obligations. Termination or expiration of this Agreement for any reason shall not release any Party hereto from any payment or other liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

10.6. Effects of Termination or Expiration. Upon expiration of this Agreement as provided in Section 10.1 or termination of this Agreement by Progenics pursuant to Section 10.2(a) or 10.3 or by Salix pursuant to Section 10.2(b) or 10.4, the following additional terms shall apply:

(a) License under Salix IP; Transfer of Third Party License(s); Non-Assertion by Salix. Salix (i) shall, and does hereby, grant to Progenics an exclusive, perpetual, irrevocable, royalty-free, fully paid-up license under the Salix Collaboration Patent Rights and the Salix Collaboration Know-How, and an exclusive, perpetual, irrevocable, royalty-free, fully paid-up license in the Field under Salix’s interest in the Joint Patent Rights and Salix’s interest in the Joint Know-How, in each case with a right to sublicense, to research, make, have made, use, Develop, sell, offer to sell or use, have sold, market, promote, import, export, or otherwise Commercialize the Compound or any other liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

(b) Termination by Salix Because of Serious Safety or Efficacy Reasons. If one or more safety or efficacy issues arise with respect to a Product which are sufficiently serious that Salix would cease Development or Commercialization of the Product if the Product were a product or proposed product owned solely by it, or to which it had exclusive rights, that was of similar commercial potential and at a similar stage in its development or product life, Salix shall promptly inform Progenics of such safety or efficacy issues(s) and convene a meeting of the JSC to discuss such safety or efficacy issues and their implications for Development and Commercialization of the Product. If the JSC is unable to agree on a plan to continue Development and Commercialization of the Product, the [*] of Salix and the [*] of Progenics will discuss whether there is any viable alternative to ceasing Development and Commercialization of the Product. Thereafter, Salix may terminate this Agreement with respect to such Product throughout the Territory immediately upon notice to Progenics.

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the event that, despite Progenics’s good faith and diligent efforts, there should be any delay in effecting any of the transfers

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contemplated by this Section 10.6(b), then the Parties shall negotiate in good faith provisions for interim arrangements between them and in respect of the Development and Commercialization of Products as necessary to afford such additional period as may be reasonably required in order for such transfer to be completed.

(c) Right of Reference. Salix shall promptly deliver to Progenics a copy of and grant, and does hereby grant, to Progenics a right of reference in accordance with Section 12.2 to any and all data contained or referenced in any Regulatory Approvals and other Regulatory Documentation relating to Products.

(d) Ongoing Studies. Salix will cooperate with Progenics to transfer any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced or, if reasonably practicable and requested by Progenics, allow Progenics to complete such trials (and then assign all related Regulatory Documentation and investigator and other agreements relating to such studies), all at Salix’s expense.

(e) Transfer of Technical Information. Without limiting this Section 10.6, Salix shall cooperate with Progenics in transferring to Progenics or a Third Party, as Progenics may direct, within [*] [*] days of the termination hereof, all of the Salix Collaboration Know-How and Progenics Confidential Information in the possession of Salix or its Sublicensees, except that Salix may retain one (1) copy of such Salix Collaboration Know-How and Progenics Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes, but not for any other use or purpose. Salix shall, within [*] [*] days of the event giving rise to the termination, transfer to Progenics copies of all data, reports, records and materials in its possession or control that relate to the Products or Compound and return to Progenics, or destroy at Progenics’s request, all relevant records and materials in Salix’s or its Affiliates’ possession or control containing Confidential Information of Progenics.

(f) Assistance. Salix shall, and, subject to Section 10.8, shall cause its Sublicensees to, provide Progenics, at its request and expense, with such assistance as is reasonably necessary to effectuate a smooth and orderly transition of any Development and Commercialization of Products in the Territory (including any ongoing clinical studies) to Progenics or its designee so as to minimize any disruption of such activities.

(g) Supply of Products. As to Products then being manufactured by or on behalf of Salix or its Affiliates, the Parties shall negotiate in good faith a supply agreement for such Products on commercially reasonable terms to ensure that Progenics shall have for a period of [*] [*] years a continuous supply of such Products. In addition, to the extent permitted under the terms of such agreements, Salix shall use Commercially Reasonable Efforts to assign to Progenics, at Progenics’s request, any of Salix’s rights under any agreements for the supply or manufacture of Products or packaging or the supply of API. Salix shall cooperate with Progenics in good faith to arrange for the supply of API to

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

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Progenics and shall waive any exclusivity right it may have with such suppliers as necessary to permit Progenics to enter into direct supply agreements with such suppliers. Furthermore, at Progenics’s request, Salix shall sell to Progenics any of the inventory (including manufactured Product, packaging materials, Promotional Materials and any other commercial items) held by Salix or its Affiliates or Sublicensees at a price equal to their cost. And in any case, Salix shall use Commercially Reasonable Efforts to transfer, license or sublicense to Progenics or its designee at no cost all documentation and technology in Salix’s Control necessary to enable Progenics or its designee to manufacture Products.

(h) Termination with Respect to a Product. Notwithstanding Section 10.6(a) through (g), in the case of a termination with respect to a particular Product under Section 10.2(b), such provisions shall apply only to the terminated Product.
10.7. Sale of Inventory. In the event of any termination of this Agreement, Salix may continue to sell its existing inventories and any work-in-process of Products until the occurrence of either: (a) Salix’s completion of the transfer of all Regulatory Approvals and related Regulatory Documentation for Products and completion of performance under all then-existing contracts with Third Parties for the marketing, sale or manufacture of Products, or (b) Progenics’s directing Salix to halt all sales of Products by notice, provided that at Progenics’s request, Salix shall promptly provide Progenics copies of each such Third Party contract, for purposes of Progenics’s determining whether to direct Salix to halt sales of Products pursuant to the foregoing clause (b). If either such event occurs prior to the sale of all of Salix’s inventories and work-in-process of Products and the performance by Salix of its obligations under such Third Party contracts in the case of a termination by Progenics pursuant to Section 10.2(a) or 10.3 or by Salix pursuant to Section 10.4, then Salix shall sell to Progenics, and Progenics shall purchase, at Salix’s cost therefor, any remaining Salix inventory and work-in-process of any Products that are useable and saleable within a commercially reasonable period of time. Progenics shall have the right to continue to use supplies of materials carrying the name or trademark of Salix, its Affiliates or Sublicensees until those supplies have been depleted, but in no event for a period of more than [*] ([*]) days.

