

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q/A**

(Amendment No. 2)

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

**FOR THE QUARTERLY PERIOD ENDED June 30, 2011**

**OR**

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

**FOR THE TRANSITION PERIOD FROM TO**

**COMMISSION FILE NUMBER 000-19319**

**VERTEX PHARMACEUTICALS INCORPORATED**

(Exact name of registrant as specified in its charter)

**MASSACHUSETTS**

(State or other jurisdiction of  
incorporation or organization)

**04-3039129**

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

**130 WAVERLY STREET  
CAMBRIDGE, MASSACHUSETTS**  
(Address of principal executive offices)

**02139-4242**

(Zip Code)

**(617) 444-6100**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

**Common Stock, par value \$0.01 per share**

Class

**208,087,899**

Outstanding at July 29, 2011

We are filing this Amendment No. 2 to our Quarterly Report on Form 10-Q for the three months ended June 30, 2011, which was originally filed with the Securities and Exchange Commission on August 9, 2011 and amended by Amendment No. 1, which was filed with the Securities and Exchange Commission on August 19, 2011 (collectively, the "Quarterly Report"), for the sole purposes of filing, with fewer redactions, one exhibit for which we requested confidential treatment. The Exhibit Index also is being amended to add new officer certifications in accordance with Rule 13a-14(a) of the Exchange Act. This Amendment No. 2 continues to speak as of August 9, 2011, the date of the original filing of the Quarterly Report, and we have not updated the disclosures contained therein to reflect any events that occurred at a later date.

**Item 6. Exhibits**

Exhibit No.	Description	Filed with this Form 10Q/A	Incorporation by Reference		
			Form or Schedule	Filing Date with SEC	SEC File Number
10.1	License and Collaboration Agreement, dated June 13, 2011, by and between Alios BioPharma, Inc. and Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Switzerland) LLC. † (1)	X			
10.2	Research, Development and Commercialization Agreement, dated May 24, 2004, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated. †		10-Q/A	August 19, 2011	000-19319
10.3	Amendment No. 5 to Research, Development and Commercialization Agreement, effective as of April 1, 2011, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated. †		10-Q	August 9, 2011	000-19319
10.4	Lease, dated May 5, 2011, between Fifty Northern Avenue LLC and Vertex Pharmaceuticals Incorporated. †		10-Q	August 9, 2011	000-19319
10.5	Lease, dated May 5, 2011, between Eleven Fan Pier Boulevard LLC and Vertex Pharmaceuticals Incorporated. †		10-Q	August 9, 2011	000-19319
10.6	Amendment No. 2 to Research, Development and Commercialization Agreement, effective as of January 1, 2006, between Vertex Pharmaceuticals Incorporated and Cystic Fibrosis Foundation Therapeutics Incorporated.		10-Q/A	August 19, 2011	000-19319
31.1	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.		10-Q	August 9, 2011	000-19319
31.2	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.		10-Q	August 9, 2011	000-19319
31.3	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.		10-Q/A	August 19, 2011	000-19319
31.4	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.		10-Q/A	August 19, 2011	000-19319
31.5	Certification of the Chief Executive Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.6	Certification of the Chief Financial Officer under Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		10-Q	August 9, 2011	000-19319
101.INS	XBRL Instance*		10-Q	August 9, 2011	000-19319
101.SCH	XBRL Taxonomy Extension Schema*		10-Q	August 9, 2011	000-19319
101.CAL	XBRL Taxonomy Extension Calculation*		10-Q	August 9, 2011	000-19319
101.LAB	XBRL Taxonomy Extension Labels*		10-Q	August 9, 2011	000-19319
101.PRE	XBRL Taxonomy Extension Presentation*		10-Q	August 9, 2011	000-19319
101.DEF	XBRL Taxonomy Extension Definition*		10-Q	August 9, 2011	000-19319

\* Pursuant to applicable securities laws and regulations, we will be deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and will not be subject to liability under any anti-fraud provisions of the federal securities laws with respect to such interactive data files as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed and otherwise are not subject to liability, except as provided by applicable securities laws and regulations.

† Confidential portions of this document have been filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

(1) Originally filed as Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q on August 9, 2011.

4

---

### Signatures

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

March 2, 2012

VERTEX PHARMACEUTICALS INCORPORATED

By: \_\_\_\_\_ /s/ IAN F. SMITH

Ian F. Smith  
*Executive Vice President and Chief Financial Officer*  
*(principal financial officer and*  
*duly authorized officer)*

5

---

Confidential Treatment Requested. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Execution Version

**LICENSE AND COLLABORATION AGREEMENT**

**BY AND BETWEEN**

**ALIOS BIOPHARMA, INC.**

**AND**

**VERTEX PHARMACEUTICALS INCORPORATED**

**AND**

**VERTEX PHARMACEUTICALS (SWITZERLAND) LLC**

**DATED**

**June 13, 2011**

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**TABLE OF CONTENTS**

	<u>Page</u>
ARTICLE 1 DEFINITIONS	1
ARTICLE 2 OVERVIEW AND MANAGEMENT OF THE COLLABORATION	13
2.1 Overview	13
2.2 Reports; Inspection	17
2.3 Alios’ Membership on the JSC and Joint Operational Teams	17
2.4 Diligence	18
ARTICLE 3 RESEARCH PROGRAM	18
3.1 Term of the Research Program	18
3.2 Selection of Selected Back-Up Compounds and Selected Follow-on Compounds	18
3.3 [***]	18
ARTICLE 4 DEVELOPMENT AND REGULATORY	19
4.1 Scope of Development	19
4.2 IND Filings	19
4.3 Transition Plan	19
4.4 Use of Information	19
4.5 Approval Applications and Regulatory Approvals	19
4.6 Selected Regimen	20
4.7 Reporting Adverse Events	20
ARTICLE 5 COMMERCIALIZATION	21
5.1 Scope of Commercialization	21
5.2 Commercial Diligence	21
5.3 Commercialization Reports	21
ARTICLE 6 MANUFACTURE AND SUPPLY	22
6.1 Manufacture and Supply of Pre-Clinical and Clinical Materials	22
6.2 Commercial Supply of Licensed Products and Combination Products	22
6.3 Technology Transfer	22
ARTICLE 7 FINANCIAL TERMS	22
7.1 Initial Payment	22

7.2	Payment of Costs related to Research and Development Programs	22
7.3	Research Milestone Payments	23
7.4	Development Milestone Payments	23
7.5	Commercial Milestone Payments	25
7.6	Royalties	26
7.7	Taxes and Withholding	30
7.8	Currency	30

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

7.9	Payments; Late Payments	30
ARTICLE 8 LICENSES		31
8.1	Licenses	31
ARTICLE 9 INTELLECTUAL PROPERTY		33
9.1	Ownership of Intellectual Property	33
9.2	Prosecution and Maintenance of Patent Rights; Abandonment	33
9.3	Prosecution and Maintenance of Joint Patents; Abandonment	34
9.4	Interference, Opposition, Reexamination and Reissue	35
9.5	Enforcement of Patent Rights	35
9.6	Settlement with a Third Party	37
9.7	Infringement of Third Party Rights	37
9.8	Trademarks	38
9.9	Approval Applications and Regulatory Approvals	38
ARTICLE 10 CONFIDENTIALITY		39
10.1	Confidentiality; Exceptions	39
10.2	Authorized Disclosure	40
10.3	Return of Confidential Information	40
10.4	Publications	41
10.5	Press Releases	41
ARTICLE 11 REPRESENTATIONS, WARRANTIES AND COVENANTS		42
11.1	Representations and Warranties of the Parties	42
11.2	Representations, Warranties and Covenants of Alios	43
11.3	Representations, Warranties and Covenants of Vertex	44
11.4	Disclaimer	45
ARTICLE 12 INDEMNIFICATION, INSURANCE, LIMITATION OF LIABILITY		45
12.1	Indemnification by Vertex	45
12.2	Indemnification by Alios	46
12.3	Indemnification Procedure	46
12.4	Insurance	48
12.5	Limitation of Liability	48
ARTICLE 13 TERM AND TERMINATION		48
13.1	Term	48
13.2	Termination at Will or for Technical Failure	49
13.3	Termination for Cause	49
13.4	Termination for Insolvency	50
13.5	HSR Filing	50
13.6	Termination for Inactivity	51
13.7	Termination for Patent Challenge	51
13.8	Rights on Termination	51

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

13.9	Licensed Product and Licensed Compound Reversion and Commercial Development by Alios	52
13.10	Accrued Rights	55
13.11	Survival	55

ARTICLE 14 GOVERNING LAW AND DISPUTE RESOLUTION 55

14.1	Governing Law	55
14.2	Referral to Responsible Executives	55
14.3	Dispute Resolution	56

ARTICLE 15 GENERAL PROVISIONS 61

15.1	Assignment, Binding Agreement	61
15.2	Force Majeure	61
15.3	Further Actions	62
15.4	Governmental Approvals; Compliance with Law	62
15.5	Notices	62
15.6	Waiver	63
15.7	Disclaimer of Agency	63
15.8	Interpretation	63
15.9	Severability	64
15.10	Entire Agreement	64
15.11	Amendment	65
15.12	Counterparts; Electronic Delivery	65

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**LIST OF SCHEDULES AND EXHIBITS**

	<u>Page</u>
Exhibit A Research Plan	69
Exhibit B Development Plan	71
Exhibit C Press Release	85
Schedule 1.7 Alios Patent Rights	92
Schedule 1.8 ALS-2158	93
Schedule 1.9 ALS-2200	94

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**VERTEX PHARMACEUTICALS INCORPORATED**

**LICENSE AND COLLABORATION AGREEMENT**

**THIS LICENSE AND COLLABORATION AGREEMENT** (this “**Agreement**”) is entered into on June 13, 2011 (“**Execution Date**”) by and between Alios BioPharma, Inc., a corporation organized under the laws of the State of Delaware, having offices at 260 East Grand Avenue, 2nd Floor, South San Francisco, California 94080, United States of America (“**Alios**”) and Vertex Pharmaceuticals Incorporated, a Massachusetts corporation having offices at 130 Waverly Street, Cambridge, Massachusetts 02139, United States of America, and its wholly-owned subsidiary Vertex Pharmaceuticals (Switzerland) LLC (together, “**Vertex**”). Alios and Vertex are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties.**”

**RECITALS**

1. Alios is engaged in the discovery and development of novel small molecule pharmaceuticals to treat viral disease using its proprietary nucleoside/nucleotide chemistries.
2. Vertex is engaged in the discovery, development, manufacture and marketing of human pharmaceutical products, including INCIVEK™ (telaprevir) and other product candidates, for the treatment of chronic hepatitis C, and for other diseases and indications.

3. Alios is developing novel compounds for the treatment of chronic hepatitis C, and Alios owns or has rights under certain patents, patent applications, other valuable technology and know-how relating to such compounds.

4. Vertex and Alios wish to collaborate on the research, development and commercialization of Licensed Products and/or Combination Products (defined below) for the treatment of chronic hepatitis C according to the terms and conditions of this Agreement.

5. In consideration of the premises and of the mutual covenants and obligations set forth herein, the Parties hereby agree as set out below.

## ARTICLE 1 DEFINITIONS

The following capitalized terms shall have the following meanings:

**1.1 “Affiliate”** means any individual, corporation, association or other business entity which directly or indirectly controls, is controlled by or is under common control with the Party in question. As used in this definition of “Affiliate,” the term “control” means the direct or indirect ownership of more than fifty percent (50%) of the stock having the right to vote for directors thereof or the ability to otherwise control the management of the corporation, association or other business entity whether through the ownership of voting securities, by contract, resolution, regulation or otherwise.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

**1.2 “Alios Compound” [\*\*\*].**

**1.3 “Alios’ FTE Rate”** means Alios’ [\*\*\*]. Alios’ FTE rate for the period from the Effective Date until December 31, 2012 shall be [\*\*\*] per Calendar Year per FTE. Alios’ FTE rate shall be adjusted annually thereafter by a percentage equal to the percentage change in the Bureau of Labor Statistics consumer price index for the San Francisco Bay area over the [\*\*\*] month period reported in such index prior to the Effective Date.

**1.4 “Alios IP”** means Alios Patent Rights, Alios IP Improvements, and Alios Know-How.

**1.5 “Alios IP Improvement(s)”** means any Improvement that (a) falls within at least one Valid Claim of the Alios Patent Rights existing as of the date such Improvement was conceived; or (b) is a derivative of one or more Alios Compounds, Licensed Compounds or Licensed Products.

**1.6 “Alios Know-How”** means any Know-How Controlled by Alios at any time during the Term that relates to the use, Manufacture, or composition of matter of any Licensed Compound or Licensed Product.

**1.7 “Alios Patent Rights”** means any Joint Patent or Patent Right Controlled by Alios at any time during the Term that claims the use, Manufacture, or composition of matter of any Licensed Compound or Licensed Product. The Alios Patent Rights in existence as of the Effective Date are set forth on Schedule 1.7 (Alios Patent Rights) to this Agreement.

**1.8 “ALS-2158”** means the Alios Compound described in Schedule 1.8 (ALS-2158) to this Agreement, [\*\*\*].

**1.9 “ALS-2200”** means the Alios Compound described in Schedule 1.9 (ALS-2200) to this Agreement, [\*\*\*].

**1.10 “API”** means active pharmaceutical ingredient, which is also commonly referred to as drug substance. For the avoidance of doubt, API shall include any prodrug form.

**1.11 “Applicable Laws”** means all laws, statutes, ordinances, codes, rules and regulations which have been enacted by a Governmental Authority and are in force as of the Effective Date or come into force during the Term, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement. For purposes of this Agreement, good clinical practices (“GCP”), GLP and GMP shall be deemed to be within the term “Applicable Laws.”

**1.12 “Approval Application”** means any NDA or equivalent application (such as a Marketing Authorization Approval (“MAA”) in the EU) necessary and appropriate to obtain a Regulatory Approval, together with all required documents, data and information concerning any Licensed Product or Combination Product which is the subject of such application. For clarity, “Approval Application” shall not include an IND.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

**1.13 “Back-Up Compound”** means [\*\*\*].

**1.14 “Business Day”** means a day other than Saturday, Sunday or any day on which commercial banks located in San Francisco, California or Boston, Massachusetts are authorized or obligated by Applicable Law to close.

**1.15 “Calendar Quarter”** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; *provided, however*, that (a) the first Calendar Quarter of any particular period shall extend from the commencement of such period to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter shall end upon the expiration or termination of this Agreement.

**1.16 “Calendar Year”** means (a) for the first Calendar Year of the Term, the period beginning on the Effective Date and ending on December 31, 2011, (b) for each Calendar Year of the Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last Calendar Year of the Term, the period beginning on January 1 of the Calendar Year in which the Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement.

**1.17 “Change of Control”** means a transaction or series of related transactions that result in (a) the holders of outstanding voting securities of a Party immediately prior to such transaction ceasing to represent at least [\*\*\*] of the combined outstanding voting power of the surviving entity immediately after such transaction; (b) any Third Party (other than a trustee, financial investor, or other fiduciary holding securities under an employee benefit plan) becoming the beneficial owner of [\*\*\*] or more of the combined voting power of the outstanding securities of a Party; or (c) a sale or other disposition to a Third Party of all or substantially all of a Party’s assets or business; *provided, however*, that, notwithstanding (a), (b), or (c) above, a stock sale to financial investors for capital raising purposes or to underwriters of a public offering of such Party’s capital stock shall not constitute a Change of Control.

**1.18 “Clinical Development”** means, with respect to a Licensed Product or Combination Product, [\*\*\*] as the case may be, [\*\*\*].

**1.19 “[\*\*\*] Milestone Event”** means that the [\*\*\*].

**1.20 “Clinical Trials”** means Phase 1 Clinical Trials, Phase 2 Clinical Trials, Phase 3 Clinical Trials, Phase 4 Clinical Trials, and Post-Approval Commitment Studies and their foreign equivalents.

**1.21 “Collaboration”** means all activities by the Parties under this Agreement.

**1.22 “Combination Product”** means [\*\*\*].

**1.23 “Commercialization” or “Commercialize”** means, with respect to a Licensed Product or Combination Product, any and all activities directed to the marketing, promotion, distribution, offering for sale, and selling of such Licensed Product or Combination Product,

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

importing and exporting such of Licensed Product or Combination Product for sale, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall also include Phase 4 Clinical Trials.

**1.24 “Control”** means, with respect to intellectual property, that the Party named as having Control owns such intellectual property, or otherwise possesses the ability to grant a license, sublicense or other rights under or with respect to such intellectual property without violating the terms of any agreement between that Party and a Third Party.

**1.25 “Development” or “Develop”** means the combination of activities directly and specifically relating to the Pre-Clinical Testing, IND-Enabling Studies, and Clinical Development of a Licensed Compound, Licensed Product or Combination Product, including [\*\*\*].

**1.26 “Development Plan”** means the development plan attached hereto as Exhibit B, as it may be amended from time to time in accordance with the terms of this Agreement.

**1.27 “Development Work”** means the Development of Licensed Compounds, Licensed Products and/or Combination Products.

**1.28 “Effective Date”** means the later of (a) the Execution Date or (b) if an HSR Filing is made, the second Business Day immediately following the HSR Clearance Date.

**1.29 “EMA”** means the European Medicines Agency, and any successor thereto.

**1.30 “EU”** means the European Union, as it exists from time to time.

**1.31 “FDA”** means the United States Food and Drug Administration, and any successor thereto.

**1.32 “FD&C Act”** means the United States Federal Food Drug and Cosmetic Act, as amended (21 U.S.C. §302 et seq.).

**1.33 “Field”** means the prophylaxis, treatment, amelioration, mitigation, and diagnosis of human diseases and conditions.

**1.34 “First Commercial Sale”** means the first sale of a Licensed Product or Combination Product by Vertex, its Affiliates or its Sublicensees (including its co-promotion and co-marketing partners) for use or consumption of such Licensed Product or Combination Product. Sale of a Licensed Product or Combination Product by Vertex to an Affiliate of Vertex or a Sublicensee of Vertex shall not constitute a First Commercial Sale unless such Affiliate or such Sublicensee is the end user of the Licensed Product or Combination Product.

**1.35 “Follow-on Compound”** means an [\*\*\*].

**1.36 “Full Time Equivalent” or “FTE”** means the full time equivalent effort of one (1) Person who participates directly in the activities under the Research Program or Development Program on behalf of Alios or Vertex, as the case may be. For purposes of this Agreement “full

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*



time equivalent effort” means [\*\*\*] per Calendar Year by such Person. For the avoidance of doubt, employees who work fewer than [\*\*\*] in a Calendar Year (whether via working a partial year or part-time) are included in an FTE, *provided* their hours are combined so as to complete one FTE. By way of example, but not limitation, an employee working [\*\*\*] in a given Calendar Year would be combined with an employee working [\*\*\*] in the same Calendar Year to form one (1) FTE. Similarly, any employee can be allocated at a percentage of time equaling less than one hundred percent (100%) of their work Calendar Year, *provided* that FTEs are calculated [\*\*\*] increments.

1.37 “GAAP” means United States generally accepted accounting principles, consistently applied.

1.38 “GLP” means, as to the United States and the EU, applicable good laboratory practices as in effect in the United States and the EU, respectively, during the Term and, with respect to any other jurisdiction, laboratory practices equivalent to good laboratory practices as then in effect in the United States or the EU.

1.39 [\*\*\*] Milestone Event [\*\*\*].

1.40 “GMP” means, as to the United States and the EU, applicable good manufacturing practices as in effect in the United States and the EU, respectively, during the Term and, with respect to any other jurisdiction, manufacturing practices equivalent to good manufacturing practices as then in effect in the United States or the EU.

1.41 “Governmental Authority” means any supranational, national, regional, state or local government, court, governmental agency, authority, board, bureau, instrumentality or regulatory body.

1.42 “HCV Field” means the prophylaxis, treatment, amelioration, mitigation, or diagnosis of Hepatitis C Virus infection.

1.43 “Hepatitis C Virus” or “HCV” means the hepatitis C virus of the flaviviridae family of viruses, including all genotypes, subtypes, and quasispecies of HCV.

1.44 “HSR Act” means the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations promulgated thereunder.

1.45 “HSR Clearance Date” means the earliest date on which the Parties have actual knowledge that all applicable waiting periods under the HSR Act with respect to the transactions contemplated hereunder have expired or have been terminated.

1.46 “HSR Filing” means filings by Vertex and Alios with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice of a Notification and Report Form for Certain Mergers and Acquisitions (as that term is defined in the HSR Act) with respect to the matters set forth in this Agreement, together with all required documentary attachments thereto.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

1.47 “Improvement(s)” means any future new or useful discovery, invention, contribution, finding, or improvement, whether or not patentable, and all related Know-How, that is conceived, reduced to practice or otherwise developed by Alios or Vertex, either solely or jointly, as the case may be.

1.48 “IND” means (a) an Investigational New Drug application, as defined in the FD&C Act and the regulations promulgated thereunder, filed with or submitted to the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto, or a foreign equivalent filing with a Regulatory Authority, such as a Clinical Trial Application in the EU or Canada, necessary to commence Clinical Trials, and (b) all supplements and amendments that may be filed with respect to any of the foregoing.