10.8. Effect of Termination on Sublicenses Granted by Salix. Any and all sublicense agreements entered into by Salix or any of its Affiliates with a Sublicensee pursuant to this Agreement shall survive the termination of this Agreement (other than pursuant to Section 10.4), except to the extent that any such Sublicensee under any Sublicense is in material breach of this Agreement or such Sublicense or Progenics elects to grant such Sublicensee a direct license of the Sublicensed rights on the same terms applicable to Salix under this Agreement. Salix shall, at the request of Progenics, assign any such Sublicense (to the extent not terminated pursuant to the preceding sentence) to Progenics or its Affiliates and, upon such assignment, Progenics or its Affiliates, as applicable, shall assume such Sublicense, as applicable, provided that at Progenics’s request, Salix shall promptly provide to Progenics copies of each such Sublicense for purposes of Progenics’s determining whether to instruct Salix to assign such Sublicense to Progenics or its Affiliates. For clarity, any sublicense agreement entered into by Salix with any of its Affiliates shall terminate upon the termination of this Agreement.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

10.9. Milestone Payments; Royalties. Following any termination of this Agreement in its entirety, Salix shall not be responsible for any (a) milestone payments for milestone events that are achieved under Sections 6.2 or 6.3 following the effective date of such termination or (b) any royalty payments that accrue under Section 6.5(a) following the effective date of such termination, in each case (a) and (b) unless and to the extent Salix, itself or through an Affiliate or Sublicensee, continues to sell Products pursuant to Section 10.7 or 10.8.

10.10. Surviving Provisions.

(a) Termination. Except as otherwise expressly provided therein, the following Articles and Sections of this Agreement shall survive any termination of this Agreement for any reason: Sections 2.8, 2.11, 6.6, 7.1, 7.2(c), and 7.3(b) (inssofar as it relates to Joint Patent Rights), Article 8, Sections 9.1, 9.2, 9.3, 9.4(f), 10.5, 10.6, 10.7, 10.8, and 10.9, this Section 10.10, Section 10.11, and Articles 11, 12, and 13 and, to the extent required to give effect to the following provisions, Article 1.

(b) Expiration. Except as otherwise expressly provided therein, the following Articles and Sections of this Agreement shall survive any expiration of this Agreement for any reason: Sections 2.4, 2.6, 2.7, 2.8, 2.11, 2.12, 2.13, 5.5, 6.6, 7.1, 7.2(c), 7.3(b) (inssofar as it relates to Joint Patent Rights), and 7.5, Article 8, Sections 9.1, 9.2, 9.3, 9.4(f), 10.5, 10.6, 10.7, 10.8, and 10.9, this Section 10.10, Section 10.11, and Articles 11, 12, and 13 and, to the extent required to give effect to the following provisions, Article 1.

(c) Non-Surviving Provisions. Except as otherwise provided in Section 10.5(b) and this Section 10.10, all rights and obligations of the Parties under this Agreement shall terminate upon expiration or termination of this Agreement for any reason.

10.11. Bankruptcy-Related Matters. All rights and licenses granted under or pursuant to this Agreement are licenses of rights to “intellectual property” as defined in Section 365(n) of Title 11 of the United States Code (“Title 11”). Each Party agrees that the other Party, as licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under Title 11. Each Party agrees during the Term, to create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. If a case is commenced by or against a Party (the “Debtor Party”) under Title 11, the Debtor Party (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee) shall:

(a) as the other Party (the “Non-Debtor Party”) may elect in a written request, immediately upon such request:

(i) perform all of the obligations provided in this Agreement to be performed by the Debtor Party including, where applicable and without limitation, providing to the Non-Debtor Party portions of such intellectual property (including embodiments thereof) held by the Debtor Party and such successors and assigns or otherwise available to them; or

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party or a breach by Salix of any of its representations, warranties or covenants set forth in this Agreement.

in each case, (a), (b), (c), (d) and (e), to the extent caused by the gross negligence or intentional misconduct of Salix or any Salix Indemnified

party set forth in this Agreement, provided that with respect to those contained in Section 9.2, such indemnification shall be subject to Section 9.3; except,

or any Progenics Indemnified Party or a breach by Progenics of any of its representations, warranties or covenants set forth in this Agreement.

Section 4.6(d) and (e), if any, in respect of Progenics Third Party Agreements assigned and delegated by Progenics or its Affiliates or licensees

or “royalties” within the meaning of Title 11 or relate to licenses of intellectual property under this Agreement.

or licensees to Salix pursuant to such Section; or (e) the material breach by any Progenics Party of any of its representations, warranties or covenants set

Progenics studies identified in Schedule 9.2(p), in respect of the Compound or Products; (d) liabilities retained by Progenics and its Affiliates pursuant to

Triad Recall; (c) the conduct by Progenics or its Affiliates or licensees or Sublicensees of any pre-clinical or clinical studies, including Clinical

person as a result of use of any Product containing the Compound supplied or sold by Progenics or its Affiliates or licensees or Sublicensees

employees, officers, directors and agents (each, a “Progenics Indemnified Party”) from and against any and all liability, loss, damage, expense

employees, officers, directors and agents (each, a “Salix Indemnified Party”) from and against any and all liability, loss, damage, expense

and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, Title 11) in the event of the

for the research, Development, Manufacture and Commercialization of the Product in the Territory; and

the Non-Debtor Party shall have the right to perform the obligations of the Debtor Party under this Agreement with respect to such intellectual property, but neither such provision nor such performance by the Non-Debtor Party shall release the Debtor Party from any such obligation or liability for failing to perform it. The Parties hereto acknowledge and agree that the milestone payments to be paid under Section 6.2 (and any other payment by Salix to Progenics under this Agreement other than the royalties to be paid under Section 6.5 and milestone payments to be paid under Section 6.3) do not constitute

right to access to any intellectual property (including all embodiments thereof) of the Debtor Party, or any Third Party with whom the

provides to the Non-Debtor Party any of the intellectual property licensed under this Agreement (or any embodiment thereof to the

Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of: (a) any intentional misconduct or gross negligence on the part of Progenics or its Affiliates in performing any activity contemplated by this Agreement; (b) personal injury or death of any person as a result of use of any Product

or any Progenics Indemnified Party from a breach by Progenics of any of its representations, warranties or covenants set forth in this Agreement.

or any Progenics Indemnified Party to a breach by Salix of any of its representations, warranties or covenants set forth in this Agreement.

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11.3. Procedure. Each Party will notify the other Party in writing in the event it becomes aware of a Claim for which indemnification may be sought hereunder. 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 Article 11, such Party (the "Indemnified Party") shall promptly notify the other Party (the "Indemnifying Party") in writing and the Indemnifying Party and Indemnified Party shall meet to discuss how to respond to any Claims that are the subject matter of such proceeding. The Indemnified Party shall cooperate fully with the Indemnifying Party in defense of such matter. The Indemnifying Party, upon request of the Indemnified Party, shall retain counsel reasonably satisfactory to the Indemnified Party to represent the Indemnified Party and shall pay the fees and expenses of counsel related to such proceeding. In any such Claim, the Indemnified Party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party unless (a) the Indemnifying Party and the Indemnified Party shall have mutually agreed to the retention of such counsel or (b) the named parties to any such Claim (including any impleaded parties) include both the Indemnifying Party and the Indemnified Party and representation of both Parties by the same counsel would be inappropriate due to actual or potential differing interests between them. All such fees and expenses shall be reimbursed as they are incurred. The Indemnifying Party shall not be liable for any settlement of any Claim effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to indemnify the Indemnified Party from and against any loss or liability by reason of such settlement or judgment. The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened Claim in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes an unconditional release of the Indemnified Party from all liability on Claims that are the subject matter of such proceeding.

11.4. Insurance.

(a) Progenics shall obtain and maintain, during the Term of this Agreement, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers to cover its indemnification obligations under Section 11.1, in each case with limits of not less than [*] dollars ($[*]) per occurrence and in the aggregate. Insurance shall be procured with carriers having an [*] Rating of [*] or better.

(b) Salix shall obtain and maintain, during the Term of this Agreement, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers to cover its indemnification obligations under Section 11.1, in each case with limits of not less than [*] dollars ($[*]) per occurrence and in the aggregate. Insurance shall be procured with carriers having an [*] Rating of [*] or better.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

12. REGULATORY MATTERS, PRODUCT SAFETY ISSUES, PRODUCT RECALLS


(a) Salix Responsibilities. Salix shall be solely responsible for and shall:

(i) prepare and submit and/or revise and amend Registrational Filings for Products in the Field in the Territory;

(ii) obtain and maintain Regulatory Approvals including Regulatory Marketing Approvals for Products in the Field in the Territory; and

(iii) prepare and submit all other communications with applicable Regulatory Authorities relating to the Development and Commercialization of Products in the Field in the Territory, including (A) all correspondence submitted to Regulatory Authorities related to the design, conduct or results of non-clinical studies and clinical trials for Products in the Field in the Territory; (B) all correspondence submitted to Regulatory Authorities related to the Manufacture of Products in or for the Field in the Territory; (C) all proceedings relating to Drug Price Approval for Products in the Field in the Territory; and (D) all proposed Product Labeling for Products in the Territory.

provided in each case that Salix at its expense shall provide to Progenics a copy of any significant Regulatory Documentation filed by Salix or its Affiliates with, and shall make reasonable efforts to cause its Sublicensees to provide a copy of any significant Regulatory Documentation filed by a Sublicensee with, and Regulatory Authorities in respect of Products in Major Market Countries. Salix shall be solely responsible for all costs and expenses of preparing, maintaining, formatting, and submitting Registrational Filings and any other regulatory filings for Products in the Field in the Territory and for all other costs and expenses in connection with seeking and maintaining Regulatory Approvals for Products in the Territory, including all user fees in connection thereto.

(b) Certain Initial Regulatory Marketing Approvals in the United States. In the case of Regulatory Documentation prepared by Salix for filing with Regulatory Authorities in respect of an initial Regulatory Marketing Approval for a Chronic Pain Product or an initial Regulatory Marketing

(a) In Favor of Salix. Solely for purposes of filing Registrational Filings and obtaining Regulatory Marketing Approvals for Products in the Territory, Progenics hereby grants Salix (i) rights to cross-reference, file or incorporate by reference, with the right to grant further rights of reference to Sublicensees, any data or documentation used in support of regulatory filings for Products by Progenics or its licensees or their Sublicensees or its or their Affiliates, including any technical documentation, CMC documentation, and other Regulatory Documentation, Clinical Data, Regulatory Approvals, drug master files, and any other data or information necessary to the conduct of clinical trials or the submission or approval of any Registrational Filing, in each case to the extent Controlled by Progenics or its Affiliates or otherwise prepared by or on behalf of Progenics, in accordance with Applicable Law, including Directive 93/42/EEC and Directive 2001/83/EC, as and to the extent necessary or useful to support Development activities and any applications for Regulatory Approvals that Salix or its Sublicensees may make with respect to Products in the Field; and (ii) a “right of reference or use” (as that term is defined in 21 C.F.R. §314.3(b), as amended from time to time), and any non-United States equivalents (including Article 10c of Directive 2001/83/EC, as amended), to any and all data contained or referenced in any Regulatory Approvals and other Regulatory Documentation relating to Products, including all Clinical Data, reports, correspondence and conversation logs, in each case to the extent Controlled by Progenics or its Affiliates, and Progenics shall provide appropriate notification of Salix’s access and reference rights to the applicable Regulatory Authorities, including an informed consent letter under Article 10c of Directive 2001/83/EC as amended.