1.49 “IND-Enabling Studies” means studies comprising *in vitro* testing and *in vivo* animal testing on Licensed Compounds and/or Licensed Products, conducted under GLP, the protocol and results of which are included in or used to support an IND, including [\*\*\*].

1.50 “Joint Compound(s)” means any [\*\*\*] invented jointly by Alios and Vertex.

1.51 “Joint IP” means any invention, development, or discovery, whether or not patentable, made or created during the course of performance of the Research Work or the Development Work jointly by (a) employees or agents of Alios or any of its Affiliates, and (b) employees or agents of Vertex or any of its Affiliates, and consequent Joint Patents.

1.52 “Joint Patents” means all Joint IP that constitute Patent Rights that are filed by or on behalf of Alios and/or Vertex or an Affiliate of either pursuant to **Section 9.3 (Prosecution and Maintenance of Joint Patents; Abandonment)**.

1.53 “Know-How” means information, data and proprietary rights of any type whatsoever (other than the Patent Rights) in any tangible or intangible form whatsoever, including inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data (including pharmacological, biological, chemical, biochemical, toxicological, Pre-Clinical Testing, IND-Enabling Studies, and Clinical Development data), analytical and quality control data, stability data, results of studies, technical drawings, regulatory requirements and strategies, business processes, price data and information, marketing data and information, sales data and information, marketing plans and market research, and related copyrights, and other similar information.

1.54 “Lead Compound” means ALS-2158 or ALS-2200.

1.55 **“Licensed Compound”** means a Lead Compound, a Selected Back-Up Compound, or a Selected Follow-on Compound.

1.56 **“Licensed Product(s)”** means any pharmaceutical preparation or formulation (also commonly referred to as drug product) containing one or more Licensed Compounds [\*\*\*].

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

6

---

1.57 **“Major Market Countries”** means (a) with respect to [\*\*\*] and (b) with respect to the [\*\*\*], the [\*\*\*].

1.58 **“Manufacture”** means all activities related to the manufacturing of a Licensed Compound and/or Licensed Product and/or Combination Product, API or any inactive component or ingredient thereof, including test method development and stability testing, formulation, process development, manufacturing scale-up, manufacturing API, Licensed Product and/or Combination Product quality assurance/quality control development, quality control testing (including in-process, in-process release and stability testing), packaging, release of Licensed Compound, Licensed Product or Combination Product, API, or any inactive component or ingredient thereof, quality assurance activities related to manufacturing and release of Licensed Compound, Licensed Product and/or Combination Product, API, or any inactive component or ingredient thereof, and regulatory activities related to all of the foregoing. “Manufactured” and “Manufacturing” have a correlative meaning.

1.59 **“NDA”** means a New Drug Application that is submitted to the FDA for marketing approval for a Licensed Product or Combination Product, under Section 505 of the FD&C Act (21 USC §355), and its associated regulations.

1.60 **“Net Sales”** means the aggregate gross amount invoiced by Vertex or its Affiliates or Sublicensees, on all sales or transfers for consideration of a Licensed Product or a Combination Product (subject in the case of a Combination Product to the last paragraph of this definition) in the Territory to a Third Party, less the following deductions, as determined in accordance with GAAP:

- (a) [\*\*\*];
- (b) trade, quantity and cash discounts and any other adjustments, including those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns, recalls, rebates, chargeback rebates, reasonable fees, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health care insurance carriers, managed care entities or other institutions, including any government-mandated rebates;
- (c) freight, packing, handling, shipping, postage and insurance charges;
- (d) customs or excise taxes, including import duties, sales tax and other taxes (except income taxes) or duties relating to importation, use or sales of Licensed Product or Combination Product; and
- (e) distribution, packing, handling and transportation charges for such Licensed Product or Combination Product.

The foregoing adjustments shall be documented and included in the invoiced price of Licensed Product or Combination Product or otherwise directly paid or incurred by Vertex or its Affiliates or Sublicensees without reimbursement, other than payment by a Third Party customer.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

7

---

In the event a Combination Product is sold, then the Net Sales for any such Combination Product shall be determined [\*\*\*].

1.61 **“Outside Contractor”** means any Person, other than a Sublicensee, contracted by Alios or Vertex to provide products or services, including pre-clinical services, contract Manufacturing services, and regulatory services, which are material to the performance of its responsibilities under the Research Program or the Development Program or are material to a Licensed Product or Combination Product or any component or ingredient therein, including any such arrangements which might result in any work product or other information that Alios or Vertex would include or might reasonably be expected to include in any document or report, including an Approval Application submitted to a Governmental Authority or be subject to review by a Governmental Authority, including the FDA.

1.62 **“Patent Costs”** means all preparation, filing, prosecution and maintenance out-of-pocket fees and expenses, actually incurred in connection with the establishment and maintenance of rights under the Patent Rights.

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

1.64 **“Person”** means any person or legal entity.

**1.65 “Phase 1 Clinical Trial”** means a human clinical study as described in 21 C.F.R. § 312.21(a), as amended, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

**1.66 “Phase 1a Clinical Trial”** means a single ascending dose (“SAD”) Phase 1 Clinical Trial of a pharmaceutical product, the principal purpose of which is a preliminary determination of safety and pharmacokinetic parameters in healthy individuals.

**1.67 “Phase 1b Clinical Trial”** means a multiple ascending dose (“MAD”) Phase 1 Clinical Trial of a pharmaceutical product, the principal purpose of which is a further determination of safety, pharmacokinetic, and pharmacodynamic (i.e., measurement of plasma HCV RNA) parameters of the pharmaceutical product in patients.

**1.68 “[\*\*\*] Milestone Event”** means that [\*\*\*].

**1.69 “Phase 2 Clinical Trial”** means a human clinical study as described in 21 C.F.R. § 312.21(b), as amended, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

8

---

**1.70 “Phase 2a Clinical Trial”** means a Phase 2 Clinical Trial of a pharmaceutical product, the principal purpose of which is to establish a dose range, appropriate combinations, and further safety and tolerability over a longer duration of dosing, and initial efficacy.

**1.71 “[\*\*\*] Milestone Event”** means [\*\*\*].

**1.72 “Phase 2b Clinical Trial”** means a Phase 2 Clinical Trial of a pharmaceutical product, the principal purpose of which is to establish a dose range, appropriate combinations, and further safety and tolerability over a longer duration of dosing, and initial efficacy on a sufficient number of patients and for a sufficient period of time to confirm the optimal manner of use of such product (in terms of dose and dose regimen) prior to initiation of the pivotal Phase 3 Clinical Trials.

**1.73 “[\*\*\*] Milestone Event”** means [\*\*\*].

**1.74 “Phase 3 Clinical Trial”** means a human clinical study as described in 21 C.F.R. § 312.21(c), as amended, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

**1.75 “Phase 4 Clinical Trials”** means clinical trials of a pharmaceutical product commenced for the purpose of generating data for purposes of marketing the applicable product and not for the purpose of obtaining Regulatory Approval, which are commenced after receipt of Regulatory Approval for such pharmaceutical product, as described in 21 C.F.R. § 312.85, as amended, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

**1.76 “Post-Approval Commitment Studies”** means clinical studies mandated by FDA (or other Regulatory Authorities) to be performed after approval of a Licensed Product or Combination Product, as a condition of such approval.

**1.77 “Pre-Clinical Testing”** means *in vitro* and *in vivo* testing, including pharmacological profiling, biochemical, cell-based, replicon studies, and initial *in vivo* screening and initial safety, needed to evaluate the Licensed Compounds [\*\*\*].

**1.78 “Reasonable Commercial Efforts”** means, with respect to the efforts to be expended by any Person with respect to any objective, [\*\*\*].

**1.79 “Regulatory Approval”** means, with respect to a country or, where applicable, a multinational jurisdiction, any approvals, licenses, registrations or authorizations necessary for the Commercialization of a Licensed Product or Combination Product in such country or such jurisdiction.

**1.80 “Regulatory Authority”** means any national (e.g., the FDA), supranational (e.g., the EMA), regional, state or local regulatory agency, department bureau, commission, council or other government entity in any jurisdiction of the world involved in the granting of Regulatory Approval for pharmaceutical products.

**1.81 “Research Payment”** means the [\*\*\*] amount of [\*\*\*].

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

9

---

**1.82 “Research Plan”** means the initial research plan attached to this Agreement as **Exhibit A**, as it may be amended from time to time in accordance with the terms of this Agreement.

**1.83 “Research Term”** means the period commencing on the Effective Date and expiring [\*\*\*] thereafter, unless terminated earlier by mutual written agreement or extended at Vertex’s option as set forth in the Research Plan.

**1.84 “Research Work”** means the research to be conducted by the Parties under the Research Program during the Research Term.

**1.85** “**Royalty Term**” means, with respect to a Licensed Product or Combination Product in a country, the period commencing on the First Commercial Sale of such Licensed Product or Combination Product in such country and ending on the later of (a) the expiration of the term of the last Valid Claim [\*\*\*] ten (10) years after such First Commercial Sale.

**1.86** [Intentionally Omitted.]

**1.87** “**Selected Back-Up Compound**” means a Back-Up Compound selected by Vertex pursuant to **Section 3.2 (Selection of Selected Back-Up Compounds and Selected Follow-on Compounds)**.

**1.88** “**Selected Follow-on Compound**” means a Follow-on Compound selected by Vertex pursuant to **Section 3.2 (Selection of Selected Back-Up Compounds and Selected Follow-on Compounds)**.

**1.89** “**Sublicensee**” means an authorized or permitted sublicensee of Vertex.

**1.90** “**Technical Failure**” with respect to a Licensed Compound means either [\*\*\*].

**1.91** “**Territory**” means worldwide.

**1.92** “**Third Party**” means any Person other than Alios or Vertex or their respective Affiliates.

**1.93** “**Third Party Costs**” means amounts actually incurred and paid to Outside Contractors by a Party that are incurred as the result of research, Development, Manufacturing or Commercialization of Licensed Compounds, Licensed Products and/or Combination Products.

**1.94** “**United States**” means the District of Columbia, the fifty (50) United States of America, and its territories and possessions.

**1.95** “**Valid Claim**” means (a) any claim of an issued, unexpired patent that has not been held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction following exhaustion (or expiration) of all possible appeal processes, and that has not been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or has not been made unenforceable due to a failure to pay maintenance fees, or (b) any

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

composition of matter, article of manufacture or method of use claim contained in an application for a patent that has been pending for less than ten (10) years.

**1.96** “**Vertex FTE Rate**” means Vertex’s [\*\*\*]. Vertex’s FTE rate for the period from the Effective Date until [\*\*\*] shall be [\*\*\*] dollars ([\*\*\*)] per Calendar Year per FTE. The Vertex FTE Rate shall be adjusted annually thereafter by a percentage equal to the percentage change in the Bureau of Labor Statistics consumer price index for the Boston, Massachusetts area over the last [\*\*\*] period reported in such index prior to the Effective Date.

**1.97** “**Vertex IP**” means Vertex Patent Rights and Vertex Know-How.

**1.98** “**Vertex Know-How**” means any Know-How Controlled by Vertex that relates to the use, Manufacture, or composition of matter of any Licensed Compound and that (a) is Controlled by Vertex as of the Effective Date or (b) is discovered, created or developed in the course of Vertex’s performance of the Research Program or Development Program.

**1.99** “**Vertex Patent Rights**” means all Patent Rights Controlled by Vertex or any of its Affiliates that (a) are necessary for the Development, Manufacture, and/or Commercialization of Licensed Compounds or Licensed Products or (b) claim or disclose inventions Controlled by Vertex or any of its Affiliates that are conceived or reduced to practice in the course of either Vertex’s performance of the Development Program or Research Program, or of Manufacturing activities, under this Agreement.

**1.100** “**Washout Period**” shall mean the period between the [\*\*\*].

The following terms are defined in the body of this Agreement:

**1.101** “**Agreement**” has the meaning set forth in the first paragraph of this Agreement.

**1.102** “**Alios**” has the meaning set forth in the first paragraph of this Agreement.

**1.103** “**Accelerated Rules**” has the meaning set forth in **Section 14.3.3 (Accelerated Arbitration)**.

**1.104** “**Alliance Manager**” has the meaning set forth in **Section 2.1.8 (Alliance Managers)**.

**1.105** “**Appeal Arbitrator**” has the meaning set forth in **Section 14.3.2(g) (Arbitration)**.

**1.106** “**Confidential Information**” has the meaning set forth in **Section 10.1 (Confidentiality; Exceptions)**.

**1.107** “**Confidentiality Agreement**” has the meaning set forth in **Section 10.1 (Confidentiality; Exceptions)**.

**1.108** “**CPR**” has the meaning set forth in **Section 14.3.2 (Arbitration)**.

- 1.109 “Development Program” has the meaning set forth in Section 4.1 (Scope of Development).
- 1.110 “Disclosing Party” has the meaning set forth in Section 10.1 (Confidentiality; Exceptions).
- 1.111 “Execution Date” has the meaning set forth in the first paragraph of this Agreement.
- 1.112 “[\*\*\*]” has the meaning set forth in Section 2.1.4(h) (Change of Control or Assignment).
- 1.113 “Indemnitee” has the meaning set forth in Section 12.3 (Indemnification Procedure).
- 1.114 “Indemnitor” has the meaning set forth in Section 12.3 (Indemnification Procedure).
- 1.115 “Infringement” has the meaning set forth in Section 9.5.1 (Notice).
- 1.116 “Joint Operational Team” has the meaning set forth in Section 2.1.5 (Joint Operational Teams).
- 1.117 “Joint Steering Committee” or “JSC” has the meaning set forth in Section 2.1.4 (Joint Steering Committee).
- 1.118 “Losses” has the meaning set forth in Section 12.1 (Indemnification by Vertex).
- 1.119 “Minimum Requirements” has the meaning set forth in Section 2.1.1(b) (Generally).
- 1.120 “Party” or “Parties” has the meaning set forth in the first paragraph of this Agreement.
- 1.121 “[\*\*\*]” has the meaning set forth in Section 9.1.4 (Assigned Rights).
- 1.122 “Receiving Party” has the meaning set forth in Section 10.1 (Confidentiality; Exceptions).
- 1.123 “Research Program” has the meaning set forth in Section 3.1 (Term of the Research Program).
- 1.124 “Responsible Executive” has the meaning set forth in Section 14.3 (Dispute Resolution).
- 1.125 “Right” has the meaning set forth in Section 15.6 (Waiver).

- 1.126 “Royalty(ies)” has the meaning set forth in Section 7.6 (Royalties).
- 1.127 “Selected Regimen” has the meaning set forth in Section 4.6 (Selected Regimen).
- 1.128 “SVR” has the meaning set forth in Section 1.71.
- 1.129 “Term” has the meaning set forth in Section 13.1.1 (Expiration).
- 1.130 “Transition Plan” has the meaning set forth in Section 4.3 (Transition Plan).
- 1.131 “Vertex” has the meaning set forth in the first paragraph of this Agreement.
- 1.132 “Vertex Trademarks” has the meaning set forth in Section 9.8.1 (Ownership).

## ARTICLE 2 OVERVIEW AND MANAGEMENT OF THE COLLABORATION

### 2.1 Overview

**2.1.1 Generally.** The Parties intend to collaborate on the research, development and commercialization of certain anti-HCV nucleotide prodrugs and nucleoside prodrugs discovered by Alios, including the Lead Compounds, for the treatment of chronic Hepatitis C. On the Effective Date and pursuant to the terms of this Agreement, Alios shall commence the Research Work in accordance with the Research Plan and the Development Work in accordance with the Development Plan. It is the Parties’ intention that Alios shall be responsible for Development of the Lead Compounds through completion of Phase 1 Clinical Trials for the Lead Compounds. Upon completion of the Phase 1 Clinical Trials for a Lead Compound, Alios shall promptly assign the IND(s) for such Lead Compound to Vertex. [\*\*\*]. Upon completion of all Phase 1 Clinical Trials for a Lead Compound, Alios shall transfer all

responsibility for Development of such Lead Compound to Vertex, and Vertex shall be responsible to Develop and Commercialize Licensed Product(s) or Combination Product(s) containing such Lead Compound as set forth in this Agreement.

(a) **Research.** Alios shall conduct the Research Work upon the terms set out in this Agreement and in the Research Plan. The Research Plan shall not be amended without the written consent of the Parties. Alios shall conduct the Research Program in good scientific manner and in compliance in all material respects with all Applicable Laws to achieve the goals of the Research Program efficiently and expeditiously.

(b) **Development.** Vertex and Alios each shall use Reasonable Commercial Efforts to perform its obligations under the Development Program upon the terms set forth in this Agreement and the Development Plan. Subject to the minimum requirements set forth in the Development Plan (“**Minimum Requirements**”), which Minimum Requirements shall not be amended without the consent of Alios, the Development Plan shall be subject to review and update by the JSC as necessary to address all relevant data and information as they become available, but in any event not less frequently than once per year. Subject to such review and

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

13

---

amendment by the JSC, the Development Plan will set forth expectations with respect to the relative contributions of each Party to the Development Program. Each Party shall perform its obligations under the Development Plan in good scientific manner and in compliance with Applicable Laws, GCP, GMP and GLP, and, subject to appropriate notification and discussion with the other Party, shall have the authority to fulfill its regulatory responsibilities with respect to Clinical Trials for which it serves as the sponsor. Vertex will be responsible for its own costs in performing its obligations under the Development Plan.

(c) **Selected Regimen(s)/Diligence.** Upon completion of the Phase 2a Clinical Trials, Vertex may, in accordance with **Section 4.6 (Selected Regimen)**, choose a Selected Regimen or Selected Regimens for further Development. Upon choosing a Selected Regimen, Vertex shall use Reasonable Commercial Efforts to Develop that Selected Regimen, and upon obtaining all necessary Regulatory Approvals, Vertex shall use Reasonable Commercial Efforts to Commercialize the Selected Regimen in each of the Major Market Countries. Notwithstanding the foregoing, if Vertex chooses more than one Selected Regimen for further Development, the foregoing obligation to use Reasonable Commercial Efforts shall apply only to the Selected Regimen that best meets the standard set forth in the Development Plan.

(d) **Exclusivity [\*\*\*].** During the Term, Alios covenants that it shall not [\*\*\*], except to perform its obligations under this Agreement. If Alios undergoes a Change of Control and Alios is not a surviving entity after such Change of Control, then the foregoing covenant [\*\*\*] shall survive solely with respect to [\*\*\*]. For the avoidance of doubt, the foregoing covenant under this **Section 2.1.1(d) (Exclusivity [\*\*\*])** does not apply to [\*\*\*].

**2.1.2 Allocation of Resources.** The Parties shall assign responsibilities for the various operational aspects of the Collaboration to those portions of their respective organizations which have the appropriate resources, expertise and responsibility for such functions. In all matters related to the Collaboration, the Parties shall strive to balance the legitimate interests and concerns of the Parties and to realize the economic potential of Licensed Products or Combination Products (taking into account the risks and costs of further Development and Commercialization). Each Party agrees to commit the personnel, facilities, expertise and other resources needed to perform this Agreement in accordance with its terms; *provided, however*, that neither Party warrants that the Collaboration shall achieve any of the objectives contemplated by them.

**2.1.3 Independence.** Subject to the terms and conditions of this Agreement, including the governance of the JSC, the activities and resources of each Party shall be managed by such Party, acting independently and in its individual capacity.

**2.1.4 Joint Steering Committee.** Promptly after the Effective Date, the Parties shall establish a Joint Steering Committee (the “**Joint Steering Committee**” or “**JSC**”), as more fully described in this **Section 2.1.4 (Joint Steering Committee)**, to review and oversee all Research Work and Development, Manufacture and Commercialization activities for Licensed Products or Combination Products, and to make recommendations regarding the same; *provided, however*, that the JSC shall have no authority to amend this Agreement, the Research Plan or the Minimum Requirements. Each Party agrees to keep the JSC reasonably informed of its progress and activities performed under this Agreement.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

14

---

(a) **Membership.** The JSC shall be comprised of [\*\*\*] of representatives from each of Vertex and Alios. The initial number of representatives [\*\*\*], or such other number as the Parties may agree. Each Party shall provide the other with a list of its initial members of the JSC within [\*\*\*] after the Effective Date. Notwithstanding that each Party shall use all reasonable efforts to maintain the continuity of its representation, each Party may replace or substitute any or all of its representatives and/or appoint a proxy at any time. Each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend meetings of the JSC. The presence in person or by telephone of half or more of each Party’s representatives (including any substitutes or proxy representatives) shall constitute a quorum for the meeting.

(b) **Chair.** The chair of the JSC shall be designated by [\*\*\*].

(c) **Meetings.** During the term of this Agreement, the JSC shall meet at least [\*\*\*] and as otherwise agreed by the Parties, on such dates, and at such places and times, as provided herein or as the Parties may agree. [\*\*\*] Meetings of the JSC that are held in person shall alternate between the offices of the Parties, or such other place as the Parties may agree. Meetings of JSC may be held by audio or video teleconference with the consent of each Party; *provided, however*, that at least one (1) [\*\*\*] per Calendar Year shall be held in person.

(d) **Minutes.** The chair of the Joint Steering Committee shall be responsible for scheduling each meeting, and issuing appropriate minutes of each meeting of the JSC within [\*\*\*] of the date of such meeting. The chair of the JSC may appoint a designee to handle these responsibilities. The minutes shall be considered as accepted if, within [\*\*\*] after receipt, no representative has objected in writing to the chair.

(e) **Decision Making.** Each Party shall have [\*\*\*]. The members of the JSC shall attempt in good faith to reach consensus on all matters properly brought before the JSC. If a decision is made at the JSC and the minutes of the JSC meeting documenting such decision have been in place for [\*\*\*] after receipt and no representative has objected in writing to the chair with a copy to the Alliance Manager, then the terms and conditions of the JSC decision shall be considered accepted and no escalation of this decision to the Responsible Executives shall be allowed. If agreement on any matter appropriately brought before the JSC under **Section 2.1.7 (Responsibilities of JSC)** cannot be reached after a good faith, reasonable and open discussion among the members of the JSC, the dispute shall be subsequently referred for resolution to the Responsible Executives pursuant to **Section 14.2 (Referral to Responsible Executives)**. Failing agreement of the Responsible Executives to resolve such dispute, [\*\*\*] shall have the right to make the final decision. [\*\*\*].

(f) **Alternatives to Meeting.** Any decision required or permitted to be taken by the Joint Steering Committee may be taken without a meeting in person or by audio or video teleconference taking place, if a consent in writing, setting forth the decision so taken, is signed by all designated members of the JSC.

(g) **Expenses.** Each Party shall be responsible for its representatives' expenses incurred in attending meetings of the JSC.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

15

---

(h) **Change of Control or Assignment.** If Alios undergoes a Change of Control in which the acquiring company is [\*\*\*], then at Vertex's option, upon written notice from Vertex, Alios or [\*\*\*], as applicable, shall lose the right to participate in the JSC under this **ARTICLE 2 (Overview and Management of the Collaboration)** and shall only be entitled to reports as if it had withdrawn from the JSC pursuant to **Section 2.3 (Alios' Membership on the JSC and Joint Operational Teams)**.

**2.1.5 Joint Operational Teams.** From time to time the JSC may establish and delegate duties to other committees, sub-committees, or directed teams (each a "**Joint Operational Team**") on an "as needed" basis to oversee particular projects or activities. It is envisaged that the JSC will establish a Joint Operational Team to oversee technology transfer and the implementation of the Transition Plan. Each such Joint Operational Team shall be constituted and shall operate as the JSC determines. Joint Operational Teams may be established on an *ad hoc* basis for purposes of a specific project, or on such other basis as the JSC may determine. Each Joint Operational Team and its activities shall be subject to the oversight, review and approval of, and shall report to, the JSC. The authority of the Joint Operational Team cannot exceed that specified for the JSC in this **ARTICLE 2 (Overview and Management of the Collaboration)**. Any disputes within a Joint Operational Team shall be referred to the JSC for resolution.

**2.1.6 Interactions Between Committees and Internal Teams.** The Parties recognize that while they will establish the JSC and Joint Operational Teams for the purpose of the Collaboration, each Party possesses internal committees, teams and review boards that may be involved in administering such Party's activities under this Agreement. If requested by a Party, the JSC and Joint Operational Teams shall establish procedures to facilitate communications between the JSC or such Joint Operational Team and the relevant internal committee, team or review board of the requesting Party. Such procedures may include, to the extent reasonably necessary, requiring appropriate members of the JSC or Joint Operational Team to be available at reasonable times and places and upon reasonable prior notice for making appropriate oral reports to, and responding to reasonable inquiries from, the relevant internal committee, team or review board.

**2.1.7 Responsibilities of JSC.** Each Party shall keep the JSC informed about, and the JSC shall review, and make recommendations with regard to, research, Development, Manufacture and Commercialization activities performed by that Party hereunder. To that end, the JSC shall also be responsible, without limitation, for the following:

(a) coordination of interactions between Vertex and Alios;

(b) oversight of all Research Work, Development Work and Manufacturing activities undertaken with respect to each Licensed Product and Combination Product;

(c) review and comment on Commercialization activities both prior to and after First Commercial Sale, including marketing strategy for each Licensed Product and/or Combination Product;

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

16

---

(d) review and approval of supplements, modifications and updates to the Development Plan (other than the Minimum Requirements);

(e) review and comment on the regulatory strategy for Licensed Products and/or Combination Products, including labeling strategy, and any material modifications to either the regulatory strategy or the labeling strategy;

(f) review and comment on the marketing plans in their initial form and as they may be supplemented, modified or updated;

- (g) ensure the exchange of relevant information and materials relating to each activity undertaken or contemplated under this Agreement; and
- (h) such other responsibilities as may be assigned to the Joint Steering Committee as mutually agreed upon by the Parties in writing from time to time.

**2.1.8 Alliance Managers.** Promptly after the Effective Date, each Party shall appoint one or two individuals to act as that Party's primary points of contact between the Parties for matters relating to the Collaboration (the "**Alliance Managers**"). Each Alliance Manager who is not otherwise a member of the JSC shall be permitted to attend meetings of the JSC. The Alliance Managers shall be the primary point of contact for the Parties regarding the activities contemplated by this Agreement and shall facilitate all such activities hereunder. Each Party may change its designated Alliance Manager(s) from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

**2.2 Reports; Inspection.** Each Party shall maintain, and shall cause its Outside Contractors to maintain, accurate and reasonably complete records of all Research Work and all Development Work, as consistent with the responsibilities of such Party under this Agreement, and all results of any Clinical Trials, Pre-Clinical Testing, IND-Enabling Studies, and other investigations conducted under this Agreement by or on behalf of such Party, its Affiliates, and Outside Contractors, as applicable.

**2.3 Alios' Membership on the JSC and Joint Operational Teams.** The JSC will dissolve upon the expiration of the Term. Alios' membership on the JSC and any Joint Operational Team shall be at its sole discretion, as a matter of right and not obligation, for the sole purpose of participation in governance, decision-making, and information exchange with respect to activities within the jurisdiction of the JSC or Joint Operational Team, as the case may be. At any time prior to the dissolution of the JSC, Alios shall have the right to withdraw from membership in the JSC or any Joint Operational Team upon [\*\*\*]' prior written notice to Vertex, which notice shall be effective as to the JSC or Joint Operational Team, as the case may be, upon the expiration of such [\*\*\*] period. Following the issuance of such notice, (a) Alios' membership in the JSC or Joint Operational Team, as the case may be, shall be terminated and (b) Alios shall have the right to continue to receive the information it would otherwise be entitled to receive under this Agreement. If, at any time, following issuance of such written notice Alios wishes to resume participation in the JSC or any Joint Operational Team, Alios shall notify Vertex in writing and, thereafter, Alios'

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

17

---

representatives to the JSC or such Joint Operational Team, as the case may be, will be entitled to attend any subsequent meeting and participate in the activities of, and decision-making by, the JSC or such Joint Operational Team as provided in this **ARTICLE 2 (Overview And Management of the Collaboration)** as if a withdrawal notice had not been issued by Alios pursuant to this **Section 2.3 (Alios' Membership on the JSC and Joint Operational Teams)**. If the JSC is dissolved, then any data and information that otherwise would have been provided to the JSC shall be provided by each Party directly to the other Party.

**2.4 Diligence.** Vertex shall use Reasonable Commercial Efforts: (a) to advance Licensed Products through completion of Phase 2a Clinical Trials in accordance with the Development Plan; and (b) to conduct the Research Work to be performed by Vertex under the Research Plan (if any) and (c) to conduct the Development Work under the Development Plan; *provided, however,* that after completion of Phase 2a Clinical Trials, Vertex shall have no obligation to use Reasonable Commercial Efforts to Develop any Licensed Compound that is not incorporated into a Selected Regimen.

### **ARTICLE 3 RESEARCH PROGRAM**

**3.1 Term of the Research Program.** Alios shall conduct the Research Work under the research program (the "**Research Program**") as provided by the Research Plan during the Research Term. Upon completion of the activities under the Research Plan, Alios may [\*\*\*]. Throughout the period during which research is conducted hereunder during the Research Term, Alios shall prepare and maintain an inventory list of all compounds that satisfy the Selection Criteria, as set forth in **Section 3.2 (Selection of Selected Back-up Compounds and Selected Follow-on Compounds)**, and shall provide such list to the JSC. Such inventory list will be deemed complete at the end of the Research Term.

**3.2 Selection of Selected Back-Up Compounds and Selected Follow-on Compounds.** Within [\*\*\*] after the Effective Date, the Parties shall agree upon the criteria (the "**Selection Criteria**") for the selection of Back-up Compounds and Follow-on Compounds synthesized and screened by Alios during the Research Term to be Selected Back-Up Compounds and Selected Follow-on Compounds, respectively, and shall amend the Research Plan to incorporate the Selection Criteria. Alios shall promptly notify Vertex in writing each time it synthesizes and screens a compound during the Research Term that meets the Selection Criteria, and shall provide additional information to Vertex about such compound, including the chemical structure of such compound and all data related to screening of such compound, as is requested by Vertex to allow for further evaluation of the compound by Vertex. [\*\*\*].

**3.3 [\*\*\*].**

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

18

---

### **ARTICLE 4 DEVELOPMENT AND REGULATORY**



**4.1 Scope of Development.** In accordance with the terms and conditions set forth below, the Development Work for any Licensed Compound, Licensed Product and/or Combination Product will be conducted solely in the HCV Field by or on behalf of the Parties pursuant to the Development Plan (the “**Development Program**”). At Vertex’s cost as provided in **Section 7.2 (Vertex’s Cost and Reimbursement Obligations)**, the Parties intend that [\*\*\*] will be responsible for (a) [\*\*\*]. [\*\*\*] shall be primarily responsible for all other evaluation and Development of Licensed Products and Combination Products as set forth in the Development Plan, *provided, however*, that Vertex shall have no obligation to conduct further Development of any Licensed Compound that has experienced a Technical Failure subject to the last sentence of **Section 1.90 (Technical Failure)**. All Development by the Parties, or either of them, of any and all Licensed Compounds, Licensed Products and/or Combination Products for any indication in the HCV Field, until the filing of an NDA for each such Licensed Product or Combination Product, will be subject to the oversight of the JSC as provided in **Section 2.1.4 (Joint Steering Committee)** and elsewhere in this Agreement and shall be conducted solely as provided under this Agreement.

**4.2 IND Filings.** Promptly after completion [\*\*\*].

**4.3 Transition Plan.** On the Effective Date, Alios shall provide to Vertex all data and information in its possession pertaining to the Lead Compounds, including information available on the Effective Date that would be covered by the Transition Plan. The JSC shall develop a plan to transition from Alios to Vertex, as such information is generated but, no less frequently than quarterly, all data and information about all material aspects of Development Work with respect to Licensed Compounds (the “**Transition Plan**”). The Transition Plan will include with respect to each such Licensed Compound the transfer of (a) any IND as filed and as amended, (b) any studies or data included in such IND or IND amendment, (c) all correspondence with the FDA or applicable Regulatory Authorities, (d) details of all on-going studies, (e) any Phase 1 Clinical Trial data, and (f) API and drug product, if available.

**4.4 Use of Information.** Any information contained in reports made pursuant to this **ARTICLE 4 (Development and Regulatory)** or otherwise communicated between the Parties will be subject to the confidentiality provisions of **ARTICLE 10 (Confidentiality)**.

**4.5 Approval Applications and Regulatory Approvals.**

**4.5.1 Responsible Party.** Except as otherwise set forth in this Agreement, Vertex at its sole cost and expense as provided in **Section 7.2 (Vertex’s Cost and Reimbursement Obligations)**, shall have sole authority to file in its name all Approval Applications and have sole authority over all Approval Applications and all communication with Regulatory Authorities; *provided, however*, that Vertex shall provide Alios with copies of all material correspondence with FDA and Regulatory Authorities in Major Market Countries in advance, where possible; *provided, further* that Alios shall have the right to comment in a timely fashion on any such Approval Applications or communication with Regulatory Authorities, which comments Vertex shall reasonably consider.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

19

---

**4.5.2 Clinical Trials.** Subject to the terms of this Agreement and the Development Plan, the Party conducting a Clinical Trial shall have sole authority to assemble all regulatory filings required to conduct such Clinical Trial with any Licensed Product or Combination Product Developed or to be Developed under the Development Plan.

**4.5.3 Manufacturing Approval.** Vertex shall have sole authority to obtain and maintain Regulatory Approval to Manufacture Licensed Products and Combination Products. Vertex will promptly send to Alios copies of each Regulatory Approval of any Licensed Product or Combination Product (including English translations thereof, if Vertex has in its possession such an English translation) and any material related correspondence with any Governmental Authority in Major Market Countries relating to the Manufacture of any Licensed Products or Combination Products.

**4.5.4 Marketing Approval.** Vertex shall have sole authority to obtain and maintain Regulatory Approval to Commercialize Licensed Products and Combination Products in the Major Market Countries and any other country where Vertex determines to Commercialize Licensed Products and/or Combination Products. Vertex will promptly send to Alios copies of all Regulatory Approvals of any Licensed Product or Combination Product (including English translations thereof, if Vertex has in its possession such an English translation) and any material related correspondence with any Governmental Authority in Major Market Countries relating to the marketing of any Licensed Products or Combination Products.

**4.5.5 Filing of Regulatory Reports.** Vertex shall have sole authority to file all reports required to be filed by it under Applicable Laws in order to maintain any Regulatory Approvals granted to Vertex or its Affiliates or licensees for marketing and sale of any and all Licensed Products or Combination Products developed under this Agreement, including adverse drug experience reports. Notwithstanding the foregoing, to the extent Alios has or receives any information regarding any adverse drug experience that may be related to the use of any Licensed Product or Combination Product, Alios shall promptly provide Vertex with all such information in accordance with Alios’ obligations under Applicable Laws.

**4.6 Selected Regimen.** After receipt and analysis of data [\*\*\*], Vertex shall have [\*\*\*] to (a) select one or more combinations of active pharmaceuticals, with each combination containing at least one Licensed Compound, on the basis of the criteria set forth in the Development Plan or as otherwise agreed by the Parties, (each, a “**Selected Regimen**”), for further Development or (b) shall terminate this Agreement in accordance with **Section 13.2.1 (Termination at Will)**. [\*\*\*].

**4.7 Reporting Adverse Events.**

**4.7.1 Report.** Each Party shall, throughout the Term, inform the other Party about serious and unexpected related adverse events (IND safety reports in the United States, expedited safety reports elsewhere) with respect to the use of Licensed Products or Combination Products in activities conducted by that Party. The Parties agree to handle data and information about serious adverse events occurring or having occurred in connection with the use of any Licensed Product or Combination Product according to the Applicable Laws. Alios shall be solely responsible for reporting serious adverse drug experiences to the Governmental Authorities during

[\*\*\*]. Vertex shall be solely responsible for signal detection activities and reporting serious adverse drug experiences to the Governmental Authorities thereafter. After completion of [\*\*\*], Vertex will provide Alios with a copy of the IND Annual report and the EU Annual Safety Report (as well as other foreign equivalents, if applicable). Alios may participate as observers in the Vertex Disease Area Safety Team (DST) for the Development Program as a means to maintain current information regarding the safety of the Licensed Compounds.

**4.7.2 Clinical Safety Database.** Serious adverse events related to the use of Licensed Products during [\*\*\*] shall be entered into a database selected and under the oversight and control of [\*\*\*]; thereafter serious adverse events related to the use of Licensed Products or Combination Products in the Territory shall be entered in a single database, centralized, held and owned by [\*\*\*]. Upon the completion of the [\*\*\*] shall transfer to [\*\*\*] all the historical clinical safety data and the global safety database promptly upon [\*\*\*] request. Upon completion of the transfer of such historical clinical safety data, [\*\*\*] shall thereafter be responsible for safety reporting for each Licensed Product and Combination Product.

**4.7.3 Safety Data Exchange.** The data referenced in **Section 4.7.1 (Report)** and **Section 4.7.2 (Clinical Safety Database)** shall be exchanged and transferred between the Parties through a mechanism or agreement to be determined by the Parties within [\*\*\*] after the Effective Date and in no event any later than [\*\*\*].

## ARTICLE 5 COMMERCIALIZATION

**5.1 Scope of Commercialization.** Subject to the terms and conditions of this Agreement, Vertex shall be responsible for the establishment, control and implementation of the strategy, plans and budgets for Commercialization of the Selected Regimen in the Field. Under all circumstances, Vertex shall record all sales in the Territory.

**5.2 Commercial Diligence.** Upon obtaining all necessary Regulatory Approvals, Vertex shall use Reasonable Commercial Efforts to Commercialize the Selected Regimen in the Major Market Countries; *provided* that Vertex shall not be required to conduct any Phase 4 Clinical Trials.

**5.3 Commercialization Reports.** After submission of an NDA for a Licensed Product or Combination Product, on at least a Calendar Year basis, or as otherwise requested by the JSC, Vertex shall provide the JSC with a written summary of Vertex's planned and completed Commercialization activities with respect to such Licensed Product or Combination Product in the Field and the Territory, covering subject matter at a level of detail sufficient to enable Alios to determine Vertex's compliance with its diligence obligations in **Section 5.2 (Commercial Diligence)**.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## ARTICLE 6 MANUFACTURE AND SUPPLY

### 6.1 Manufacture and Supply of Pre-Clinical and Clinical Materials.

**6.1.1 Alios Obligations.** Subject to **Section 7.2.3 (Manufacturing Costs)**, Alios shall Manufacture or have Manufactured, and supply Licensed Compounds and/or Licensed Products for [\*\*\*] that it is responsible to conduct under the Research Program and in the Development Program (and, at Vertex's request, for [\*\*\*]).

**6.1.2 Vertex Obligations.** Vertex shall Manufacture, or have Manufactured, at its cost and expense as provided under **Section 7.2.2 (Development Program)**, all quantities of Licensed Compounds, Licensed Products or Combination Products required for Clinical Trials other than [\*\*\*].

**6.2 Commercial Supply of Licensed Products and Combination Products.** Vertex shall be responsible for Manufacture of all Licensed Products and Combination Products for commercial sale in the Territory at its sole cost and expense, in conformance with the specifications set forth in the respective applications for Regulatory Approval and any amendments or supplements thereto, and any substitutes.

**6.3 Technology Transfer.** Promptly after the Effective Date, Alios shall deliver to Vertex: [\*\*\*]. If Vertex desires additional technical assistance, then Alios shall provide such assistance and Vertex shall compensate Alios [\*\*\*].

## ARTICLE 7 FINANCIAL TERMS

**7.1 Initial Payment.** In consideration of the license rights granted by Alios to Vertex pursuant to this Agreement and as reimbursement for previously incurred research activities, Vertex shall pay to Alios a non-refundable, non-creditable payment of Sixty Million dollars (US\$60,000,000) within [\*\*\*] Business Days after the Effective Date.

### 7.2 Payment of Costs related to Research and Development Programs

**7.2.1 Research Program.** In consideration of Alios' performance of Research Work, Vertex shall make the Research Payment to Alios within [\*\*\*] (with the first such payment pro-rated for the portion of the [\*\*\*] in which Alios is performing research services hereunder). Alios shall



shall be paid only once as indicated in the table below, and shall be non-creditable and non-refundable. The commercial milestones are set forth in the table on the next page. The remainder of this page is intentionally left blank.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
Total Commercial Milestone Payments	US\$ 750,000,000

7.5.2 [\*\*\*]

## 7.6 Royalties.

**7.6.1** Vertex shall pay the following incremental (non-cumulative) royalties on annual Net Sales of Licensed Products or Combination Products as set forth below ("**Royalty(ies)**"). Such Royalties shall be payable on Net Sales on a Licensed Product-by-Licensed Product or Combination Product-by-Combination Product basis during the Royalty Term. Each Royalty shall be payable only once with respect to a particular Licensed Product or Combination Product. The royalty rates are set forth in the table on the next page. The remainder of this page is intentionally left blank.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

**7.6.2** The applicable Royalty Rates will be based on total Net Sales in the Territory, and not any particular region or country. [\*\*\*].

### **7.6.3 Royalty Adjustment for Third Party Patent Rights.**

(a) If the Development, Manufacture or Commercialization of a Licensed Product or Combination Product by Vertex in the Territory in accordance with this Agreement would infringe any Third Party patent right due to the Licensed Compound component of such Licensed Product or Combination Product or Vertex believes it necessary or desirable to obtain a license under such Third Party's patent rights to avoid any claims or litigation by a Third Party against Vertex anywhere in the Territory concerning infringement with respect to the Licensed Compound component of a Licensed Product or Combination Product, then [\*\*\*].

(b) If the license is necessary to avoid any claims or litigation by a Third Party that a Licensed Compound component of such Licensed Product or Combination Product infringes such Third Party's intellectual property rights, [\*\*\*] under this **Section 7.6.3(b)(ii)** [\*\*\*].