(b) In Favor of Progenics. Solely for purposes of filing Registrational Filings and obtaining Regulatory Approvals for Products outside the Field or outside the Territory, Salix hereby grants Progenics (i) rights to cross-reference, file or incorporate by reference, with the right to grant further rights of reference to sublicensees, any data or documentation used in support of regulatory filings for Products by or on behalf Salix or its Sublicensees, including any technical documentation and other Regulatory Documentation, Clinical Data, Regulatory Approvals and drug master files to the extent Controlled by Salix or its Sublicensees or otherwise prepared by or on behalf of Salix or its Sublicensees in accordance with Applicable Law, including Directive 93/42/EEC and Directive 2001/83/EC, as and to the extent necessary or useful to support any applications for Regulatory Approvals that Progenics or its licensees may make with respect to Products outside the Field or outside the Territory; and (ii) a “right of reference or use” (as that term is defined in 21 C.F.R. §314.3(b), as amended from time to time), and any non-United States equivalents (including Article 10c of Directive 2001/83/EC, as amended), to any and all data contained or referenced in any Regulatory Approvals and other Regulatory Documentation relating to Products, including all Clinical Data, reports, correspondence and conversation logs, to the extent Controlled by Salix, and Salix shall provide appropriate notification of the Progenics’s access and reference rights to the applicable Regulatory Authorities, including an informed consent letter under Article 10c of Directive 2001/83/EC as amended.

12.3. Communications with Regulatory Authorities.

(a) Regular Updates. Each Party shall keep the other Party reasonably and regularly informed of the preparation of all Registrational Filings and other Regulatory Documentation, Regulatory Authority review of all Registrational Filings and other Regulatory Documentation, meetings with Regulatory Authorities, and Regulatory Approvals for Products, in each case whether conducted or accomplished by the Party or by its licensees or Sublicensees, pursuant to procedures to be developed by the JSC.

(b) Certain Notifications. Without limiting the generality of its obligations under Section 12.3(a), each Party shall keep the other Party informed, in a timely manner, of any action by, or notification or other information which it or its licensees or sublicensees receives (directly or indirectly) from, any Regulatory Authority that: (i) [*]; (ii) indicates or suggests [*]; (iii) is reasonably likely to lead to (A) [*], (B) the [*], (C) the imposition of a [*], or (D) any [*]; or (iv) relates to [*]. Each Party shall also provide the other Party in a timely manner with a copy of all correspondence received from a Regulatory Authority specifically regarding the matters referred to above.

(c) Meetings and Communications with Regulatory Authorities. Salix shall be responsible for the scheduling, conduct and preparation of materials for meetings and other communications with Regulatory Authorities relating to the Compound or Products. Salix shall use reasonable efforts to notify Progenics reasonably in advance of any scheduled or anticipated meeting or telephonic communication with Regulatory Authorities relating to an [*] or an [*], and shall promptly provide to Progenics any communications sent or received from any Regulatory Authority in respect of an [*] or an [*]. Progenics may, upon reasonable prior notice to Salix, elect to have its representatives participate in any meeting or telephonic communication with Regulatory Authorities relating to an [*] or an [*].
12.4. Regulatory Audits. If a Regulatory Authority desires to conduct an inspection or audit of any facility in which any Development or Manufacturing activities are being carried out by or on behalf of a Party or its licensees or Sublicensees in respect of the Compound or Products or any data (including Clinical Data) generated in the conduct of activities by or on behalf of a Party or its licensees or Sublicensees in respect of the Compound or Products, then the Party receiving notice of such inspection or audit (a) shall promptly notify the other Party of such inspection or audit, (b) shall immediately update the other Party during (in the case of multi-day inspections or audits) and following such inspection or audit of any information relating to the Compound or Products, and (c) shall promptly provide to the other Party the [•] or [*] of such [•]; provided, that the Party shall have the right to redact any material from such [•] or [*] that do not relate to the Compound or Products, and (d) shall provide a copy of [•] to the other Party, as it relates to the Compound or Products. Each Party agrees to use Commercially Reasonable Efforts to cause its licensees and Sublicensees and Third Party contractors to accept and abide by an audit mechanism substantially similar to the mechanism described in this Section 12.4.

12.5. Ownership of Regulatory Documentation, Registrational Filings and Regulatory Approvals; Transfer of Registrational Filings and Regulatory Approvals.

(a) Ownership. Salix shall own all right, title and interest in all Regulatory Documentation, Registrational Filings and Regulatory Approvals (including Regulatory Marketing Approvals) for any Product and any applications therefor in the Field in the Territory. Nothing in this Section 12.5(a) shall limit Salix’s ability to authorize any Salix Affiliate to seek or obtain any Regulatory Approval in the Territory for any Product or own any such Regulatory Approval obtained as a result of any such application or Salix’s ability to assign ownership of any Regulatory Approval or application therefor to an Affiliate.

(b) Transfer. Progenics, for itself and its Affiliates, hereby assigns and transfers to Salix its entire right, title and interest in and to and all Registrational Filings and Regulatory Approvals in the Territory relating to the Compound or Products held by it or its Affiliates and in connection therewith shall, promptly upon Salix’s request, execute and deliver to any and all relevant Regulatory Authorities all such documents, in such form as may be required by Applicable Law and approved by Salix, as are necessary to effect such transfer of ownership of any and all such Registrational Filings and Regulatory Approvals to Salix. Progenics shall provide Salix with complete and accurate copies of all such Registrational Filings and Regulatory Approvals as soon as reasonably practicable, but in any event within [*] ([*]) days, following the Effective Date. The provisions of this Section 12.5(b) are in addition to, and not by way of limitation of, the provisions of the Transition Agreement.

12.6. Medical and Customer Inquiries. During Commercialization of any Product, Salix and its Affiliates, as appropriate, shall be responsible for responding to all inquiries related to such Product raised by health care professionals or other customers in the Field in the Territory.

12.7. Safety Agreement. Promptly following execution of this Agreement, the Parties will designate pharmacovigilance responsible person(s) who will be responsible for implementing a safety data exchange agreement (the “Safety Agreement”). Such Safety Agreement shall be executed within [*] ([*]) days from the Effective Date or such earlier date as may be required by Applicable Law and shall govern the [*] in order for each Party to meet its regulatory and ethical obligations with respect to the Development and Commercialization of Products. In general, each Party will be primarily responsible for submission of all required reports with respect to adverse events where such Party is obligated to do so under Applicable Law.


(a) Product Recalls in the Territory. Salix shall be solely responsible at Salix’s expense for all contact with Regulatory Authorities in the Territory relating to any Recall of any Product in the Field in the Territory. Salix shall be solely responsible at Salix’s expense for implementing, directing and administering any Recall of any Product in the Field in the Territory required or recommended by any Regulatory Authority in the Territory or court of competent jurisdiction, or determined by Salix, in its sole discretion, to be necessary or advisable. If Salix is required or voluntarily decides to initiate a Recall in the Territory with respect to any Product, whether or not such Recall has been requested or ordered by any Regulatory Authority in the Territory, Salix shall promptly notify Progenics of such requirement or decision. Further, Salix shall promptly notify Progenics of any event that Salix believes affects continuation of development or commercialization of any Product outside the Territory.
(b) Product Recalls outside the Territory. Progenics shall promptly notify Salix of any event that Progenics believes affects continuation of Development or Commercialization of any Product in the Field in the Territory, and any Recall of any Product outside the Field or outside the Territory, including, subject to any applicable confidentiality obligations, promptly disclosing to Salix any and all information related to any such Recall of any Product provided to Progenics by Ono.

(c) Cost of Recalls. As between Salix and Progenics, Salix shall be solely responsible for the cost of any Recall in the Field in the Territory. As between Salix and Progenics, Progenics shall be solely responsible for the cost of any Recall outside the Field or outside the Territory.

(d) [*]. Notwithstanding the provisions of Section 12.8(c):

(i) As between Salix and Progenics, [*] shall be responsible for any and all out-of-pocket costs of [*] of any [*] occasioned by or resulting from the [*] and follow-on matters relating to the [*] or the [*] (but, for the avoidance of doubt, not including or extending to any [*]). [*] shall promptly reimburse [*] for any and all such out-of-pocket costs that may be incurred by [*] in connection with any such [*], including [*].

(ii) [*] shall [*] any costs incurred by it which are required to be reimbursed to it by [*] pursuant to this Section 12.8(d) and are not subject to good faith dispute against any payments owed by [*] to [*] under this Agreement.

13. MISCELLANEOUS

13.1. Force Majeure. No Expanded Party shall be liable to the other Expanded Parties for any failure or delay in performing any obligation under this Agreement (other than any payment or confidentiality obligations) when such failure or delay is caused by events beyond its reasonable control, including fire, flood, other natural disasters, acts of God, war, labor disturbances, interruption of transit, accident, explosion, acts of terrorism and civil commotion; provided that the Expanded Party so affected shall give prompt notice thereof to the other Expanded Parties and shall use reasonable efforts to mitigate the adverse consequences thereof. No such failure or delay shall terminate this Agreement, and each Expanded Party shall complete its obligations hereunder as promptly as reasonably practicable following cessation of the cause or circumstances of such failure or delay.

13.2. Agency. No Expanded Party is, nor will be deemed to be, an employee, agent or legal representative of the other Expanded Parties for any purpose. No Expanded Party will be entitled to enter into any contracts in the name of, or on behalf of the other Expanded Parties, nor will an Expanded Party be entitled to pledge the credit of the other Expanded Parties in any way or hold itself out as having authority to do so.

13.3. Choice of Law. This Agreement shall be governed by and construed in accordance with the laws in effect in the State of New York. The Agreement of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

13.4. Notices. All notices, requests, demands, waivers, consents, approvals or other communications to any Expanded Party hereunder shall be in writing and shall be deemed to have been duly given if delivered personally to such Expanded Party or sent to such Expanded Party by facsimile transmission (receipt confirmed) or by registered or certified mail, postage prepaid, or by internationally recognized commercial delivery service to the addresses listed below, or to such other address as the addressee may have specified in notice duly given to the sender as provided herein.

If to Salix:
Salix Pharmaceuticals, Inc.
1700 Perimeter Park Drive
Morrisville, North Carolina 27560
USA
Attention: General Counsel
Fax No.: 919.447.3417
with copies (which will not constitute notice) to:
Salix Pharmaceuticals, Inc.
1700 Perimeter Park Drive
Morrisville, North Carolina 27560
USA
Attention: Senior Vice President Business Development
Fax No.: 919.228.4222

and
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, D. C. 20004
USA
Attention: Edward C. Britton, Esq.
Fax No.: 202.778.5248
If to the Progenics Parties:
Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
USA
Attn: Chief Executive Officer
Fax: [*]
with a copy to:
Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591
USA
Attn: President
Fax: [*]

and
Dewey & LeBoeuf LLP
1301 Avenue of the Americas
New York, New York 10019
USA
Attention: Stanton J. Lovenworth, Esq.
Fax No.: [*]
13.5. Severability. In the event that any provision of this Agreement shall be found in any jurisdiction to be in violation of public policy or illegal or unenforceable in law or equity, such finding shall not invalidate any other provision of this Agreement in that jurisdiction. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdictions then, to the fullest extent permitted by Applicable Law:

(a) all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Expanded Parties hereto as nearly as may be possible;

(b) such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction; and

(c) the Expanded Parties shall promptly negotiate in good faith a replacement provision to carry out the intention of the invalid, illegal or unenforceable provision to the fullest extent permitted by Applicable Law.

To the extent permitted by Applicable Law, each Expanded Party hereby waives any provision of Applicable Law that would render any provision hereof prohibited or unenforceable in any aspect.

13.6. Entire Agreement.

(a) This Agreement, together with the exhibits and schedules attached hereto and the Related Agreements, states the entire agreement reached between the Expanded Parties hereto with respect to the transactions contemplated hereby. This Agreement, together with the Related Agreements, replaces and supersedes any and all previous agreements and understandings between the Expanded Parties regarding the subject matter hereof and thereof, whether written or oral.