### **7.6.4 Royalty Adjustment for Unlicensed Competing Product.**

(a) If one or more Third Parties is, during the Term, (i) selling a product containing a Licensed Compound without benefit of a sublicense from Vertex in a given country for any Calendar Quarter during which royalties are due under this Agreement, and (ii) such sales of such product in such country for such Calendar Quarter are, in the aggregate (on a unit basis), greater than [\*\*\*] of the sales of the Licensed Product and/or Combination Product containing such Licensed Compound being sold under this Agreement and such unlicensed products in such country for such Calendar Quarter (calculated in accordance with **Section 7.6.4(b)**), then the Royalties due to Alios under this **Section 7.6.4 (Royalties)** for any sales beginning in such Calendar Quarter and continuing into the future shall be [\*\*\*] from what they would otherwise have been according to the Royalty then being paid under this **Section 7.6 (Royalties)**. If such Third Party sales are greater than [\*\*\*] of the sales of Licensed Product and/or Combination Product containing such Licensed Compound, then such [\*\*\*]. Such [\*\*\*] shall be first applied with respect to such country starting with sales in the Calendar Quarter following the [\*\*\*] where the sales of the such Third Party product in such country exceed the applicable level noted above of the unit sales volume of the applicable Licensed Product and/or Combination Product, and shall expire on the day after [\*\*\*]. For the avoidance of doubt, if the royalty rate set forth in **Section 7.6.1** has already been reduced pursuant to **Section 7.6.5 (Royalty Adjustment in Countries with No Patent Protection)**, then the royalty reduction set forth in **Section 7.6.5 (Royalty Adjustment in Countries with No Patent**

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**Protection)** shall no longer apply and the royalty reduction set forth in this **Section 7.6.4(a)** shall take precedence.

(b) The percentage of sales of the unlicensed product relative to all sales of unlicensed products and Licensed Products and Combination Products shall be based on [\*\*\*], calculated using data [\*\*\*], or if such data is not available, another reliable data source that is mutually acceptable to Vertex and Alios.

(c) If sales of Licensed Products and/or Combination Products by a Third Party in a given country are pursuant to a compulsory license granted or ordered to be granted by a Governmental Authority, or if the Parties agree that the granting of a license to a Third Party in view of the threat of a compulsory license is warranted, then the Royalty payable by Vertex on Net Sales in such country shall [\*\*\*]. If Vertex or Alios receives any compensation from the Third Party subject to such a license, then Vertex and Alios shall [\*\*\*].

**7.6.5 Royalty Adjustment in Countries with No Patent Protection.** In each country in which there is no Valid Claim within the Alios Patent Rights or Joint Patents covering the making, using, selling, offering for sale, or importation or exportation of any given Licensed Product or Combination Product, the Royalties due to Alios under this **Section 7.6 (Royalties)** shall [\*\*\*] according to the Royalty then being paid under this **Section 7.6 (Royalties)** for such country. Royalties payable under this **Section 7.6.5** for such Licensed Products and Combination Products shall be in consideration of the Alios Know-How and other rights and items provided under this Agreement.

**7.6.6 Royalty Payments and Reports.** Within [\*\*\*] after the end of each Calendar Quarter, Vertex shall make all Royalty payments payable to Alios under this Agreement with respect to such Calendar Quarter by wire transfer of immediately available funds to such United States bank account as will be designated by Alios. Along with such payments, Vertex shall simultaneously provide a written report to Alios that summarizes: (a) the Net Sales in the Territory during such Calendar Quarter by or on behalf of Vertex, its Affiliates, and Sublicensees in the currency in which sales were made and in United States dollars after the application of the exchange rate during the reporting period, (b) the Royalties payable in United States dollars that have accrued under this Agreement in respect of such Net Sales and the basis for calculating those Royalties in sufficient detail to enable the calculation of such Royalties due pursuant to this **Section 7.6 (Royalties)**, (c) the exchange rates and other methodology used under **Section 7.8 (Currency)** in converting into United States dollars, from the currencies in which sales were made, (d) disposition of Licensed Products or Combination Products other than pursuant to sale for cash, and (e) withholding taxes, if any required by Applicable Laws to be deducted in respect of such Royalties.

**7.6.7 Records and Audit.** Each Party shall keep, and shall require its Affiliates and Sublicensees to keep, full, true and accurate books of account containing all particulars that may be necessary for the purpose of calculating all payments under this Agreement. Such books of accounts shall be kept at their principal place of business.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

(a) **Alios Right to Audit Vertex.** At the expense of Alios, Alios has the right to engage an independent registered public accounting firm of nationally recognized standing to perform, on behalf of Alios, an audit of such books and records of Vertex and its Affiliates, and Sublicensees, that are deemed necessary by such independent registered public accounting firm to report on Net Sales of Licensed Products and Combination Products in the Territory for the period or periods requested by Alios and the correctness of any report or payments made under this Agreement.

(b) **Vertex’s Right to Audit.** At the expense of Vertex, Vertex has the right to engage an independent registered public accounting firm of nationally recognized standing to perform, on behalf of Vertex, an audit of such books and records of Alios and its Affiliates, that are deemed necessary to report on (i) Research Work and Development costs and expenses incurred by Alios, including FTE costs and Third Party and Outside Contractor costs, under the Research Program and the Development program as described in **ARTICLE 3 (Research Program)** and **ARTICLE 4 (Development and Regulatory)**, and (ii) Manufacturing costs incurred by Alios under **ARTICLE 6 (Manufacture and Supply)**, for the period or periods requested by Vertex and the correctness of any report or payments made under this Agreement.

(c) **Audit Procedure.** Upon at least [\*\*\*] Business Days’ prior written notice from the auditing Party, such audit shall be conducted with respect to the countries specifically requested by the auditing Party, during regular business hours in such a manner as to not unnecessarily interfere with the normal business activities of the Party being audited. Such audit shall not be performed more frequently than [\*\*\*] nor more frequently than [\*\*\*]. All information, data, documents and abstracts herein referred to shall be used only for the purpose of verifying Royalty statements or costs and expenses incurred and shall be treated as the Confidential Information of the Party being audited subject to the obligations of this Agreement and need neither be retained more than [\*\*\*] after completion of an audit hereof, if an audit has been requested; nor more than [\*\*\*] from the end of the Calendar Year to which each shall pertain; nor more than [\*\*\*] after the date of expiration or termination of this Agreement. Audit results and findings shall be made without interpretation of contractual language and shared by Vertex and Alios and the accounting firm shall disclose to the auditing Party only whether the royalty reports or expense reports, as applicable, are correct or incorrect and the specific details concerning any discrepancies. If the audit reveals an overpayment, then the auditing Party shall reimburse the Party being audited for the amount of the overpayment within [\*\*\*]. If the audit reveals an underpayment, then the Party being audited shall make up such underpayment within [\*\*\*]. Upon expiration of [\*\*\*] following the end of any Calendar Year, the calculation of Royalties payable or costs and expenses with respect to such Calendar Year shall be binding and conclusive upon the Parties, and the Party obligated to make such royalty payments or the Party receiving reimbursement of costs and expenses hereunder, its Affiliates and Sublicensees shall be released from any liability or accountability with respect to such payments for such Calendar Year. The auditing Party shall pay for any such audit, except that if (i) Vertex underpaid payments by more than [\*\*\*] during the period in question as per the audit or (ii) Alios overstated its costs and expenses by more than [\*\*\*] during the period in question as per the audit, such audited Party shall pay the reasonable costs of the audit.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**7.7 Taxes and Withholding.** All payments under this Agreement will be made without any deduction or withholding for or on account of any tax unless such deduction or withholding is required by Applicable Laws. If the paying Party is so required to deduct or withhold, such Party will (a) promptly notify the other Party of such requirement, (b) pay to the relevant authorities 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 the other Party, (c) promptly forward to the other Party an official receipt (or certified copy) or other documentation reasonably acceptable to the other Party evidencing such payment to such authorities.

**7.8 Currency.** All amounts payable and calculations made hereunder shall be in United States dollars regardless of the country(ies) in which sales are made. Net Sales and any other amounts related to the calculation of any amounts payable hereunder which are not recorded in United States dollars shall be translated into United States dollars using Vertex's then-current standard exchange rate methodology, fairly applied, for the translation of foreign currency into United States dollars as employed on a consistent basis throughout Vertex's operations and consistent with GAAP.

**7.9 Payments; Late Payments.** Each Party shall make all payments due the other Party under this Agreement by wire transfer of immediately available funds to such account as is designated by the receiving Party from time to time to the other Party in writing in accordance with the provisions of **Section 15.5 (Notices)**. If any sum due and payable under this Agreement shall not have been paid on or before the applicable due date, [\*\*\*] shall accrue on the unpaid amount at the rate of [\*\*\*] or, if less, the maximum rate permitted under Applicable Laws, from the payment due date until the actual date of payment without prejudice to any other claim or remedy available to the non-paying Party; *provided, however*, that no interest shall accrue on any portion of an unpaid amount that is the subject of a good faith, legitimate dispute. If any such dispute is resolved against the paying Party, the date of resolution shall be deemed to be [\*\*\*] after the date that payment to the other Party originally was due.

**7.10 Vertex Information Rights.** Alios acknowledges that Vertex may, as a result of the application of the terms of this Agreement, be required to prepare and publicly file financial statements that consolidate the financial results of both Parties. Alios agrees to use good faith efforts to provide to Vertex any and all financial information in Alios' possession on such timetables and in sufficient detail, in each case as reasonably requested by Vertex, to allow Vertex to timely file any such financial statements, and Vertex shall reimburse Alios for any and all costs and expenses incurred by Alios in connection therewith, including any Third Party costs and expenses.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## ARTICLE 8 LICENSES

### 8.1 Licenses.

**8.1.1 License by Alios to Vertex.** Subject to the terms and conditions of this Agreement, Alios hereby grants to Vertex an exclusive license (even as to Alios except as set forth in **Section 8.1.3 (Alios Retained Rights and Vertex License to Alios)**), under Alios Patent Rights, Alios' rights in Joint IP and Alios IP Improvements, in the Territory, with the right to grant sublicenses in accordance with **Section 8.1.2 (Right to Sublicense)**, (a) to make, have made, use, have used, import and export Licensed Compounds, Licensed Products, and Combination Products in the HCV Field for the performance of its research and Development obligations under this Agreement and (b) to offer to sell, sell, import, export, make, have made, use, and have used Licensed Products and Combination Products in the Field for the Commercialization of Licensed Products and Combination Products during the Term. For the avoidance of doubt, the license set forth in clause (b) covers activities related to expanded access programs, compassionate use sales and named patient sales.

**8.1.2 Right to Sublicense.** Vertex shall have the right to grant sublicenses under the license granted to it in **Section 8.1.1 (License by Alios to Vertex)**, *provided that*:

- (a) any such sublicense shall oblige the Sublicensee to comply with all the terms of this Agreement (except those provisions which, by their clear meaning, are not applicable to a Sublicensee) and that Vertex remains liable to Alios for all material acts and omissions of any such Sublicensee;
- (b) if Vertex wishes to grant a sublicense to a Third Party of its Development or Commercialization rights in any of the Major Market Countries, Vertex shall provide written notice to Alios of any such proposed sublicense, along with a summary of the principal non-financial terms of that sublicense relating, among other things, to its scope, the proposed sublicensee's duties and representations, and indemnification, at least [\*\*\*] prior to the execution thereof, and shall obtain Alios' consent to each such sublicense, such consent not to be unreasonably withheld;
- (c) if Vertex wishes to grant a sublicense to a Third Party of its Development or Commercialization rights in any jurisdiction other than a Major Market Country, Vertex shall not be obligated to seek Alios' consent, but may choose to request such consent, which consent shall not be unreasonably withheld;
- (d) any such sublicense must refer to this Agreement and shall be subordinate to and consistent with the terms and conditions of this Agreement, and shall not limit (i) the ability of Vertex (individually or through the activities of its Sublicensees) to fully perform all its obligations under this Agreement or (ii) Alios' rights under this Agreement;
- (e) Vertex will remain responsible for the performance of this Agreement and the performance of its Sublicensees hereunder;

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit*

(f) Vertex may grant to a Sublicensee the right to grant further sublicenses of the same or lesser scope as its sublicense from Vertex (the other party to such further sublicense also being a Sublicensee), *provided* that such further sublicenses shall be in accordance with and subject to all of the terms and conditions of this **Section 8.1.2 (Right to Sublicenses)** (i.e., such Sublicensee shall be subject to this **Section 8.1.2 (Right to Sublicenses)** in the same manner and to the same extent as Vertex);

(g) any sublicenses granted by Vertex to sell Licensed Products and/or Combination Products that are subject to Royalty payments under **Section 7.6 (Royalties)** must include an obligation for the Sublicensee to account for and report its sales of Licensed Products and/or Combination Products on the same basis as if such sales were Net Sales by Vertex. Vertex shall remain responsible to Alios for all Development and Commercialization milestones for such Licensed Products and/or Combination Products under **Section 7.4 (Development Milestone Payments)** and **Section 7.5 (Commercial Milestone Payments)** of this Agreement; and

(h) any sublicenses of Vertex's rights under this Agreement for which Vertex does not obtain consent from Alios must provide that Alios may, upon expiration or early termination (except for termination by Vertex under **Section 13.3 (Termination for Cause)** or under **Section 13.4 (Termination for Insolvency)**) of this Agreement, terminate such sublicense on [\*\*\*] written notice from Alios, and a copy of any such sublicense shall be provided by Vertex to Alios within [\*\*\*] of execution of such sublicense. Subject to Alios' right to request Vertex to assign sublicenses under **Section 13.9.2 (Post Termination Technology Transfer)**, Alios further agrees to negotiate with any Sublicensee upon request of such Sublicensee either the assumption of applicable terms of such sublicense or the execution of a new sublicense with such Sublicensee, but any such assumption or new sublicense will be in Alios' sole discretion.

**8.1.3 Alios Retained Rights and Vertex License to Alios.** Notwithstanding the foregoing, Alios shall retain rights under the Alios IP and Alios' rights in Joint IP to the extent (a) necessary or useful to discharge its obligations and exercise its rights under this Agreement and (b) outside the field restrictions set forth in **Section 8.1.1 (License by Alios to Vertex)**. Subject to the terms of this Agreement, Vertex hereby grants to Alios a non-exclusive research license, under Patent Rights and Know-How Controlled by Vertex, to the extent necessary to permit Alios to perform its research and Development obligations under this Agreement.

**8.1.4 No Other Rights and Retained Rights.** This Agreement confers no right, license or interest by implication, estoppel, or otherwise under any Patent Rights, Know-How or other intellectual property rights of either Party except as expressly set forth in this **ARTICLE 8 (Licenses)** and elsewhere in this Agreement. Each Party hereby expressly retains and reserves all rights and interests with respect to patents, patent applications, know-how or other intellectual property rights not expressly granted to the other Party hereunder. For the avoidance of doubt, Alios grants no rights to Vertex to any compounds that are not Licensed Compounds. Subject to the terms and conditions of this Agreement, Alios shall retain and reserve all rights and interests to Alios Compounds that are not Licensed Compounds.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## ARTICLE 9 INTELLECTUAL PROPERTY

### 9.1 Ownership of Intellectual Property.

**9.1.1 Alios IP.** As between the Parties, subject only to the licenses and covenants set forth in **ARTICLE 8 (Licenses)**, Alios shall retain and own all right, title and interest in and to the Alios IP.

**9.1.2 Vertex IP.** As between the Parties, subject only to the licenses and covenants set forth in **ARTICLE 8 (Licenses)** and Vertex's obligation to assign certain rights under **Section 9.1.4 (Assigned Rights)**, Vertex shall retain and own all right, title and interest in and to the Vertex IP.

**9.1.3 Joint IP and Joint Patents.** Subject to **Section 9.1.4 (Assigned Rights)**, the Parties shall jointly own any Joint IP.

**9.1.4** [\*\*\*].

**9.1.5 Inventorship.** Inventorship of inventions shall be determined in accordance with rules and guidelines regarding inventorship as established under United States patent law.

### 9.2 Prosecution and Maintenance of Patent Rights; Abandonment.

**9.2.1 Responsibility.** Each of Alios and Vertex, or each Party's designee, shall have the responsibility to diligently file, prosecute and maintain the Alios Patent Rights, as to Alios, and the Vertex Patent Rights, as to Vertex, and shall bear all Patent Costs associated therewith. Subject to **Section 9.1.4 (Assigned Rights)**, each Party shall provide to the other Party an opportunity to review and comment on the nature and text of new or pending applications for such Patent Rights claiming a Licensed Compound, Licensed Product or Combination Product, or its use or Manufacture, in the Territory. Each Party agrees to keep the other Party informed of the course of patent prosecution or other proceedings relating to such Patent Rights to the extent known by each Party.

**9.2.2 Abandonment, Opt-In Rights.** If Alios elects, in any country, not to file or not to continue to prosecute and thereby abandon an application for a patent claiming a Licensed Compound, Licensed Product or Combination Product, or their use or Manufacture, within the Alios Patent Rights, or any patent application that was assigned to Alios pursuant to **Section 9.1.4 (Assigned Rights)**, or not to maintain and thereby abandon a patent

claiming a Licensed Compound or Licensed Product or Combination Product, or their use or Manufacture, within the Alios Patent Rights, or patent that was assigned to Alios pursuant to **Section 9.1.4 (Assigned Rights)**, then Alios shall notify Vertex not less than [\*\*\*] before such relevant deadline, or, if such deadline is within less than [\*\*\*], then within a reasonable time period, and thereafter Vertex shall have the right, but not the obligation, to pursue, at Vertex's expense and in Vertex's sole discretion, prosecution of such patent application or maintenance of such issued patent; *provided, however,*

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

33

---

that (i) Vertex provides Alios with copies of all documents proposed to be submitted to the relevant Governmental Authority [\*\*\*] prior to the proposed submission date and (ii) with respect to any patent application or patent licensed to Alios by a Third Party, Vertex shall only have a right to pursue prosecution or maintenance to the extent permitted in any applicable agreement with such Third Party in effect as of the Effective Date.

**9.3 Prosecution and Maintenance of Joint Patents; Abandonment.** The Parties agree to discuss in good faith and implement a mutually agreeable patent strategy with respect to all Joint IP that may be patentable. With respect to all Joint IP for which the Parties agree patent protection should be sought, the Parties shall cooperate in the preparation, filing and prosecution of Joint Patents, 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 regarding steps to strengthen such Joint Patents.

**9.3.1 Vertex as Lead Party.** Vertex shall be considered the lead Party as further described in **Section 9.3.3 (Joint Patents Prosecution and Costs)** for Joint Patents other than those described in **Section 9.3.2 (Alios as Lead Party)**, or as otherwise agreed to by the Parties.

**9.3.2 Alios as Lead Party.** Alios shall be considered the lead Party as further described in **Section 9.3.3 (Joint Patents Prosecution and Costs)** for Joint Patents drawn to compositions, methods of making or methods of use of Joint Compounds or as otherwise agreed to by the Parties.

**9.3.3 Joint Patents Prosecution and Costs.** The lead Party as identified in either **Section 9.3.1 (Vertex as Lead Party)** or **9.3.2 (Alios as Lead Party)** shall have the right to file, prosecute and maintain such Joint Patents in the Territory, and the Parties shall bear all Patent Costs associated therewith equally. The lead Party shall take no significant steps relating to Joint Patents without the prior approval of the other Party for so long as the other Party is paying its share of the Patent Costs relating thereto. In the event that the lead Party elects not to prosecute a patent application on a particular Joint IP, the other Party may do so at its sole discretion and expense, and all rights in such Joint IP and any Joint Patent claiming such Joint IP shall be assigned to the other Party. Either Party may choose at any time not to continue to pay any such Patent Costs with respect to a particular Joint Patent, and shall thereafter assign all its rights in such Joint Patent to the Party that pays all such Patent Costs. Such assignment shall take place in a timely manner to enable the non-assigning Party to meet any external requirement concerning prosecution matters and paying Patent Costs. If a Party elects, at any time, not to participate in the preparation, filing and prosecution of any patent application covering Joint IP, then such Party shall provide reasonable assistance to the other Party, at the expense of such other Party, with respect to any activities determined by such other Party as necessary to obtain patent protection for such Joint IP.

**9.3.4 Patent Term Extension.** The Parties shall use Reasonable Commercial Efforts to obtain patent term extensions or supplemental protection certificates or their equivalents in any country in the Territory where applicable to the Alios Patent Rights and Joint Patents and shall cooperate with each other, including providing necessary information, documents and assistance as the other Party may reasonably request.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

34

---

## **9.4 Interference, Opposition, Reexamination and Reissue.**

**9.4.1 Notice.** Each Party shall promptly inform the other Party upon learning of any Third Party request for, or filing or declaration by the relevant patent office, of any interference, opposition, or reexamination proceeding relating to the Alios Patent Rights or Joint Patents. Alios shall be the lead Party on any such proceeding involving Alios Patent Rights or Joint Patents. Alios and Vertex shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The parties shall have the right to review and comment on any submission to be made in connection with such proceeding.

**9.4.2 Restriction.** Neither Party may initiate or request any interference, opposition, reexamination or reissue proceeding relating to patent applications or patents licensed to the other Party under this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld; *provided, however,* that [\*\*\*].

**9.4.3 Cooperation.** In connection with any interference, opposition, reexamination or reissue proceeding relating to patent applications or patents licensed to the other Party under this Agreement, Vertex and Alios shall cooperate fully and shall provide each other with any information or assistance that either Party may reasonable request. The Parties shall keep each other informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.

**9.4.4 Costs.** [\*\*\*] shall bear the expense of any interference, opposition, reexamination, or reissue proceeding relating to its respective patent applications or patents [\*\*\*] under this Agreement.

## **9.5 Enforcement of Patent Rights.**



**9.5.1 Notice.** If any patent within the Alios Patent Rights is or might reasonably be infringed by a Third Party [\*\*\*], which product is competitive with a Licensed Product or Combination Product (an “**Infringement**”), then the Party to this Agreement first having knowledge of such Infringement shall promptly notify the other Party in writing. Such notice shall set forth the facts of the Infringement in reasonable detail.

**9.5.2 Enforcement of Alios Patent Rights or Joint Patent Rights.** Alios shall have the first right, but not an obligation, at its expense to institute, prosecute and control, using counsel of Alios’ choice, any action or proceeding with respect to an Infringement of a patent within the Alios Patent Rights or the Joint Patents, which, if continued, in either Party’s reasonable judgment would be expected to materially affect the Manufacture, use or sale of a Licensed Product or Combination Product; *provided, however*, that (a) prior to initiating any such suit or proceeding, the Parties shall discuss the extent and impact of the Infringement; (b) Alios shall promptly disclose to Vertex all material information related to such action or proceeding; and (c) Alios shall reasonably consider input from Vertex regarding the strategy for such action or proceeding, including the decision to initiate legal action with respect to the Infringement. If Alios institutes any such action or proceeding, then Vertex agrees to be joined as a party plaintiff if necessary for

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

35

---

Alios to institute and prosecute such action or proceeding, and to give Alios reasonable assistance and authority to institute and prosecute such action or proceeding. In addition, if the patent alleged to be infringed is owned by a Third Party and Alios does not have authority to require such Third Party to join as a party plaintiff, Alios agrees to use Reasonable Commercial Efforts to cause such Third Party to agree to be joined as a party plaintiff if helpful or necessary for the Parties to prosecute an action or proceeding, and to give Alios reasonable assistance and authority to institute and prosecute such action or proceeding. No settlement of any action or defense which restricts the scope or affects the enforceability of a patent within the Alios Patent Rights may be entered into by Alios without the prior written consent of Vertex, which shall not be unreasonably withheld or delayed. If Alios fails to institute and thereafter prosecute an action or proceeding with respect to such an Infringement within a period of [\*\*\*] after the earlier of (i) the date of the Parties’ determination that such infringement, in the Parties’ reasonable judgment, if continued, would affect materially the Manufacture, use or sale of a Licensed Product or Combination Product, or (ii) the date of Vertex’s request to institute such an action or proceeding, then Vertex shall have the right, but not the obligation, to institute and/or prosecute and control an action or proceeding in its name with respect to such an Infringement by counsel of Vertex’s choice. To the extent required by Applicable Laws, in the event that Vertex institutes any such action or proceeding, Alios agrees to be joined as a party plaintiff if necessary for Vertex to institute and prosecute such action or proceeding, and to give Vertex reasonable assistance and authority to institute and prosecute such action or proceeding.

**9.5.3 Enforcement of Vertex Patent Rights.** Vertex shall have the first right, but not an obligation, to institute, prosecute and control, using counsel of Vertex’s choice, any action or proceeding with respect to an Infringement of a patent within the Vertex Patent Rights, which, if continued, reasonably would be expected to affect the Manufacture, use or sale of a Licensed Product or Combination Product. To the extent permitted by Applicable Laws where either (a) Vertex has brought suit, or (b) the patent alleged infringed is owned by a Third Party and Vertex is authorized to permit Alios to do so, Alios shall have the right, at its own expense, to be represented in any such action or proceeding by counsel of Alios’ choice.

**9.5.4 Recoveries.** Unless otherwise required as a result of prior written agreement, any damages or other monetary awards recovered in an action or proceeding described in **Section 9.5.2 (Enforcement of Alios Patent Rights)** or **Section 9.5.3 (Enforcement of Vertex Patent Rights)** shall be shared in order as follows: [\*\*\*].

**9.5.5 Patent Marking.** Vertex shall, and shall require its Affiliates and Sublicensees to, mark Licensed Products and Combination Products sold by or on behalf of it hereunder with appropriate patent numbers or indicia to the extent permitted by Applicable Laws, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringement of Alios Patent Rights or Joint Patents.

**9.5.6 Notification of Patent Certification.** Vertex shall notify and provide Alios with copies of any written assertions of alleged patent invalidity, unenforceability or non-infringement of an Alios Patent Right or a Joint Patent pursuant to a Paragraph IV patent certification by a Third Party filing an Abbreviated New Drug Application under Section 505(j) of the FD&C Act, an application under Section 505(b)(2) of the FD&C Act, or a similar patent

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

36

---

certification by a Third Party, and any foreign equivalent thereof. Such notification and copies shall be provided to Alios within [\*\*\*] after Vertex receives such certification. In addition, upon request by Alios, Vertex shall provide reasonable assistance and cooperation (including making available to Alios documents possessed by Vertex that are reasonably required by Alios and making available personnel for interviews and testimony) in any actions reasonably undertaken by Alios in accordance with **Section 9.5.2 (Enforcement of Alios Patent Rights or Joint Patents)** to contest any such patent certification.

**9.6 Settlement with a Third Party.** Except as otherwise expressly provided in **Section 9.4 (Enforcement of Patents Rights)**, a Party may not settle an action or proceeding against an infringer under **Section 9.4 (Enforcement of Patents Rights)** above with respect to an Infringement without the written consent of the other Party. Such consent shall not be unreasonably withheld or delayed, but may be withheld if such settlement would materially and adversely affect the interest of such other Party.

**9.7 Infringement of Third Party Rights.** This **Section 9.7 (Infringement of Third Party Rights)** shall apply in the event that a Third Party alleges that intellectual property rights owned, held or otherwise controlled by such Third Party are being infringed or have been infringed by Vertex or Alios in performing any activity which such Party is required or permitted to perform under this Agreement. If a Third Party does not allege infringement, but the

Parties agree that the development, Manufacture, or Commercialization of a Licensed Product or Combination Product in the Territory would infringe a Third Party patent right, then **Section 7.6.3 (Royalty Adjustment for Third Party Patent Rights)** will apply.

**9.7.1 Defense by Vertex.** As between Vertex and Alios, Vertex shall have the right but not the obligation to defend or, after consultation with Alios as set forth in this **Section 9.7.1 (Defense by Vertex)**, settle any legal action or proceeding arising from an allegation by a Third Party that the Manufacture, use or sale of a Licensed Product or Combination Product by Vertex or Alios infringes a patent owned, held or otherwise controlled by such Third Party with respect to any claim. In addition, Vertex shall have the right to take appropriate steps to initiate and pursue any challenge, opposition or other similar actions or proceedings, including interference proceedings, relating to a patent application or patent owned, held or otherwise controlled by a Third Party with respect to any matter relating to Licensed Products or Combination Products. Vertex shall promptly disclose to Alios all material information related to any action or proceeding and the Parties shall consult with each other concerning strategy, approaches and the consequences of approaches to be taken pursuant to this **Section 9.7.1 (Defense by Vertex)** by Vertex. Vertex shall not settle or otherwise finally resolve any legal action or proceeding under this **Section 9.7.1 (Defense by Vertex)** without consulting with Alios. If such settlement or resolution involves injunctive or other equitable relief, as opposed to merely a financial settlement, then Vertex shall obtain the written consent of Alios, such consent not to be unreasonably withheld. Alios shall provide all reasonable assistance requested by Vertex in connection with any such action or proceeding. Any and all costs and expenses incurred by either Party under this **Section 9.7.1 (Defense by Vertex)**, as well as any damages or settlement amounts that the Parties are ordered to or agree to pay, shall be shared by the Parties at a rate of (a) [\*\*\*] for infringement claims based exclusively on the practice by Vertex of any right granted by Alios to Vertex hereunder, (b) [\*\*\*]

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

37

---

for infringement claims based exclusively on the practice by Alios of any right granted by Vertex to Alios hereunder, and (c) [\*\*\*] for all other claims. Notwithstanding the above, if the resolution of such legal action results in a royalty-bearing license by such Third Party to Vertex, then Vertex shall have the right to adjust Royalty payments as set forth in **Section 7.6.3 (Royalty Adjustment for Third Party Patent Rights)**.

The rights granted to Alios and Vertex, respectively, under this **Section 9.7 (Infringement of Third Party Rights)** to settle certain legal actions or proceedings shall not create any right in Alios or Vertex to grant any right in or to any Licensed Product or Combination Product, or any Patent Right or any Know-How of the other Party, *provided* that this sentence shall not limit any rights Alios or Vertex may possess independently of this **Section 9.7 (Infringement of Third Party Rights)**.

## **9.8 Trademarks.**

**9.8.1 Ownership.** Vertex shall at its own expense select, register and maintain the trademark(s) used by Vertex, its Affiliates and Sublicensees (the “**Vertex Trademarks**”) in connection with Licensed Products or Combination Products. Alios shall have no rights in respect of Vertex Trademarks, except as expressly provided in **Section 13.9.1(d) (Licensed Product and Compound Rights Upon Early Termination)**. For the avoidance of doubt, Vertex shall have the sole and exclusive right to enforce its trademarks, as determined by Vertex in its sole discretion, and to retain all recoveries.

**9.8.2 Notice of Unauthorized Use.** Alios agrees to give Vertex prompt written notice of any unlicensed use by Third Parties of Vertex Trademarks of which Alios has knowledge.

## **9.9 Approval Applications and Regulatory Approvals.**

**9.9.1 Ownership.** Subject to the rights granted to or owned by Alios hereunder, Vertex shall own all right, title and interest in all Approval Applications necessary to obtain Regulatory Approvals required for marketing and sale of Licensed Products or Combination Products or any other activity to be engaged in by Vertex under this Agreement, together with any Regulatory Approval obtained in connection therewith. Such Approval Applications, together with any Regulatory Approvals obtained in connection therewith, shall be filed in Vertex’s name and owned by Vertex.

**9.9.2 Orange Book and Related Listings.** To the extent required by or permitted by Applicable Laws, Vertex will use Reasonable Commercial Efforts to promptly, accurately and completely list, with the applicable Regulatory Authorities during the Term, all applicable Alios Patent Rights or Joint Patents for any Licensed Product or Combination Product that Vertex intends to, or has begun to, Commercialize, and that have become the subject of an Approval Application submitted to the FDA or their foreign equivalents, such listing to include all so called “Orange Book” listings required under the Hatch-Waxman Act and all so called “Patent Register” listings as required in Canada. Prior to such listings, the Parties will meet to evaluate, identify, and agree upon all applicable Alios Patent Rights and Joint Patents to be listed.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

38

---

**9.9.3 Data Exclusivity.** With respect to data exclusivity periods provided by Regulatory Approval under the FD&C Act or its foreign equivalents or periods under national implementations of Article 9.1(a)(iii) of the Directive 2001/EC/83, any future laws or regulations covering similar subject matter, and all international equivalents, Vertex shall use Reasonable Commercial Efforts consistent with its obligations under Applicable Laws (including any applicable consent order) to seek, maintain and enforce all such data exclusivity periods available for Licensed Products or Combination Products.

**10.1 Confidentiality; Exceptions.** Except as otherwise provided in this Agreement, the Parties agree that, during the Term and for the longer of (a) [\*\*\*] after disclosure and (b) [\*\*\*] after the end of the Term, all non-public, proprietary information and data, including invention disclosures, Know-How, data, and scientific, clinical, regulatory, manufacturing, marketing, commercial, technical and financial information or data, related to the Licensed Compounds and the activities contemplated by this Agreement and including non-public, proprietary information exchanged between the Parties pursuant to a certain nondisclosure agreement entered into by the Parties dated February 15, 2011 (the “**Confidentiality Agreement**”) (collectively, “**Confidential Information**”), disclosed or submitted, either orally or in writing (including by electronic means) or through observation, by one Party (the “**Disclosing Party**”) to the other Party (the “**Receiving Party**”) hereunder shall be received and maintained by the Receiving Party in confidence, shall not be used for any purpose other than the purposes expressly permitted by this Agreement, and shall not be disclosed to any Third Party (including in connection with any publications, presentations or other disclosures) except as expressly permitted by this Agreement. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information. Confidential Information belongs to and shall remain the property of the Disclosing Party. The provisions of this **ARTICLE 10 (Confidentiality)** shall not apply to any information that can be shown by the Receiving Party:

**10.1.1** To have been known to or in the possession of the Receiving Party prior to the date of its actual receipt from the Disclosing Party without breaching any provision of this Agreement or any other agreement between the Parties or of any agreement between the Disclosing Party and a Third Party, by such Third Party;

**10.1.2** To be or to have become available to the public other than through any act or omission of the Receiving Party in breach of this Agreement or any other agreement between the Parties;

**10.1.3** To have been disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party that had no obligation to the Disclosing Party not to disclose such information to others; or

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

39

**10.1.4** To have been subsequently independently developed by the Receiving Party without use of the Confidential Information as demonstrated by competent contemporaneous tangible records.

**10.2 Authorized Disclosure.** Each Party may disclose the other Party’s Confidential Information hereunder solely to the extent such disclosure is reasonably necessary in connection with complying with Applicable Laws; *provided* that in the event of any such disclosure of the Disclosing Party’s Confidential Information by the Receiving Party, the Receiving Party will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure requirement (so that the Disclosing Party may seek a protective order and or other appropriate remedy or waive compliance with the confidentiality provisions of this **ARTICLE 10 (Confidentiality)**) and will use its Reasonable Commercial Efforts to secure confidential treatment of such Confidential Information required to be disclosed. Confidential Information may be disclosed by Alios to Third Parties bound by confidentiality and non-use restrictions at least as restrictive as those set forth in this **ARTICLE 10 (Confidentiality)** to the extent such Confidential Information (a) is disclosed to *bona fide* potential or actual investors in or acquirers of Alios; or (b) is disclosed to attorneys, bankers or other financial institutions in connection with obtaining loans, financing, or other financial services; *provided*, in each case, that Alios shall limit such disclosure of Confidential Information to information Alios reasonably determines is material to such Third Party’s potential investment in, acquisition of, loan to, financial arrangement with or other services to be provided to, Alios. Confidential Information may be disclosed by a Party to (i) those of its and its Affiliates’ or its Sublicensees’ directors, officers, employees, agents, consultants, Outside Contractors, and clinical investigators that such Party reasonably determines have a need to know such Confidential Information to achieve the purposes of this Agreement; *provided, however*, that such Party shall ensure that its and its Affiliates’ or Sublicensees’ directors, officers, employees, agents, consultants, Outside Contractors, and clinical investigators to whom disclosure is to be made are bound by confidentiality and non-use restrictions at least as restrictive as those set forth in this **ARTICLE 10 (Confidentiality)**, and (ii) to the extent such disclosure is reasonably necessary in connection with submissions to any Governmental Authority for the purposes of this Agreement or in filing or prosecuting patent applications contemplated under this Agreement; *provided* that in the event of any such disclosure of the Disclosing Party’s Confidential Information by the Receiving Party, the Receiving Party will use its Reasonable Commercial Efforts to secure confidential treatment of such Confidential Information required to be disclosed.

**10.3 Return of Confidential Information.** Each Receiving Party shall keep Confidential Information belonging to the Disclosing Party in appropriately secure locations. Upon expiration or termination of this Agreement, any and all Confidential Information possessed in tangible form by a Receiving Party, its Affiliates or Sublicensees, or its or any of their directors, officers, employees, agents, consultants, Outside Contractors, and clinical investigators and belonging to the Disclosing Party, shall, upon written request, be destroyed to the extent practicable and not used or disclosed by the Receiving Party, its Affiliates or Sublicensees, or any of their directors, officers, employees, agents, consultants, Outside Contractors, and clinical investigators; *provided, however*, that a Party may retain one (1) copy of any Confidential Information in an appropriately secure location solely for use by its legal department to ensure compliance with the confidentiality provisions of this Agreement.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

40

**10.4 Publications.** Alios and Vertex each acknowledge the other Party’s interest in publishing the results of its scientific research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Authorship of any publication shall be determined based on the accepted standards used in peer-reviewed, academic journals at the time of the proposed publication. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to **Section 10.1 (Confidentiality; Exceptions)** and **Section 10.2 (Authorized Disclosure)**, if either Party, its employees or consultants wishes to publish or present to any Third Party, results of the Research Work, or the results of any program to discover or develop Licensed Compounds, Licensed Products or Combination Products, or any clinical data or clinical information about a Licensed Compound, Licensed Product or Combination Product being Developed

pursuant to this Agreement, it shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure as soon as practicable prior to submission for publication or presentation. The reviewing Party shall notify the other Party promptly after of receipt of such proposed publication whether such draft publication contains (i) Confidential Information of the reviewing Party, or (ii) information that if published would have an adverse effect on a patent application covering the subject matter of this Agreement. The reviewing Party shall have the right to (a) propose modifications to the publication or presentation for patent reasons, trade secret reasons, confidentiality reasons or business reasons and/or (b) request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay to protect patentable information, the publishing Party shall delay submission or presentation for a period not to exceed [\*\*\*] to enable patent applications protecting each Party's rights in such information to be filed in accordance with the terms of this Agreement. Upon expiration of such [\*\*\*], the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party reasonably requests modifications to the publication or presentation to prevent disclosure of material trade secret or proprietary business information, the publishing Party shall edit such publication to prevent the disclosure of such information prior to submission of the publication or presentation.

Once approval for a publication or presentation has been granted, the Parties shall be entitled to use the specific information contained in such publication or presentation after the date of its publication or presentation without seeking further approval. General comments made by a Party relating to the relationship between Vertex and Alios established by this Agreement, including, for example, general comments made in response to inquiries at professional meetings and other similar circumstances, are not intended to be restricted by the provisions of this **ARTICLE 10 (Confidentiality)**, provided such information has been disclosed to the public previously or cleared for such disclosure by the other Party.

## **10.5 Press Releases.**

**10.5.1** Alios and Vertex shall agree upon the timing and content of an initial press release relating to this Agreement and the transactions contemplated herein, which is attached as **Exhibit C (Press Release)** to this Agreement. Except to the extent already disclosed in that initial press release, no disclosure of the subject matter of this Agreement or its terms may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party or

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

41

---

its employees in any publicity, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Laws, regulations, or judicial order. The Party desiring to make any such public announcement shall provide the other Party with a written copy of the proposed announcement in sufficient time prior to public release to allow such other Party to comment upon such announcement, prior to public release. Nothing in this **Section 10.5 (Press Releases)** shall be deemed to restrict the disclosure of any information, the content of which has been previously disclosed in a press release.

**10.5.2** In addition to the foregoing restrictions on public disclosure, if either Party concludes that a copy of this Agreement must be filed with the Securities and Exchange Commission, such Party shall provide the other Party with a copy of this Agreement showing any sections as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity and a reasonable time period to comment on any such proposal and to suggest additional portions of the Agreement for confidential treatment and will take such Party's reasonable comments into consideration before filing the Agreement. If the filing Party disagrees with the other Party's additional confidential treatment request, the Parties shall have an opportunity to discuss such matter in good faith before the Agreement is filed.

## **ARTICLE 11 REPRESENTATIONS, WARRANTIES AND COVENANTS**

**11.1 Representations and Warranties of the Parties.** Each Party represents and warrants to the other Party that:

**11.1.1** Such Party is duly organized and validly existing and in good standing under the laws of the jurisdiction of its organization;

**11.1.2** Such Party has the full corporate power and is duly authorized to enter into, execute and deliver this Agreement, and to carry out and otherwise perform its obligations hereunder;

**11.1.3** This Agreement has been duly executed and delivered by, and is the legal and valid obligation binding upon such Party and the entry into, the execution and delivery of, and the carrying out and other performance of its obligations under this Agreement by such Party (a) does not conflict with, or contravene or constitute any default under, any agreement, instrument or understanding, oral or written, to which it is a party, including its certificate of incorporation or by-laws, and (b) does not violate Applicable Law or any judgment, injunction, order or decree of any Governmental Authority having jurisdiction over it;

**11.1.4** No government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Law currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

42

---

obligations under this Agreement and such other agreements except as may be required to obtain Hart-Scott-Rodino clearance or other clearances as required by other Governmental Authorities;

**11.1.5** All of its employees, officers, contractors, and consultants have executed agreements requiring assignment to such Party of all right, title and interest in and to their inventions and discoveries they have invented or otherwise discovered or generated during the course of and as a result of their association with such Party, whether or not patentable, if any, to such Party as the sole owner thereof;

**11.1.6** All of its employees, officers, contractors, and consultants have executed agreements obligating each such employee, officer, contractor, and consultant to maintain as confidential the Confidential Information of such Party; and

**11.1.7** Neither such Party, nor any of its employees, officers, subcontractors, or consultants who have rendered or will render services relating to the Back-up Compounds, Follow-on Compounds, Licensed Compounds, Licensed Products or Combination Products: (a) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred by the FDA under 21 U.S.C. Section 335a (or subject to a similar sanction of any other Governmental Authority) or (b) has ever been under indictment for a crime for which a person or entity could be so debarred.