(b) Simultaneously herewith, (i) the Expanded Parties are entering into a 2010 Agreement Related to Progenics’s MNTX In-License with the University of Chicago and ARCH Development Corporation; (ii) Salix and Progenics are entering into a Trademark Co-operation Agreement; and (iii) the Expanded Parties are entering into the Transition Agreement (collectively, the “Related Agreements”). The effectiveness of this Agreement is expressly conditioned on the execution and delivery of each of the Related Agreements by each of the parties thereto.

13.7. Modifications; No Waiver. No amendment, modification, release, waiver or discharge shall be binding upon the Expanded Parties unless in writing and duly executed by authorized representatives of both Parties, and shall not otherwise affect the terms and provisions of this Agreement not affected thereby, which shall remain in full force and effect. The failure of any Expanded Party hereto to enforce at any time, or for any period of time, any provision of this Agreement shall not be construed as a waiver of such provision or of the right of such Expanded Party thereafter to enforce each and every provision.

13.8. Cumulative Remedies. Except to the extent expressly stated in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under equity or law.

13.9. Assignment; Binding Effect.

(a) Without the prior written consent of the other Expanded Parties hereto, which consent shall not after it has been requested be unreasonably withheld, conditioned, or delayed, no other Expanded Party shall sell, transfer, assign, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that any Expanded Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Expanded Parties (i) to any Affiliate of such Expanded Party; or (ii) to any Third Party with which it merges or consolidates, or to which it transfers all or substantially all of its assets relating to Products if in any such event (A) the assigning Expanded Party (provided that it is not the surviving entity) remains jointly and severally liable with the relevant Affiliate or Third Party assignee under this Agreement, and (B) the relevant Affiliate assignee, Third Party assignee or surviving entity assumes in writing all of the assigning Expanded Party’s obligations under this Agreement. For purposes of clarification, a Third Party that merges or consolidates with an Expanded Party or an Affiliate of an Expanded Party, or to which an Expanded Party or an Affiliate of an Expanded Party transfers all or substantially all of its assets to which this Agreement relates, shall not be deemed to grant the other Expanded Parties to this Agreement any license to such Third Party’s technology in existence as of the effective date of such merger, consolidation or transfer, unless such grant is made pursuant to a separate agreement, provided such Third Party shall maintain...
Agreement in accordance with its provisions pending the outcome of Executive Mediation under this Section 13.12.

A dispute pursuant to litigation in accordance with Section 13.17. The Expanded Parties shall continue performing their obligations under the

of the obligations of confidentiality and non-use set forth in Article 8.

Parties: [•], and (b) for Salix: [•]. If the designated officers are unable to resolve the dispute, then any Expanded Party may seek to resolve the

that are indemnifiable thereunder; and provided further that this Section 13.13 shall not apply with respect to any breach by any Expanded Party

or Schedule in or to this Agreement, unless otherwise stated. The word “including” and similar words shall mean “including without limitation” and

such negotiations shall not be admissible in any subsequent dispute resolution proceeding. Said designated officers are: (a) for the Progenics

necessary to protect the interests of such Expanded Party. This Section 13.12 shall be specifically enforceable.

13.10. Change in Control of Progenics; Acquisition.

(a) In the event a Change in Control of Progenics or an Acquisition by Progenics results in Progenics controlling, being controlled by, or being

under common control with a Salix Competitor or results in Progenics or any Person controlling, controlled by or under common control with Progenics being involved in the development or commercialization of a product Developed or Commercialized for use in the Human Field in respect of the diagnosis, treatment or prevention of constipation, then Progenics (or its

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

96

successor) shall provide Salix with notice within five (5) days following the closing date of such transaction. Salix shall have the right, in its sole discretion, (i) to terminate, by notice to Progenics (or its successor) given at any time within [*] ([*]) months following the closing date of any such transaction, any and all provisions contained in this Agreement (excluding Section [*]) that require Salix to [*], that Salix in its reasonable discretion [*], in each case insofar as such [*] and (ii) to disband, by notice to Progenics (or its successor) given at any time within [*] ([*]) months following the closing date of any such transaction, the Committees and terminate their activities and thereafter undertake all activities assigned by this Agreement to the Committees solely and exclusively by itself.

(b) For purposes of this Section 13.10, “control” and, with correlative meanings, the terms “controlled by” and “under common control with” means (i) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise, or (ii) ownership, directly or indirectly, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the voting securities, or other voting ownership interests, in the case of any limited liability company or other type of legal entity.

13.11. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original and all of

which taken together shall constitute one and the same instrument.


(a) General. If any dispute arising out of, in connection with or relating to this Agreement occurs (a “Dispute”), including any question regarding its existence, validity or termination, but, subject to Section 3.5(c), excluding any dispute relating to a matter within the jurisdiction of the JSC, any Expanded Party may, by notice to the other Expanded Parties party to such Dispute, have such Dispute referred to their respective officer designated below for attempted resolution by good faith negotiations within [*] ([*]) days after such notice is received (“Executive Mediation”). Such negotiations shall not be admissible in any subsequent dispute resolution proceeding. Said designated officers are: (a) for the Progenics Parties: [*], and (b) for Salix: [*]. If the designated officers are unable to resolve the dispute, then any Expanded Party may seek to resolve the dispute pursuant to litigation in accordance with Section 13.17. The Expanded Parties shall continue performing their obligations under the Agreement in accordance with its provisions pending the outcome of Executive Mediation under this Section 13.12.

(b) Interim Relief. Notwithstanding anything herein to the contrary, nothing in this Section 13.12 shall preclude any Expanded Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute, if necessary to protect the interests of such Expanded Party. This Section 13.12 shall be specifically enforceable.

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

97

13.13. No Consequential Damages. IN NO EVENT SHALL ANY EXPANDED PARTY OR ITS AFFILIATES BE LIABLE FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY; provided that this limitation shall not limit the indemnification obligations of either Party under Article 11 for damages claimed by a Third Party that are indemnifiable thereunder; and provided further that this Section 13.13 shall not apply with respect to any breach by any Expanded Party of the obligations of confidentiality and non-use set forth in Article 8.