**11.2 Representations, Warranties and Covenants of Alios.** Alios represents, warrants and covenants to Vertex that:

**11.2.1** There are not as of the Effective Date, nor have there been over the five (5) year period immediately preceding the Effective Date, any claims, lawsuits, arbitrations, legal or administrative or regulatory proceedings, charges, complaints or investigations by any Governmental Authority (except for any Governmental Authority with authority over the granting of patents and proceedings relating thereto) or other Third Party threatened, commenced or pending against Alios or, to Alios' knowledge, its licensors relating to, and Alios has not received any notice of infringement with respect to, the Alios IP;

**11.2.2** As of the Effective Date, Alios has full right and authority to grant the licenses and rights herein to Vertex and it has not granted any rights to any Third Party under the Alios IP that are inconsistent with the rights granted to Vertex under this Agreement;

**11.2.3** As of the Effective Date, [\*\*\*]. As of the Effective Date, Alios is the sole owner of all Alios Patent Rights set forth on **Schedule 1.7 (Alios Patent Rights)**;

**11.2.4** As of the Effective Date, [\*\*\*];

**11.2.5** In the course of performing Development Work related to any Licensed Product, Alios shall not use any employee or consultant who has ever been debarred or is the subject of debarment or convicted of a crime for which an entity or person could be debarred (including by the FDA under 21 U.S.C. § 335a (or subject to a similar sanction of any other Governmental Authority)). Alios shall notify Vertex promptly upon becoming aware that any of its

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority;

**11.2.6** Alios shall comply in all material respects with all Applicable Laws in performing Development Work and Manufacturing Licensed Products under this Agreement, including the statutes, regulations and written directives of the FDA, the EMA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U.S.C. § 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time;

**11.2.7** Alios shall not knowingly infringe the intellectual property rights of any Third Party in connection with its activities pursuant to this Agreement;

**11.2.8** All of Alios' employees, officers, contractors, and consultants involved in Development of the Licensed Compounds and Licensed Products or who are provided Confidential Information of Alios or Vertex shall be obligated to assign to Alios all inventions relating to such Licensed Compounds and Licensed Products and to maintain as confidential the Confidential Information of Alios and Vertex;

**11.2.9** As of the Effective Date, to Alios' actual knowledge, the Lead Compound clinical material required for the Phase 1 Clinical Trials that has been Manufactured by Alios' Outside Contractors is GMP-compliant;

**11.2.10** [\*\*\*]

**11.2.11** [\*\*\*].

**11.3 Representations, Warranties and Covenants of Vertex.** Vertex represents, warrants and covenants to Alios that:

**11.3.1** In the course of its Development of any Licensed Product or Combination Product, Vertex shall not use any employee or consultant who has ever been debarred or is the subject of debarment or convicted of a crime for which an entity or person could be debarred (including by the FDA under 21 U.S.C. § 335a (or subject to a similar sanction of any other Governmental Authority)). Vertex shall notify Alios promptly upon becoming aware that any of its employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority;

**11.3.2** Vertex and its Affiliates shall comply in all material respects with all Applicable Laws in the Development, Manufacture, and Commercialization of Licensed Products or Combination Product performed under this Agreement, including the statutes, regulations and written directives

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

Medicare, Medicaid and all other health care programs, as defined in 42 U.S.C. § 1320a-7b(f), and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time;

**11.3.3** Vertex shall not engage in any activities that use the Alios IP in a manner that is outside the scope of the license rights granted to Vertex under this Agreement;

**11.3.4** Vertex shall not knowingly infringe the intellectual property rights of any Third Party in connection with its activities pursuant to this Agreement; and

**11.3.5** All of Vertex’s employees, officers, contractors, and consultants involved in development of the Licensed Compounds, Licensed Products or Combination Products or provided Confidential Information of Alios or Vertex shall be obligated to assign to Vertex all inventions relating to such Licensed Compounds, Licensed Products and Combination Products and to maintain as confidential the Confidential Information of Vertex and Alios.

**11.4 Disclaimer.** The Parties understand that the Licensed Compounds, Licensed Products and Combination Products and all drugs and drug candidates that may be evaluated in combination with Licensed Compounds, Licensed Products and Combination Products pursuant to this Agreement are the subject of ongoing clinical research and development and that neither Party can assure the safety or usefulness of any Licensed Compound, Licensed Product and/or Combination Product. In addition, neither Party makes any warranties except as set forth in this **ARTICLE 11 (Representations, Warranties and Covenants)** concerning the Alios IP or the Vertex IP. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT.

## **ARTICLE 12 INDEMNIFICATION, INSURANCE, LIMITATION OF LIABILITY**

**12.1 Indemnification by Vertex.** Except for any actions or liabilities arising out of infringement of Third Party patent rights addressed by **Section 9.7.1 (Defense by Vertex)**, Vertex hereby agrees to save, defend, and hold Alios, its Affiliates and their officers, directors, employees and agents harmless from and against any and all Third Party claims or actions for losses, damages, liabilities, costs and expenses, including reasonable attorneys’ fees and expenses that arise in connection therewith, (collectively, “**Losses**”) to the extent resulting from or arising out of (a) the research of any Licensed Compound by Vertex, its Affiliates or Sublicensees or independent contractors; (b) the Development or Manufacture of Licensed Compounds, Licensed Products and Combination Products by Vertex, its Affiliates or Sublicensees or independent contractors; (c) the storage of Licensed Compounds, Licensed Products, Combination Products or the conversion of Licensed Products and Combination Products from bulk to finished form by Vertex, its Affiliates or Sublicensees or independent contractors; (d) the Commercialization of Licensed Products and Combination Products by Vertex, its Affiliates or Sublicensees or independent contractors (except in the cases of clauses (a) through (d) to the extent caused by the negligence or willful misconduct

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

of, or failure to comply with Applicable Laws or material breach of this Agreement by, Alios or its Affiliates or Outside Contractors (other than Vertex or an Affiliate of Vertex), and its or their directors, officers, agents, employees, consultants or clinical investigators, and except to the extent such Losses result from or arise out of any act or omission for which Alios is found to have an indemnification obligation pursuant to **Section 12.2 (Indemnification by Alios)** of this Agreement); (e) the negligence or willful misconduct of Vertex or its Affiliates, licensees or Sublicensees, and its or their directors, officers, agents, employees, or consultants or clinical investigators in connection with Vertex’s exercise of its rights and performance of its obligations under this Agreement; (f) the material breach by Vertex of any representation, warranty, covenant or other provision of this Agreement; or (g) any of Vertex’s activities under this Agreement that infringe any patent owned or otherwise controlled by a Third Party with respect to any component or portion of any Combination Product that does not constitute a Licensed Compound.

**12.2 Indemnification by Alios.** Except for any actions or liabilities arising out of infringement of Third Party patent rights addressed by **Section 9.7.1 (Defense by Vertex)**, Alios hereby agrees to save, defend and hold Vertex, its Affiliates and their officers, directors, employees and agents harmless from and against any and all Losses to the extent resulting from or arising out of (a) the research or Development of any Alios Compound by Alios or its Affiliates or independent contractors under this Agreement; (b) Alios’ Manufacture, use or storage of Alios Compounds, (except in cases of clauses (a) and (b) to the extent caused by the negligence or willful misconduct of, or failure to comply with Applicable Laws or material breach of terms of this Agreement by, Vertex or its Affiliates, licensees or Sublicensees and its or their directors, officers, agents, employees, consultants or clinical investigators); (c) the negligence or willful misconduct of Alios, or its Affiliates, and its or their directors, officers, agents, employees or consultants in connection with Alios’ exercise of its rights and performance of its obligations under this Agreement; or (d) the material breach by Alios of any representation, warranty, covenant or other provision of this Agreement.

### **12.3 Indemnification Procedure.**

**12.3.1** Each indemnified Party (the “**Indemnitee**”) agrees to give the indemnifying Party (the “**Indemnitor**”) prompt written notice of any Losses or discovery of fact upon which the Indemnitee intends to base a request for indemnification. Notwithstanding the foregoing, the failure to give timely notice to the Indemnitor shall not release the Indemnitor from any liability to the Indemnitee to the extent the Indemnitor is not prejudiced by the delay in providing such notice.

**12.3.2** The Indemnitee shall furnish promptly to the Indemnitor copies of all papers and official documents in the Indemnitee’s possession or control that relate to any Losses; *provided, however*, that if the Indemnitee defends or participates in the defense of any Losses, then the Indemnitor shall also provide such papers and documents to the Indemnitee. The Indemnitee shall cooperate with the Indemnitor in providing witnesses and records necessary in the defense against any Losses.

**12.3.3** The Indemnitor shall have the right, by prompt notice to the Indemnitee, to assume direction and control of the defense of any Third Party claim forming the basis of such

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

46

---

Losses, with counsel reasonably acceptable to the Indemnitee and at the sole cost of the Indemnitor, so long as (a) the Indemnitor shall promptly notify the Indemnitee in writing (but in no event more than [\*\*\*] after the Indemnitor’s receipt of notice of the claim) that the Indemnitor intends to indemnify the Indemnitee from and against any Losses the Indemnitee may suffer arising out of the claim absent the development of facts that give the Indemnitor the right to claim indemnification from the Indemnitee and (b) the Indemnitor diligently pursues the defense of the claim.

**12.3.4** If the Indemnitor assumes the defense of the claim as provided in **Section 12.3.3 (Indemnification Procedure)** or **Section 12.3.5 (Indemnification Procedure)**, the Indemnitee may participate in such defense with the Indemnitee’s own counsel, reasonably acceptable to Indemnitor, who shall be retained, at the Indemnitee’s sole cost and expense; *provided, however*, that neither the Indemnitee nor the Indemnitor shall consent to the entry of any judgment or enter into any settlement with respect to the claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. If the Indemnitee withholds consent in respect of a judgment or settlement involving only the payment of money by the Indemnitor and which would not involve any stipulation or admission of liability or result in the Indemnitee becoming subject to injunctive relief or other relief, the Indemnitor shall have the right, upon notice to the Indemnitee within [\*\*\*] after receipt of the Indemnitee’s written denial of consent, to pay to the Indemnitee, or to a trust for its or the Third Party’s benefit, as shall be established at trial or by settlement, the full amount of the Indemnitor’s obligation under **Section 12.1 (Indemnification by Vertex)** or **Section 12.2 (Indemnification by Alios)**, as applicable, with respect to such proposed judgment or settlement, including all interest, costs or other charges relating thereto, together with all attorneys’ fees and expenses incurred to such date for which the Indemnitor is obligated under this Agreement, if any, at which time the Indemnitor’s rights and obligations with respect to the claim shall cease.

**12.3.5** If the Indemnitor does not so assume the defense of such claim, the Indemnitee may conduct such defense with counsel of the Indemnitee’s choice but may not settle such case without the written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed. In addition, the Indemnitor shall have the right to assume control of the defense, at its own expense, at any time upon [\*\*\*] prior notice to the Indemnitee.

**12.3.6** Except as provided in **Section 12.3.5 (Indemnification Procedure)**, the Indemnitor shall not be liable for any settlement or other disposition of a Loss by the Indemnitee that is reached without the written consent of the Indemnitor.

**12.3.7** Except as otherwise provided in this **Section 12.3 (Indemnification Procedure)**, the portion of costs and expenses, including reasonable fees and expenses of counsel, incurred by any Indemnitee under **Section 12.3.5 (Indemnification Procedure)** in connection with any claim corresponding to the Indemnitor’s obligation under **Section 12.1 (Indemnification by Vertex)** or **Section 12.2 (Indemnification by Alios)**, as applicable, shall be reimbursed on a [\*\*\*] basis by the Indemnitor, for so long as the Indemnitee controls the defense of the claim, without prejudice to the Indemnitor’s right to contest the Indemnitee’s right to indemnification and subject to refund in the event the Indemnitor is ultimately held not to be obligated to indemnify the Indemnitee.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

47

---

**12.3.8** Each Indemnitee will take and will procure that its Affiliates take all such reasonable steps and action as are reasonably necessary or as the Indemnitor may reasonably require in order to mitigate any Third Party Claims (or potential losses or damages) under this **ARTICLE 12 (Indemnification, Insurance, Limitation of Liability)**. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

## **12.4 Insurance.**

**12.4.1 Vertex Responsibilities.** For so long as Vertex is conducting Clinical Trials using Licensed Products or Combination Products or Manufacturing, marketing, promoting, distributing and selling Licensed Products or Combination Products under this Agreement, Vertex shall either provide reasonably satisfactory evidence to Alios of Vertex’s self-insurance or obtain product liability insurance for the benefit of Vertex, covering such Licensed Products or Combination Products under terms that are similar to that obtained by Vertex for Vertex’s other similar marketed and sold products or compounds being evaluated in Clinical Trials.

**12.4.2 Alios Responsibilities.** With respect to Alios [\*\*\*] under this Agreement, Alios shall obtain product liability insurance according to industry standards for similar activities for the benefit of Alios.

**12.5 Limitation of Liability.** EXCEPT FOR EACH PARTY'S INDEMNIFICATION OBLIGATIONS HEREUNDER, ANY CLAIMS RELATED TO ONE PARTY'S INFRINGEMENT OF THE OTHER PARTY'S INTELLECTUAL PROPERTY OUTSIDE OF THE RIGHTS AND LICENSES GRANTED HEREUNDER, AND/OR ANY BREACH OF **ARTICLE 10 (CONFIDENTIALITY)**, UNDER NO CIRCUMSTANCES SHALL A PARTY HEREOF BE LIABLE TO THE OTHER PARTY HEREOF FOR CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR SPECIAL DAMAGES.

## **ARTICLE 13 TERM AND TERMINATION**

### **13.1 Term**

**13.1.1 Expiration.** This Agreement shall commence on the Effective Date and shall expire, on a country-by-country and Licensed Product-by-Licensed Product or Combination-Product-by-Combination Product basis, on the expiration of the Royalty Term under this Agreement (until the expiration of the last such Royalty Term, the "**Term**"). Notwithstanding any other provision of this Agreement, on expiration of this Agreement in accordance with the provisions of this **Section 13.1.1 (Expiration)**, the licenses granted by Alios to Vertex hereunder shall become fully paid and irrevocable in each country and as to each Licensed Product or Combination Product, as the case may be.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

48

---

**13.1.2** Notwithstanding the provisions of **Section 13.1.1 (Expiration)**, this Agreement may be terminated prior to expiration (by early termination) in accordance with the terms and conditions of this **ARTICLE 13 (Term and Termination)**.

### **13.2 Termination at Will or for Technical Failure**

**13.2.1 Termination at Will.** Vertex may terminate this Agreement in its entirety in Vertex's sole discretion, upon not less than sixty (60) days' prior written notice to Alios, at any time after completion of the Phase 2a Clinical Trial in accordance with the Development Plan.

**13.2.2 Termination for Technical Failure.** Vertex may terminate this Agreement at any time in Vertex's sole discretion, upon not less than thirty (30) days' prior written notice to Alios, in its entirety, if both Lead Compounds experience a Technical Failure and Vertex does not choose to go forward with a Selected Back-up Compound (or if Vertex elects to go forward with a Selected Back-up Compound for either Lead Compound and both Lead Compounds have experienced a Technical Failure, the Selected Back-up Compound later experiences a Technical Failure).

### **13.3 Termination for Cause.**

**13.3.1 Termination for Material Breach.** If either Party commits a material breach of this Agreement at any time, which breach is not cured within [\*\*\*] in the case of a breach consisting of an undisputed non-payment of money, or [\*\*\*] in the case of any other material breach, after written notice from the non-breaching Party specifying the breach, subject to **Section 13.3.2 (Disagreement as to Material Breach, Tolling of Cure Period)**, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party. The Parties acknowledge and agree that failure to exercise any right or option, or to take any action expressly within the discretion of a Party shall not be deemed to be a material breach hereunder.

**13.3.2 Disagreement as to Material Breach, Tolling of Cure Period.** If the Parties reasonably and in good faith disagree as to whether there has been a material breach of this Agreement, the Party that disputes that there has been a material breach may contest the allegation in accordance with **Section 14.3 (Dispute Resolution)** and the cure period shall be tolled until such time as the dispute is resolved pursuant to **Section 14.3 (Dispute Resolution)**. Any such termination of this Agreement under this **Section 13.3 (Termination for Cause)** will become effective at the end of the cure period, unless the breaching party has cured any such breach or default prior to expiration of such cure period, or, if such breach is not susceptible to cure within the cure period, then the non-breaching Party's right to termination shall be suspended only if and for so long as the breaching Party has provided to the non-breaching Party a written plan that is reasonably calculated to effect a cure and such plan is reasonably acceptable to the non-breaching Party, and the breaching Party commits to making diligent good faith efforts to carry out and does carry out such plan as provided to the non-breaching Party. The right of either Party to terminate this Agreement as provided in this **Section 13.3 (Termination for Cause)**, will not be affected in any way by such Party's waiver or failure to take action with respect to any previous default. It is understood and acknowledged that, during the pendency of such a dispute, all of the terms and

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

49

---

conditions of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations under this Agreement. Any payments that are made by one Party to the other Party pursuant to this Agreement pending resolution of the dispute shall be promptly refunded if an arbitrator determines pursuant to **Section 14.3 (Dispute Resolution)** that such payments are to be refunded by one Party to the other Party.

**13.4 Termination for Insolvency.** To the extent permitted by Applicable Laws, either Party may terminate this Agreement upon written notice to the other Party on or after the occurrence of any of the following events: (a) the appointment of a trustee, receiver or custodian for all or substantially all of the property of the other Party, or for any lesser portion of such property, if the result materially and adversely affects the ability of the other Party to fulfill its obligations hereunder, which appointment is not dismissed [\*\*\*], (b) the determination by a court or tribunal of competent jurisdiction that the other Party is insolvent such that a Party's liabilities exceed the fair market value of its assets, (c) the filing of a petition for relief in bankruptcy by the other Party on its own behalf, or the filing of any such petition against the other Party if the proceeding is not dismissed or withdrawn [\*\*\*] thereafter, (d) an assignment by the



other Party for the benefit of creditors, or (e) the dissolution or liquidation of the other Party. All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and shall otherwise be deemed to be, for the purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that both Parties, as licensees of such rights and licenses, shall retain and may fully exercise all of their rights and elections under the Bankruptcy Code.

**13.5 HSR Filing.** If Vertex reasonably determines that an HSR Filing is required, each of Alios and Vertex shall, [\*\*\*] after the Execution Date (or such later time as may be agreed to in writing by the Parties) file with the United States Federal Trade Commission and the Antitrust Division of the United States Department of Justice any HSR Filing required of it under the HSR Act. The Parties shall cooperate with one another to the extent necessary in the preparation of any such HSR Filing. Each Party shall be responsible for its own costs, expenses, and filing fees associated with any HSR Filing; *provided, however,* that Vertex shall be solely responsible for any fees (other than penalties that may be incurred as a result of actions or omissions on the part of Alios) required to be paid to any governmental agency in connection with making any such HSR filing for acquisitions by Vertex hereunder.

**13.5.1 Termination Upon HSR Denial.** If the Parties make an HSR Filing under **Section 13.5 (HSR Filing)** hereof, then this Agreement shall terminate (a) at Vertex’s option, immediately upon notice to Alios, in the event that the United States Federal Trade Commission or the United States Department of Justice seeks a preliminary injunction under the HSR Act against Alios and/or Vertex to enjoin the transactions contemplated by this Agreement; (b) at the election of either Party, immediately upon notice to the other Party, in the event that the United States Federal Trade Commission or the United States Department of Justice obtains a preliminary injunction under the HSR Act against Alios and/or Vertex to enjoin the transactions contemplated by this Agreement; or (c) at the election of either Party, immediately upon notice to the other Party, in the event that the HSR Clearance Date shall not have occurred on or prior to one hundred eighty (180) days after the effective date of the HSR Filing. Notwithstanding the foregoing, this **Section**

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

13.5 shall not apply in the event that Vertex reasonably determines that an HSR Filing is not required.

### **13.6 Termination for Inactivity.**

Alios may terminate this Agreement in its entirety at any time (a) Vertex is conducting no research, development or commercialization activity with respect to at least one Licensed Compound; (b) such inactivity has been ongoing for a period of [\*\*\*] and (c) Vertex does not commence research, development or commercialization activities within [\*\*\*] after written notice from Alios of its intention to terminate this Agreement under this Section 13.6 (Termination for Inactivity). For the avoidance of doubt, if Vertex is reasonably waiting for resolution of an issue that requires action by a Third Party before taking action or if Vertex is excused from performing actively under other provisions of this Agreement (such as, but not limited to, Section 15.2 (Force Majeure)), such waiting period shall not be considered a period in which there is no activity. Absent other research, development or commercialization activity, the act of searching for, identifying, communicating with, and/or negotiating with any Outside Contractor or with any potential Sublicensee of any or all of the rights and obligations of Vertex under this Agreement shall not constitute “activity” for purposes of this Section 13.6 (Termination for Inactivity). Alios may also terminate this Agreement if Vertex notifies Alios that it is ceasing Development or Commercialization of all Licensed Products and Combination Products in all the Major Market Countries.

**13.7 Termination for Patent Challenge.** If Vertex challenges the validity, scope, or enforceability of or otherwise opposes any Patent Rights within the Alios Patent Rights, then Alios may terminate this Agreement upon [\*\*\*] prior written notice, unless Vertex withdraws such challenge or opposition within the [\*\*\*] notice period; provided, however, that this termination right shall not be applicable if such challenge or opposition is raised by Vertex as a counterclaim to or in its defense of a patent infringement claim brought by Alios against Vertex. If a Sublicensee of Vertex or a further Sublicensee of a Sublicensee of Vertex’s commercial license challenges or opposes the validity, scope, or enforceability of or otherwise opposes any Patent Right within the Alios Patent Rights, then Vertex shall, upon [\*\*\*] prior written notice from Alios, either (a) terminate such sublicense, (b) cause such Sublicensee to withdraw such challenge or opposition, or (c) cause such Sublicensee to terminate such further sublicense or cause such further Sublicensee to withdraw such challenge or opposition. Vertex shall include provisions in all agreements under which a Third Party obtains a sublicense under any Patent Right included in the Alios Patent Rights, providing that if the sublicensee challenges the validity or enforceability or otherwise opposes any such Patent Right under which the Sublicensee is sublicensed, then Vertex may terminate such sublicense, such provisions to be included in any further sublicenses.

### **13.8 Rights on Termination.**

**13.8.1 Termination of Licenses.** If Vertex terminates this Agreement under **Section 13.2 (Termination at Will or for Technical Failure)**, or if Alios terminates this Agreement under **Section 13.3 (Termination for Cause)**, **Section 13.4 (Termination for Insolvency)**, **Section 13.6 (Termination for Inactivity)**, or **Section 13.7 (Termination for Patent Challenge)**, all rights and licenses granted to Vertex under this Agreement, other than the license

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

granted to Vertex in **Section 9.1.4 (Assigned Rights)**, shall immediately terminate and revert to Alios. Thereafter, Vertex shall have no further right or interest in, to or under any intellectual property Controlled by Alios pursuant to this Agreement and, except as provided **Section 13.9 (Licensed Product and Compound Reversion and Commercial Development by Alios)** with respect to Alios’ rights under certain circumstances to obtain certain licenses from Vertex, [\*\*\*], Alios shall have no right or interest in, to or under, or with respect to, any intellectual property of Vertex pursuant to this Agreement. All payment obligations, including license fees, milestone payments and Royalties, of Vertex that have accrued as of the date of termination notice and that are neither cancellable nor refundable, shall be immediately due and payable to Alios.

**13.8.2 Survival of Licenses in Case of Certain Vertex Terminations.** If Vertex terminates this Agreement pursuant to **Section 13.3 (Termination for Cause)** or **Section 13.4 (Termination for Insolvency)**, the licenses set forth in **Section 8.1.1 (License by Alios to Vertex)** shall survive such termination, subject to Vertex, should Vertex accept such right and license, of the grant of such right and license to Vertex and subject to Vertex's continuing Development and Commercialization milestone payment and Royalty obligations under **ARTICLE 7 (LICENSES)** of this Agreement for the remainder of the Term as defined in **Section 13.1.1 (Expiration)** without reference to the date of termination of this Agreement pursuant to **Section 13.3 (Termination for Cause)** or **Section 13.4 (Termination for Insolvency)**.

**13.8.3 Termination of Rights and Return of Confidential Information.** Except as otherwise provided in this **Section 13.8.3 (Termination of Rights and Return of Confidential Information)** and except as otherwise required to effect the other provisions of this **ARTICLE 13 (Term and Termination)**, in the event this Agreement is terminated for any reason, (a) except as otherwise expressly provided in this Agreement, all rights and obligations of the Parties under this Agreement shall terminate; (b) Vertex shall surrender to Alios, or destroy and provide Alios with a certificate signed by a Responsible Executive of Vertex attesting to the destruction of, all copies of any Confidential Information provided by Alios hereunder; and (c) Alios shall surrender to Vertex, or destroy and provide Vertex with a certificate signed by a Responsible Executive of Alios attesting to the destruction of, all copies of any Confidential Information provided by Vertex hereunder; *provided, however*, that a Party may retain one (1) copy of any Confidential Information in an appropriately secure location.

### **13.9 Licensed Product and Licensed Compound Reversion and Commercial Development by Alios.**

**13.9.1 Licensed Product and Compound Rights Upon Early Termination.** If Alios terminates this Agreement under **Section 13.3 (Termination for Cause)**, **Section 13.4 (Termination for Insolvency)**, **Section 13.6 (Termination for Inactivity)**, or **Section 13.7 (Termination for Patent Challenge)** or if Vertex terminates this Agreement under **Section 13.2 (Termination at Will or for Technical Failure)**, then, on the effective date of such termination all licenses granted hereunder to Vertex, other than the license granted to Vertex in **Section 9.1.4 (Assigned Rights)**, shall terminate as of such termination date, and Vertex shall and hereby does grant to Alios a nonexclusive, worldwide, fully paid-up, royalty-free license under Vertex IP (with the right to sublicense through multiple tiers or subcontract) solely to the extent necessary to

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

52

---

Develop, have Developed, Manufacture, have Manufactured, use, offer to sell, sell or import Licensed Compounds and Licensed Products as of the effective date of termination.

**13.9.2 Post Termination Technology Transfer.** If Alios terminates this Agreement under **Section 13.3 (Termination for Cause)**, **Section 13.4 (Termination for Insolvency)**, **Section 13.6 (Termination for Inactivity)**, or **Section 13.7 (Termination for Patent Challenge)** or if Vertex terminates this Agreement under **Section 13.2 (Termination at Will or for Technical Failure)**, then Vertex shall reasonably cooperate with Alios in order to enable Alios to promptly assume the Development and/or Commercialization of all Licensed Compounds and Licensed Products then being Commercialized or in Development by Vertex in the Territory. Such cooperation and assistance shall be provided in a timely manner (having regard to the nature of the cooperation or assistance requested) and shall include the following at no cost to Alios:

(a) All filings with Regulatory Authorities concerning Licensed Products shall be assigned or otherwise transferred to Alios as soon as practicable and at Vertex's expense, and any reports required to be made to any Regulatory Authority covering any periods prior to the effective date of termination of this Agreement shall be prepared promptly and filed at Alios direction with the appropriate Regulatory Authority or, at Alios' discretion, made available to Alios for filing by Alios. Vertex shall also promptly deliver to Alios all relevant data and information, and shall cooperate with Alios in notifying the FDA, clinical investigators, and other Third Parties involved in the Development of such Licensed Compounds and Licensed Products that such Development is now being carried out by Alios or an Affiliate or Third Party designated by Alios with the consent of Vertex. Vertex shall and hereby does grant to Alios, effective upon the date of termination, a right of reference to any and all filings with Regulatory Authorities controlled by Vertex with respect to Licensed Compounds and Licensed Products. Within [\*\*\*] of the effective date of any such termination, Vertex shall transfer to Alios (or its nominee), to the extent not previously provided, a copy of all data (including all raw data, data and database structures, and all reports containing, summarizing, or analyzing such data); information, documents, reports, and studies in its possession or control relating to any Licensed Compounds and Licensed Products then being Commercialized or in Clinical Trials sponsored by Vertex and reasonably necessary or useful for continued Development and/or Commercialization of a Licensed Compound or Licensed Product, including all information contained in Vertex's regulatory and/or safety databases, all in the format then currently maintained by Vertex. Notwithstanding **ARTICLE 10 (Confidentiality)**, Alios shall be permitted to disclose any such data and information as is necessary and appropriate to exercise its rights of Development and Commercialization (including usual and customary publication activities);

(b) Alios shall be solely responsible for obtaining an approved (by Regulatory Authorities, as required), alternate source of supply for Licensed Products as soon as reasonable practicable, *provided* that, with respect to each Licensed Product that is under Development or Commercialization at the date of delivery by Vertex of notice of termination under **Section 13.2 (Termination at Will [\*\*\*])** or by Alios of notice of termination under **Section 13.3 (Termination for Cause)**, **Section 13.4 (Termination for Insolvency)**, **Section 13.6 (Termination for Inactivity)**, or **Section 13.7 (Termination for Patent Challenge)**, (the "Termination Notice Date"), and for a period ending at the earlier of [\*\*\*] following the

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

53

---

Termination Notice Date or the date upon which Alios has established an approved source of supply, Vertex shall supply Alios with all of Alios' requirements for commercial supplies for Licensed Products [\*\*\*], under which each Licensed Product shall be supplied for commercial use in the Territory at Vertex's

fully burdened cost (including cost of variances) of Manufacturing the Licensed Product plus a [\*\*\*], to the then current specifications, and in accordance with Vertex's then-existing quality and compliance standards; and

(c) For a period of time to be agreed upon by the Parties [\*\*\*], Vertex shall assist Alios as reasonably requested in [\*\*\*]. Notwithstanding the above, if Vertex has terminated this Agreement prior to the completion of a Phase 2b Clinical Trial, then the transfer activities regarding Manufacture and testing of such Licensed Product shall be limited to the transfer of documents and shipment of Licensed Product, including reference materials and stability samples, at no cost to Alios.

**13.9.3 Post Termination Technology Transfer.** If Vertex terminates this Agreement under **Section 13.3 (Termination for Cause)**, **Section 13.4 (Termination for Insolvency)** or **Section 13.7 (Termination for Patent Challenge)**, then Alios shall reasonably cooperate with Vertex in order to enable Vertex to promptly assume the Development and/or Commercialization of all Licensed Compounds and Licensed Products then being Commercialized or in Development in the Territory. Such cooperation and assistance shall be provided in a timely manner (having regard to the nature of the cooperation or assistance requested) and shall include the following at no cost to Vertex:

(a) All INDs concerning Licensed Products shall be assigned or otherwise transferred to Vertex as soon as practicable and [\*\*\*], and any reports required to be made to any Regulatory Authority covering any periods prior to the effective date of termination of this Agreement shall be prepared promptly and filed at Vertex's direction with the appropriate Regulatory Authority or, at Vertex's discretion, made available to Vertex for filing by Vertex. Alios shall also promptly deliver to Vertex all relevant data and information, and shall cooperate with Vertex in notifying the FDA, clinical investigators, and other Third Parties involved in the Development of such Licensed Compounds and Licensed Products that such Development is now being carried out by Vertex or an Affiliate or Third Party designated by Vertex with the consent of Alios. Alios shall and hereby does grant to Vertex, effective upon the date of termination, a right of reference to any and all filings with Regulatory Authorities controlled by Alios with respect to Licensed Compounds and Licensed Products. Within [\*\*\*] of the effective date of any such termination, Alios shall transfer to Vertex (or its nominee), to the extent not previously provided, a copy of all data (including all raw data, data and database structures, and all reports containing, summarizing, or analyzing such data), information, documents, reports, and studies in its possession or control relating to any Licensed Compounds and Licensed Products then being Commercialized or in Clinical Trials sponsored by Alios and reasonably necessary or useful for continued Development and/or Commercialization of a Licensed Compound or Licensed Product, including all information contained in Alios' regulatory and/or safety databases, all in the format then currently maintained by Alios. Notwithstanding **ARTICLE 10 (Confidentiality)**, Vertex shall be permitted to disclose any such data and information as is necessary and appropriate to exercise its

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

54

---

rights of Development and Commercialization (including usual and customary publication activities);

(b) Alios shall assist Vertex as reasonably requested in (i) causing the assignment to Vertex of any and all applicable Third Party Manufacturing and supply agreements for such Licensed Product to the extent possible and providing any existing supplies of Licensed Product at Alios' fully burdened cost (including cost of variances) of Manufacturing the Licensed Product [\*\*\*], and/or (ii) transferring the Manufacturing process for such Licensed Product to Vertex or a Third Party contract manufacturer engaged by Vertex, which transfer shall be limited to the transfer of documents and shipment of Licensed Product, including reference materials and stability samples at no cost to Vertex.

**13.10 Accrued Rights.** Termination or expiration of this Agreement for any reason shall be without prejudice to any right that shall have accrued to the benefit of either Party prior to such termination or expiration, including damages arising from any breach under this Agreement. Such termination or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

**13.11 Survival.** The following articles and sections of this Agreement shall survive expiration of this Agreement pursuant to **Section 13.1.1 (Expiration)** or termination of this Agreement for any reason: **ARTICLES 1 (Definitions); 7 (Financial Terms)** to the extent that payments due thereunder remain unpaid, including any payments due by Vertex after termination of this Agreement by Vertex pursuant to **Section 13.3 (Termination for Cause)** or **Section 13.4 (Termination for Insolvency); 10 (Confidentiality); 11 (Representations, Warranties and Covenants); 12 (Indemnification, Insurance, Limitation of Liability); 14 (Governing Law and Dispute Resolution); and 15 (General Provisions); and Sections 8.1.4 (No Other Rights and Retained Rights); 9.1 (Ownership of Intellectual Property); 9.2 (Prosecution and Maintenance of Patent Rights); 9.3 (Prosecution and Maintenance of Joint Patents; Abandonment); 9.9 (Approval Applications and Regulatory Approvals); 13.8 (Rights on Termination); 13.9 (Licensed Product and Compound Reversion and Commercial Development by Alios); 13.10 (Accrued Rights); and 13.11 (Survival).**

## ARTICLE 14 GOVERNING LAW AND DISPUTE RESOLUTION

**14.1 Governing Law.** This Agreement shall be governed by and construed under the laws of the State of New York, without giving effect to the conflicts of law principles thereof that would result in the application of the laws of any other jurisdiction.

**14.2 Referral to Responsible Executives.** If for any reason the JSC cannot resolve any matter properly referred to it for resolution, either Party may refer the matter to the Responsible Executives (as defined below) for resolution. If, after discussing the matter in good faith and attempting to find a mutually satisfactory resolution to the issue, the Responsible Executives fail to come to consensus [\*\*\*] after the date on which the matter is referred to the Responsible Executives

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

55

---

(unless a longer period is agreed to in writing by the Parties), Vertex shall have final decision-making authority over such matter.

### 14.3 Dispute Resolution.

**14.3.1** The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties are unable to resolve a dispute (other than matters within the jurisdiction of the JSC, which shall be resolved pursuant to **ARTICLE 2 (Overview and Management of the Collaboration)** and **Section 14.2 (Referral to Responsible Executives)**), or if a Party reasonably challenges an assertion of breach by the other Party or an assertion by the other Party that a particular breach has not been cured under **Section 13.3.2 (Disagreement as to Material Breach, Tolling of Cure Period)**, either Vertex or Alios, by written notice to the other, may have such dispute referred to their respective executive officers designated for attempted resolution by good faith negotiations (each, a “**Responsible Executive**”).

**For Vertex:** Chief Scientific Officer or such other member of Vertex’s executive team as is designated by Vertex

**For Alios:** Chief Executive Officer of Alios

Any such dispute shall be submitted to the Responsible Executives, or their designees, [\*\*\*] following such request by either the JSC or Vertex or Alios. In the event the Responsible Executives are not able to resolve any such dispute [\*\*\*] after submission of the dispute to such Responsible Executives, (i) either Party may submit such dispute to binding Arbitration under **Section 14.3.2 (Arbitration)** or (ii) if both Parties consent with respect to such dispute, to binding Arbitration under **Section 14.3.3 (Accelerated Arbitration)**. All negotiations pursuant to this **Section 14.3 (Dispute Resolution)** shall be treated as compromise and settlement negotiations. Nothing said or disclosed, nor any document produced, in the course of such negotiations which is not otherwise independently discoverable shall be offered or received as evidence or used for impeachment or for any other purpose in any current or future mediation, arbitration, or litigation.

### 14.3.2 Arbitration.

(a) Any dispute, controversy or claim not resolved by the Responsible Executives under this **Section 14.3 (Dispute Resolution)** and not mutually chosen by the Parties for accelerated arbitration under **Section 14.3.3 (Accelerated Arbitration)** and arising from or related in any way to this Agreement (other than matters within the jurisdiction of the JSC, which shall be resolved pursuant to **ARTICLE 2 (Overview and Management of the Collaboration)** and **Section 14.2 (Referral to Responsible Executives)**) or the interpretation, application, breach, termination or validity of any term or provision of this Agreement, including any claim of inducement of this Agreement by fraud or otherwise will be submitted for resolution to binding arbitration pursuant to the rules then pertaining of the CPR Institute for Dispute Resolution (“**CPR**”), or successor, except where those rules conflict with these provisions, in which case these provisions control. The arbitration if initiated by Vertex will be held in San Francisco, California,

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

United States of America and if initiated by Alios will be held in Boston, Massachusetts, United States of America.

(b) The arbitration panel shall consist of [\*\*\*] chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators). Unless otherwise agreed by the Parties, each of the arbitrators will be (i) a lawyer [\*\*\*], and the Parties will select arbitrators with substantial experience in or with the pharmaceutical and/or biotechnology industries. In the event the aggregate damages sought by the claimant Party are stated to be [\*\*\*], and the aggregate damages sought by the counterclaimant Party are stated to be [\*\*\*], and neither side seeks equitable relief, then a [\*\*\*] shall be chosen, having the same qualifications and experience specified above. Each arbitrator shall be neutral, independent, disinterested, impartial and shall abide by The CPR-Georgetown Commission Proposed Model Rule for the Lawyer as Neutral available at <http://www.cpradr.org/Resources/ALLCPRArticles/tabid/265/ArticleType/ArticleView/ArticleID/622/Default.aspx>.

(c) The Parties agree to cooperate (i) to attempt to select the arbitrator(s) by agreement [\*\*\*] of initiation of the arbitration, including jointly interviewing the final candidates, (ii) to meet with the arbitrators [\*\*\*] of selection, and (iii) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than [\*\*\*] after selection of the arbitrators and in the award being rendered [\*\*\*] of the conclusion of the hearings, or of any post-hearing briefing, which briefing will be completed by both sides [\*\*\*] after the conclusion of the hearings.

(d) In the event the Parties cannot agree upon selection of any arbitrators, the CPR will select arbitrators as follows: CPR shall provide the Parties with a list of no less than [\*\*\*] proposed arbitrators [\*\*\*] is to be selected) having the credentials referenced above. Within [\*\*\*] of receiving such list, the Parties shall rank at least [\*\*\*] of the proposed arbitrators on the initial CPR list, after exercising cause challenges. The Parties may then interview the [\*\*\*] candidates ([\*\*\*] if a [\*\*\*] is to be selected) with the highest combined rankings for no more than one [\*\*\*] and, following the interviews, may exercise [\*\*\*] each. The panel will consist of the remaining [\*\*\*] (or [\*\*\*] is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, CPR shall select the appropriate number of arbitrators from among the members of the various CPR Panels of Distinguished Neutrals, allowing each side unlimited [\*\*\*] peremptory challenges each.

(e) In the event the Parties cannot agree upon procedures for discovery and conduct of the hearing meeting the schedule set forth in **Section 14.3.2(c)**, then the arbitrators shall set dates for the hearing, any post-hearing briefing, and the issuance of the award in accord with the schedule set forth in **Section 14.3.2(c)**. The arbitrators shall provide for discovery according to those time limits, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including document demands and depositions, but such discovery will be limited so that the **Section 14.3.2(c)** schedule may be met without difficulty. In no event will the arbitrators, absent agreement of the Parties, allow more than a total of [\*\*\*] for the hearing or permit either side to obtain more than a total of [\*\*\*] of deposition testimony from all witnesses, including both fact and expert witnesses, or serve more than [\*\*\*] individual requests for

documents, including subparts, or [\*\*\*] individual requests for admission or interrogatories, including subparts. Multiple hearing days will be scheduled consecutively to the greatest extent possible.

(f) The arbitrators must render their award by application of the substantive law of the State of New York, except regarding any patent disputes or other such issues where state law is preempted by federal law, in which event United States federal law shall apply, and are not free to apply "amiable compositeur" or "natural justice and equity." The arbitrators shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made by the arbitration panel and shall, upon request, be made available to either Party. The arbitrators shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained in confidence.

(g) In the event the panel's award exceeds [\*\*\*] in monetary damages or includes or consists of equitable relief, or rejects a claim in excess of that amount or for that relief, then the losing Party may obtain review of the arbitrators' award or decision by a single appellate arbitrator (the "**Appeal Arbitrator**") selected from the CPR Panels of Distinguished Neutrals by agreement or, failing agreement within [\*\*\*], pursuant to the selection procedures specified in **Section 14.3.2(d)**. If CPR cannot provide such services, the Parties will together select another provider of arbitration services that can provide such services. No Appeal Arbitrator shall be selected unless such Appeal Arbitrator can commit to rendering a decision [\*\*\*] following oral argument as provided in **Section 14.3.2(h)**. Any such review must be initiated [\*\*\*] following the rendering of the award referenced in **Section 14.3.2(f)**.

(h) The Appeal Arbitrator will make the same review of the arbitration panel's ruling and its basis that the United States Court of Appeals in which the arbitration hearings are held would make of findings of fact and conclusions of law rendered by a district court after a bench trial and then modify, vacate or affirm the arbitration panel's award or decision accordingly, or remand to the panel for further proceedings. The Appeal Arbitrator will consider only the arbitration panel's findings of fact and conclusions of law, pertinent portions of the hearing transcript and evidentiary record as submitted by the Parties, opening and reply briefs of the Party pursuing the review, and the answering brief of the opposing Party, plus a total of no more than [\*\*\*] of oral argument evenly divided between the Parties. The Party seeking review must submit its opening brief and any reply brief within [\*\*\*] and [\*\*\*], respectively, following the date of the award under review, whereas the opposing Party must submit its responsive brief within [\*\*\*] of such date. Oral argument shall take place within [\*\*\*] after the date of the award under review, and the Appeal Arbitrator shall render a decision [\*\*\*] following oral argument.