13.14. Interpretation. The paragraph and other headings contained in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement. All references in this Agreement to an Article, Section, or Schedule shall refer to an Article, Section, or Schedule in or to this Agreement, unless otherwise stated. The word “including” and similar words shall mean “including without limitation” and

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© 2009-2019, Wildwood Ventures Ltd. All rights reserved.
13.15. Representation by Counsel. The Expanded Parties acknowledge and agree that: (i) each Expanded Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this Agreement, and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Expanded Parties hereto and not in a favor of or against any Expanded Party, regardless of which Expanded Party was generally responsible for the preparation of this Agreement.

13.16. Further Assurances. Each Expanded Party shall execute and deliver, or cause to be executed and delivered, such further instruments and do an cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Expanded Parties may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Expanded Parties their rights and remedies under this Agreement.

13.17. Jurisdiction; Venue; Service.

(a) Jurisdiction. Subject to Section 13.12, the Expanded Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York and the United States District Court for the Southern District of New York, in either case sitting in the Borough of Manhattan in the City of New York, for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Expanded Parties irrevocably and unconditionally waive their right to a jury trial.

(b) Venue. The Expanded Parties hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York or in the United States District Court for the Southern District of New York, in either case sitting in the Borough of Manhattan in the City of New York, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

(c) Service. Each Expanded Party agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 13.4 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

13.18. Specific Enforcement. The Expanded Parties acknowledge and agree that, without restriction, the restrictions set forth in Article 8 are reasonable and necessary to protect the legitimate interests of the other Expanded Parties and that such other Expanded Parties would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any such provision or other prohibitive or mandatory provision of this Agreement may result in irreparable injury to such other Expanded Parties for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any such provision, the non-breaching Expanded Parties 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 non-breaching Expanded Parties may be entitled in law or equity. All Expanded Parties agree to waive, to the maximum extent permitted by Applicable Law, any requirement that the others (i) post a bond or other security as a condition for obtaining any such relief and (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 13.18 is intended, or should be construed, to limit any Expanded Party’s right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.19. Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed upon or related to the Progenics Parties or Salix from time to time. Each Expanded Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Expanded Parties under 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 governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in...

(a) Each Expanded Party shall have the right to subcontract any of its Development and Commercialization activities with respect to Products to one or more Third Party contractors, provided that it furnishes the other Expanded Parties with advance notice thereof and an opportunity to consult regarding such subcontract, which notice shall specify the work to be subcontracted, and obtains a written undertaking from the Third Party contractor that it shall be subject to the applicable terms and conditions of this Agreement, including the provisions of Article 8. Each Expanded Party shall be responsible for the work performed by such Third Party contractor(s), and shall remain solely responsible for all costs and expenses associated with its use of Third Party contractor(s) hereunder.

(b) Each of the Expanded Parties acknowledges that certain of the other Expanded Parties' obligations under this Agreement may be performed by Affiliates of such other Expanded Parties. Each of the Expanded Parties guarantees performance of this Agreement by any of its Affiliates.

13.21. No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Expanded Parties hereto and their successors and permitted assigns, and, with the exception of the provisions of Sections 11.1 through 11.3, they shall not be construed as conferring any rights on any other parties.

13.22. Effect of Termination of the UR Labs-Progenics Agreement.

(a) Background. Progenics and UR Labs, Inc., a Nevada corporation ("UR Labs"), entered into an Exclusive Sub-License Agreement, dated as of 21 September 2001, as amended (the "UR Labs-Progenics Agreement"), under which UR Labs granted Progenics a license, with the right to further sublicense, under certain Progenics Technology. On 22 December 2005, UR Labs assigned the UR Labs-Progenics Agreement, together with all Patent Rights and Know-How licensed thereunder, to ProNev, Progenics's wholly-owned subsidiary.

(b) Direct License to Salix. Solely for the purpose of maintaining the continuity of the licenses granted by Progenics to Salix under this Agreement, should the UR Labs-Progenics Agreement be terminated for any reason other than as a result of Salix's uncured material breach of this Agreement (a "Salix Non-Defaulting Termination"), then ProNev shall, and hereby does, grant to Salix a direct license under all Progenics Patent Rights and Progenics Know-How Controlled by ProNev. In such event, the foregoing license shall be on the terms and conditions of the UR Labs-Progenics Agreement as supplemented by this Section 13.22 and shall remain in effect for the duration of the license granted by Progenics to Salix under this Agreement. Progenics hereby consents to ProNev’s

grant of such a license to Salix. For purposes of this Section 13.22, the UR Labs-Progenics Agreement shall be deemed terminated on either (i) the date of termination pursuant to the UR Labs-Progenics Agreement after giving effect to any cure or grace periods or, (ii) in the event that Progenics initiates litigation or arbitration challenging the existence of a termination event, the date of a final determination of termination by a court of competent jurisdiction or binding arbitration panel.

(c) Termination of Direct License to Salix. If and to the extent that the license granted by Progenics to Salix under this Agreement is terminated, in whole or in part, by Progenics pursuant to Section 10.2 or 10.3, then the license granted by ProNev to Salix under Section 13.22(b) shall likewise be automatically terminated to the same extent.

(d) Payments in the Event of Termination of the UR Labs-Progenics Agreement. In consideration of the direct license granted by ProNev to Salix under Section 13.22(b), in the event of a Salix Non-Defaulting Termination of the UR Labs-Progenics Agreement, Salix shall thereafter pay to ProNev [*] (had the UR Labs-Progenics Agreement remained in effect) in connection with the license granted to Progenics to Salix under this Agreement, any such payments to be made at [*].

(e) Restatement of License Agreement. In the event of a Salix Non-Defaulting Termination of the UR Labs-Progenics Agreement, then, at Salix’s request, Salix and ProNev shall enter into an agreement memorializing and restating the direct license granted to Salix by ProNev under Section 13.22(b) on the terms and conditions provided for in this Section 13.22.

(f) Certain Representations and Warranties. ProNev hereby represents, warrants, and covenants to Salix as follows:

(i) it is a corporation duly organized and validly existing under the laws of the state or country of its incorporation;

(ii) the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action and does not require any shareholder action or approval;

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

(iv) the execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions hereof do not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (A) a loan agreement, guaranty, financing agreement, agreement relating to one or more Patent Rights or other agreement or instrument binding or affecting it or its property; (B) the
charter or operative documents or bylaws; or (C) any law, regulation, order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; and

(v) it shall at all times comply with all material laws and regulations applicable to its activities under this Agreement.

13.23. Effect of Termination of the [*] Agreement.

(a) Background. Progenics and [*] and [*] entered into the [*] Agreement under which [*] granted Progenics a license, with the right to further sublicense, under certain Progenics Technology. On [*].

(b) Direct License to Salix. Solely for the purpose of maintaining the continuity of the licenses granted by Progenics to Salix under this Agreement, should the [*] Agreement be terminated for any reason other than as a result of a Salix Non-Defaulting Termination, then [*] shall, and hereby does, grant to Salix a direct license under all Progenics Patent Rights and Progenics Know-How Controlled by [*]. In such event, the foregoing license shall be on the terms and conditions of the [*] Agreement as supplemented by this Section 13.23 and shall remain in effect for the duration of the license granted by Progenics to Salix under this Agreement. Progenics hereby consents to [*]’s grant of such a license to Salix. For purposes of this Section 13.23, the [*] Agreement shall be deemed terminated on either (i) the date of termination pursuant to the [*] Agreement after giving effect to any cure or grace periods or, (ii) in the event that Progenics initiates litigation or arbitration challenging the existence of a termination event, the date of a final determination of termination by a court of competent jurisdiction or binding arbitration panel.

(c) Termination of Direct License to Salix. If and to the extent that the license granted by Progenics to Salix under this Agreement is terminated, in whole or in part, by Progenics pursuant to Section 10.2 or 10.3, then the license granted by Excelsior to Salix under Section 13.23(b) shall likewise be automatically terminated to the same extent.

(d) Payments in the Event of Termination of the [*] Agreement. In consideration of the direct license granted by [*] to Salix under Section 13.23(b), in the event of a Salix Non-Defaulting Termination of the [*] Agreement, Salix shall thereafter pay to [*] [*] (had the [*] Agreement remained in effect) in connection with the license granted by Progenics to Salix under this Agreement, any such payments to be made [*].

(e) Restatement of License Agreement. In the event of a Salix Non-Defaulting Termination of the [*] Agreement, then, at Salix’s request, Salix and [*] shall enter into an agreement memorializing and restating the direct license granted to Salix by [*] under Section 13.23(b) on the terms and conditions provided for in this Section 13.23.


* Confidential treatment requested; certain information omitted and filed separately with the SEC.
IN WITNESS WHEREOF, duly authorized representatives of the Expanded Parties have duly executed this Agreement to be effective as of the Effective Date.

Salix Pharmaceuticals, Inc. Progenics Pharmaceuticals, Inc.

By: 

By:

Name: Carolyn J. Logan Name:

Title: President and Chief Executive Officer Title:

Progenics Pharmaceuticals Nevada, Inc.

By: 

Name:

Title:

Excelsior Life Sciences Ireland Limited

By: 

Name:

Title:

[Signature page for License Agreement]

Schedule 1.32
CHEMICAL DRAWING OF THE COMPOUND

[*] 

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 1.135
SALIX COGs

As used in this Agreement, “Salix COGs” means:

I. [*] 

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 1.139
SALIX COMPETITORS

[*] 

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 4.1
INITIAL DEVELOPMENT OUTLINE

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 4.6(d)

MAJOR SUPPLY AND OTHER CONTRACTS

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 5.1(a)

INITIAL COMMERCIALIZATION OUTLINE

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule [*]

[*]

[*]

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule [*]

[*]

National Phase Countries European Patent Office Member States

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(a)(i)

LICENSED PATENT RIGHTS

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(a)(ii)

PROGENICS THIRD PARTY AGREEMENTS

[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.
Schedule 9.2(b)(i)

WYETH COLLABORATION PATENT RIGHTS

See the properties on Schedule 9.2(a)(i) where Wyeth is listed as sole owner.

Schedule 9.2(b)(ii)

WYETH COLLABORATION JOINT PATENT RIGHTS

See the properties on Schedule 9.2(a)(i) where Wyeth is listed as joint owner with Progenics.

Schedule 9.2(c)(i)

EXCEPTIONS TO OWNERSHIP OF PATENT RIGHTS

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(c)(ii)

EXCEPTIONS TO OWNERSHIP OF INTEREST IN JOINT PATENT RIGHTS

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(d)

EXCEPTIONS AS TO INVENTORS

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(e)

EXCEPTIONS AS TO PRIOR ART

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(f)

EXCEPTIONS AS TO INTEREST IN PROGENICS KNOW-HOW

[*]

* Confidential treatment requested; certain information omitted and filed separately with the SEC.
Schedule 9.2(i)
EXCEPTIONS AS TO FREEDOM TO OPERATE
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(j)(i)
EXCEPTIONS AS TO VALIDITY AND ENFORCEABILITY OF PROGENICS PATENT RIGHTS
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(j)(ii)
EXCEPTIONS AS TO MISAPPROPRIATION
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(j)(iii)
EXCEPTIONS AS TO CLAIMS OF INVALIDITY OR UNENFORCEABILITY OF LICENSED PATENT RIGHTS
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(m)
RELISTOR MARKS
Registrations and Applications:
[*]
Exceptions:
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(o)
ADVERSE INFORMATION
Exceptions:
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.
Schedule 9.2(p)
STUDIES
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(r)(i)
REGULATORY APPROVALS
[*]
Exceptions:
[*]
* Confidential treatment requested; certain information omitted and filed separately with the SEC.

Schedule 9.2(s)
PROMOTIONAL MATERIALS
U.S.:
The Promotional Materials enumerated on the [*].
Ex-U.S.:
The Promotional Materials enumerated in the [*].
* Confidential treatment requested; certain information omitted and filed separately with the SEC.