#### **14.3.3 Accelerated Arbitration**

(a) Any dispute, controversy or claim not resolved by the Responsible Executives under this **Section 14.3 (Dispute Resolution)** that the Parties mutually agree to settle under this **Section 14.3.3 (Accelerated Arbitration)** will be submitted for resolution to binding accelerated arbitration in accordance with the International Institute for CPR Global Rules for

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

Accelerated Commercial Arbitration (the "**Accelerated Rules**"), in effect on the date the arbitration is commenced. The accelerated arbitration if initiated by Vertex will be held in San Francisco, California, United States of America and initiated by Alios will be held in Boston, Massachusetts, United States of America.

(b) The arbitration panel shall consist of [\*\*\*] arbitrators chosen from the CPR Panels of Distinguished Neutrals (or, by agreement, from another provider of arbitrators). Unless otherwise agreed by the Parties, each of the arbitrators will be (i) [\*\*\*], and the Parties will select arbitrators with substantial experience in or with the pharmaceutical and/or biotechnology industries. In the event the aggregate damages sought by the claimant Party are stated to be [\*\*\*], and the aggregate damages sought by the counterclaimant Party are stated to be [\*\*\*], and neither side seeks equitable relief, then [\*\*\*] shall be chosen, having the same qualifications and experience specified above.

(c) In order to ensure the expedited resolution of any disputes submitted for accelerated arbitration (i) the Parties shall select the arbitrators by agreement [\*\*\*] of initiation of the arbitration, (ii) the party initiating the arbitration shall submit the statement of claim [\*\*\*] after selection of the arbitrators, (iii) the respondent shall submit the statement of defense (including any counterclaims) [\*\*\*] of submission of the statement of claim, (iv) the Parties and the arbitrators shall conduct the hearing within no more than [\*\*\*] after selection of the arbitrators, and (v) the arbitrators shall render an award or decision in writing within seventy-five (75) days of the initiation of the accelerated arbitration.

(d) If the Parties cannot agree as to the choice of arbitrators by the deadlines, then the CPR may select such arbitrator(s) [\*\*\*] of the deadline for the Parties to select such arbitrators, subject to the requirements as to the background and training of such arbitrators set forth in **Section 14.3.3(b)**. Each Party may challenge [\*\*\*] for cause, *provided* such challenge is submitted to CPR [\*\*\*] of CPR's selection of such arbitrator. The CPR will then select a [\*\*\*].

(e) The arbitrators shall determine the manner and scope of discovery necessary, taking into account the above timelines, to resolve the dispute, including (i) the production and exchange of documents and evidence, and (ii) disclosure of witnesses and exchange of witness statements. The arbitrators will have the discretion to deny any request for production of documents or addition of witnesses by one Party if such request or addition will delay the above timelines, unless the other Party stipulates to any such delay.

(f) The arbitrators must render their award by application of the substantive law of the State of New York, except regarding any patent disputes or other such issues where state law is preempted by federal law, in which event United States federal law shall apply, and are not free to apply “amiable compositeur” or “natural justice and equity.” The arbitrators shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. A transcript of the evidence adduced at the hearing shall be made by the arbitration panel and shall, upon request, be made available to either Party. The arbitrators shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of such ruling on evidence. To the extent possible, the arbitration hearings and award will be maintained in confidence.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

59

---

**14.3.4 Jurisdiction and Initial Entry of Judgment.** The Parties consent to the jurisdiction of the State or Federal District Court in which an arbitration is held under **Section 14.3.2 (Arbitration)** or **Section 14.3.3 (Accelerated Arbitration)**, for the enforcement of these provisions and the entry of judgment on any award rendered hereunder (including after review by the Appeal Arbitrator where such an appeal is pursued). Should such court for any reason lack jurisdiction, any court with jurisdiction shall act in the same fashion.

**14.3.5 Decisions and Awards and Additional Entry of Judgment.** All decisions or awards by the arbitrators under **Section 14.3.2 (Arbitration)** **Section 14.3.3 (Accelerated Arbitration)** (and any decision by the Appeal Arbitrator where a decision or award by the arbitrators may be appealed pursuant to **Section 14.3.2(g)**) will be final, binding, incontestable, and not subject to further review, except pursuant to the Federal Arbitration Act, and may be used as a basis for judgment thereon and may be entered in any court in any jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Subject to and to the extent permitted by Applicable Laws, including the Federal Arbitration Act, and except as permitted above pursuant to **Section 14.3.2(g)**, the Parties hereby expressly agree to waive the right to appeal from the decision of the arbitrators and the Appeal Arbitrator, there shall be no appeal to any court or other authority (government or private) from the decision of the arbitrators or Appeal Arbitrator, and the Parties shall not dispute nor question the validity of such decision or award before any regulatory or other authority in any jurisdiction where enforcement action is taken by the Party in whose favor the decision or award is rendered, except in the case of fraud.

**14.3.6 Costs and Attorney’s Fees.** Each Party shall bear its own costs and attorney’s fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrators and Appeal Arbitrator and the arbitration, and appeal proceedings; *provided, however*, that the arbitrators may exercise discretion to award costs, including attorney’s fees, to the prevailing Party where such arbitrators have held that the losing Party acted in bad faith, or committed intentional misconduct, or fraud. For the avoidance of doubt, if either Party unreasonably or intentionally delays, fails to respond or otherwise fails to act, or otherwise interferes with the dispute resolution processes set forth in this **Section 14.3 (Dispute Resolution)**, and any such delay or failure was not caused by a delay or failure of the other Party, then the arbitrators shall take such delay or failure or actions or inactions by such Party into account when determining whether such party acted in bad faith and may award such costs, including attorney’s fees, on that basis, and including (a) determining that such costs shall not be granted to the prevailing Party due to such bad faith by such Party, (b) awarding such costs to the prevailing Party solely on that basis, or (c) any other action such arbitrators deem appropriate under the circumstances as to an award of such costs.

**14.3.7 Trial By Jury.** EACH PARTY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

**14.3.8 Preliminary Injunctions.** Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any dispute.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

60

---

**14.3.9 Patent Disputes.** Notwithstanding anything this Agreement to the contrary, any and all issues regarding the scope, construction, validity and enforceability of one or more Patent Rights of a Party or Joint Patents or any other patent shall be determined in a court of competent jurisdiction under the local patent laws of the jurisdictions having issued the patent or patents in question.

**14.3.10 Confidentiality.** All proceedings and decisions of the arbitrator(s) shall be deemed Confidential Information of each of the Parties, and shall subject to **ARTICLE 10 (Confidentiality)**.

## ARTICLE 15 GENERAL PROVISIONS

### 15.1 Assignment, Binding Agreement.

**15.1.1 Assignment.** Neither Party may assign or otherwise transfer its rights or obligations under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, except that a Party may assign or otherwise transfer its rights or obligations in whole or in part without such consent (a) to an Affiliate of such Party, *provided* that no such assignment shall relieve any Party as the primary obligor hereunder, or (b) to a Third Party that merges with, consolidates with, or acquires substantially all of the assets or voting control of the assigning Party. In the case of a permitted assignee in accordance with this **Section 15.1.1 (Assignment)**, such assignee will be entitled to all of the benefits hereunder, including, for example, any covenant not to sue. Any assignment in violation of this **Section 15.1.1 (Assignment)** shall be null and void. Notwithstanding anything to the contrary in this Agreement, in the event of any assignment of this Agreement, the licenses granted herein shall not include a license of any intellectual property rights of the assignee that were not subject to this Agreement immediately prior to such assignment. [\*\*\*].

**15.1.2 Binding Agreement.** This Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

**15.2 Force Majeure.** Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action (including any clinical hold), war (whether war be declared or not), insurrections, riots, terrorism, fire, explosion, flood, tornadoes, earthquake, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, *provided* that the Party claiming force majeure shall promptly notify the other Party in writing setting forth the nature of such force majeure, shall use its reasonable efforts to eliminate, remedy or overcome such force majeure and shall resume performance of its obligations hereunder as soon as reasonably practicable after such force majeure ceases. Except as provided in the previous sentence, if any force majeure continues due to any negligent or willful act of a Party for more than [\*\*\*], such force majeure shall cease to be force majeure for the purposes of this Agreement. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of a force majeure event affecting such Party.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

61

**15.3 Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**15.4 Governmental Approvals; Compliance with Law.** The Parties shall make all filings with Government Authorities as shall be required by Applicable Laws in connection with this Agreement and the activities contemplated by this Agreement. In fulfilling its obligations under this Agreement each Party agrees to comply in all material respects with all Applicable Laws.

**15.5 Notices.** All notices required or permitted to be given under this Agreement, including all invoices provided by Alios to Vertex, shall be in writing and shall be deemed given if delivered personally or by facsimile transmission receipt verified, mailed by registered or certified mail return receipt requested, postage prepaid, or sent by express courier service, to the other Party at the following addresses, or at such other address for a Party as shall be specified by like notice, *provided* that notices of a change of address shall be effective only upon receipt thereof.

**If to Alios, addressed to:**

**Alios BioPharma, Inc.**  
260 East Grand Avenue, 2nd Floor  
South San Francisco, California 94080  
United States of America  
Attention: Lawrence Blatt, CEO  
Telephone: (650) 635-5501  
Facsimile: (650) 872-0584

**With a copy, except  
for invoices, (which alone  
will not constitute notice) to:**

**Latham & Watkins LLP**  
12636 High Bluff Drive  
San Diego, California 92130  
United States of America  
Attention: John E. Wehrli, Esq.  
Telephone: (858) 523-3937  
Facsimile: (858) 523-5450

**If to Vertex addressed to:**

**Vertex Pharmaceuticals Incorporated**  
130 Waverly Street  
Cambridge, Massachusetts 02139  
Attn: Office of Business Development  
Telephone: (617) 444-6100  
Facsimile: (617) 444-6632

**And:**

Attn: Office of the General Counsel  
Facsimile: (617) 444-7117

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

62

The date of receipt of any notice given under this Agreement, including any invoice provided by Alios to Vertex, shall be deemed to be (a) the date given if delivered personally or by facsimile transmission receipt verified; (b) [\*\*\*] after the date mailed if mailed by registered or certified mail return receipt requested, postage prepaid; and (c) [\*\*\*] after the date sent if sent by express courier service. Notices hereunder will not be deemed sufficient if provided only between or among each Party's representatives at addresses other than as set forth above.

**15.6 Waiver.** No failure of either Party to exercise and no delay in exercising any right, power or remedy in connection with this Agreement (each a "Right") will operate as a waiver thereof, nor will any single or partial exercise of any Right preclude any other or further exercise of such Right or the exercise of any other Right.

**15.7 Disclaimer of Agency.** The relationship between Alios and Vertex established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (a) give either Party the power to direct or control the day-to-day activities of the other; (b) constitute either Party as the legal representative or agent of the other Party or the Parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking; or (c) allow either Party to create or assume any liability or obligation of any kind, express or implied, against or in the name of or on behalf of the other Party for any purpose whatsoever, except as expressly set forth in this Agreement.

## **15.8 Interpretation.**

**15.8.1** Wherever used, the word “shall” is understood to mean “has a duty to” when used after the name of a Party or Person, and both the word “shall” and the word “will” are each understood to be imperative or mandatory in nature and are otherwise interchangeable with one another.

**15.8.2** Wherever used, the word “may” is understood to be permissive and discretionary in nature.

**15.8.3** Wherever used, the word “can” is understood to indicate a Party’s or Person’s ability to perform as indicated.

**15.8.4** Whenever any provision of this Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” and “including, but not limited to” (or “includes without limitations” and “includes, but is not limited to”) regardless of whether the words “without limitation” or “but not limited to” actually follow the term “including” (or “includes”);

**15.8.5** “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used;

**15.8.6** All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural;

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

63

---

**15.8.7** Where used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders;

**15.8.8** The recitals set forth at the start of this Agreement, along with the Exhibits and Schedules to this Agreement, and the terms and conditions incorporated in such recitals and Exhibits and Schedules, are integral parts of this Agreement and all references in this Agreement shall embrace them all. If there is any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals or Exhibits and Schedules, then the terms of this Agreement will control;

**15.8.9** If there is any conflict between the terms and conditions of this Agreement and any terms and conditions that are set forth on any order, invoice, verbal agreement or otherwise, then the terms and conditions of this Agreement will govern;

**15.8.10** This Agreement will be construed as if both Parties drafted it jointly, and will not be construed against either Party as principal drafter;

**15.8.11** The Article and Section headings and references contained herein are for the purpose of convenience only and are not intended to define or limit the contents of said Articles or Sections, except that any conflict between a Section reference number and any textual reference to the Section title noted next to such reference, will be resolved in favor of the textual reference. Unless otherwise provided, all references in this Agreement to Sections, Articles, Exhibits, and Schedules are references to Sections, Articles, Exhibits, and Schedules of this Agreement; and

**15.8.12** Any reference to any federal, national, state, local or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise.

**15.9 Severability.** If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable by a court or administrative agency of competent jurisdiction, then (a) the remainder of this Agreement, and the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law; and (b) the Parties covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

**15.10 Entire Agreement.** This Agreement, including all Schedules and Exhibits attached hereto, which are hereby incorporated herein by reference, sets forth all covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties and supersedes and terminates all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as set forth herein. For clarity,

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

64

---



the following agreements shall not be superseded and shall remain in full force and effect in accordance with their terms: (a) the Confidential Disclosure Agreement among Alios, Vertex, Lisa Dixon, and Joon Chung dated June 11, 2011, (b) the Confidential Disclosure Agreement among Alios, Vertex, and Mark Namchuk dated May 19, 2011, and (c) the Confidential Disclosure Agreement among Alios, Vertex, Patricia Hurter and Daniel Belmont dated May 19, 2011.

**15.11 Amendment.** No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

**15.12 Counterparts; Electronic Delivery.** This Agreement may be executed in one (1) or more counterparts, by original, facsimile or PDF signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

(Remainder of page intentionally left blank)

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

65

---

(Page intentionally left blank)

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

66

---

(Page intentionally left blank)

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

67

---

In Witness Whereof, the Parties have executed this Agreement by their proper officers as of the Execution Date.

**Alios BioPharma, Inc.**

By: /s/ Lawrence Blatt  
Name: Lawrence Blatt  
Title: CEO

**Vertex Pharmaceuticals Incorporated**

By: /s/ Matthew Emmens  
Name: Matthew Emmens  
Title: Chairman and CEO

**Vertex Pharmaceuticals  
(Switzerland) LLC**

By: /s/ Matthew Emmens  
Name: Matthew Emmens  
Title: Manager

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

68

---

**Exhibit A**

**Research Plan**

The Research Program will be dedicated to the discovery of anti-HCV nucleosides and nucleotides for the treatment of chronic hepatitis C. [\*\*\*] Capitalized terms used in this Research Plan shall have the meanings ascribed to such terms in the License and Collaboration Agreement, dated June 13, 2011, between Alios BioPharma, Inc., Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Switzerland) LLC (the "Agreement").

**Goals**

The principle objectives of the Research Program will be to identify:

[\*\*\*]

[\*\*\*]

**Target Criteria**

Target criteria for the identification of [\*\*\*]:

[\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

Both Parties agree to produce a more detailed research target profile, which will more thoroughly define the target criteria for potential Back-Up Compounds and Follow-on Compounds. This more thoroughly defined target profile will be completed within [\*\*\*] after the Effective Date.

The Research Program will be structured to allow collaboration between Vertex and Alios. Alios will provide [\*\*\*] updates regarding the progress of the Research Program, but it is not expected that Alios will provide detailed information regarding [\*\*\*] except as described below.

Compounds identified as candidates (compounds meeting the research target profile) will be presented to Vertex for potential selection for potential development. Alios will present to Vertex all data pertaining to such compounds [\*\*\*]. [\*\*\*] the evaluation of the potential Back-up Compound and/or Follow-on Compound.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**Resources**

[\*\*\*]. Vertex will support [\*\*\*].

[\*\*\*]. For example, if [\*\*\*] it would need to [\*\*\*].

Vertex agrees to [\*\*\*] of the Agreement. Any decision by [\*\*\*].

**Minimum Requirements**

This Research Plan cannot be amended without the consent of both Parties.

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**VERTEX PHARMACEUTICALS INCORPORATED**

**Exhibit B**

**Development Plan**

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

HCV Treatment Regimen Development Plan for both ALS-2200 and ALS-2158

Vertex Pharmaceuticals Incorporated  
130 Waverly Street  
Cambridge, Massachusetts 02139-4242

**CONFIDENTIAL & PROPRIETARY**

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

**Table of Contents**

<b>1</b>	<b>Preface</b>	<b>4</b>
<b>2</b>	<b>Definitions and Abbreviations</b>	<b>5</b>
<b>3</b>	<b>Executive Summary</b>	<b>6</b>
<b>4</b>	<b>Development Plan</b>	<b>7</b>
	4.1 Program Plan	7
<b>5</b>	<b>Commercial Development</b>	<b>8</b>
	5.1 Medical Need and Market Opportunity	8
	5.2 Target Product Profile	8
<b>6</b>	<b>Preclinical program</b>	<b>10</b>
<b>7</b>	<b>Clinical Development</b>	<b>11</b>
	7.1 Phase 1 program	11
	7.1.1 Phase 1 SAD Study	11
	7.1.2 Phase 1 VK Study	11
	7.1.3 DDI (Drug-Drug Interaction) Study	11
	7.1.4 Conduct of the Phase 1 Study	11
	7.2 Phase 2a Program	11
	7.2.1 Phase 2a Program [***]	12
	7.3 Phase 2b Program	12
	7.4 Phase 3 Program	12
	7.5 [***]	12
	7.6 [***]	12
<b>8</b>	<b>Non-Clinical Development</b>	<b>13</b>
	8.1 Non-Clinical Plan Overview	13
<b>9</b>	<b>CMC</b>	<b>14</b>
	9.1 Product Development Plan Overview	14

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

**1 Preface**

The Development Plan will be regularly reviewed and revised by the Joint Steering Committee (“JSC”) under the Parties’ License and Collaboration Agreement dated June 13, 2011 (the “Agreement”), [\*\*\*]. No major revisions shall be made to the Development Plan without review and authorization by the JSC as described in Article 2 of the Agreement.

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit*

## 2 Definitions and Abbreviations

CMC	Chemistry, Manufacturing and Controls
DAA	Direct Acting Antiviral
DDI	Drug-Drug Interaction
HCV	Chronic Hepatitis C
PegIFN	Pegylated Interferon alfa-2a/b (Pegasys™, PegIntron™)
PI	Protease Inhibitor
QD	Once-Daily
RBV	Ribavirin (Copegus™, Rebetron™)
SOC	Standard of Care
SVR	Sustained Viral Response
TBD	To Be Determined
SAD	Single Ascending Dose
MAD	Multiple Ascending Dose
HV	Healthy Volunteers
VK	Viral Kinetics

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## 3 Executive Summary

### OPPORTUNITY

<b>Guiding Principle</b>	[***]
<b>Project Objectives</b>	[***]
<b>Product Positioning</b>	[***]
<b>Target Indication (initial)</b>	For the treatment of adults with chronic hepatitis C, with compensated liver disease, who are previously untreated or have failed any previous treatment regimens
<b>Target Patient Population (initial)</b>	Adult chronic hepatitis C patients
<b>Additional Potential Indications</b>	<ol style="list-style-type: none"> <li>1) HCV/HIV co-infected patients</li> <li>2) Decompensated liver disease/pre-liver transplant</li> <li>3) Post liver transplant</li> <li>4) Pediatrics</li> <li>5) [***]</li> </ol>

### DRUG CANDIDATE

<b>Mechanism of Action</b>	[***]
<b>TARGET PRODUCT PROFILE (initial)*</b>	
<b>Efficacy</b>	[***]
<b>Safety</b>	[***]
<b>Ease of Use</b>	[***]
<b>Treatment Regimen</b>	Best regimen for chronic hepatitis C patients consisting of [***]
<b>[***] Clinical Studies supporting Initial Registration</b>	<ul style="list-style-type: none"> <li>· Phase 1 study in both healthy volunteers and in HCV-infected patients</li> <li>· Clinical DDI studies in healthy volunteers supporting anticipated Phase 2a combination regimens</li> <li>· Dose ranging study of several dose levels of ALS-2158 and ALS-2200, [***]</li> <li>· Broad Phase 2a study [***]</li> <li>· Subsequent Phase 2b and 3 trials [***]</li> </ul>

[\*\*\*]

[\*\*\*]

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## 4 Development Plan

The primary objective of the Development Plan is to achieve registration of [\*\*\*] consisting of ALS-2200 and/or ALS-2158 with or without INCIVEK and with or without VX-222 (based on clinical data), [\*\*\*].

[\*\*\*]

#### 4.1 Program Plan

The program plan below illustrates the current plan for all of the anticipated efficacy studies expected to be conducted in order to support the primary registration [\*\*\*] in treatment naïve and treatment experienced patients.

[\*\*\*]

[\*\*\*]

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

### 5 Commercial Development

#### 5.1 Medical Need and Market Opportunity

Infection with the hepatitis C virus is a major cause of chronic liver disease, affecting approximately 170 million people worldwide.

In general, the chronic phase of the disease is indolent and progresses slowly over the course of 30 to 40 years to cirrhosis and hepatic failure. In the United States, HCV-related chronic liver disease causes approximately 10,000 deaths per year and is expected to grow substantially over the next decade. HCV is the primary reason for liver transplantation(1) and correlates strongly with the development of hepatocellular carcinoma, particularly in individuals with advanced liver disease.

The previous SOC for patients chronically infected with genotype 1 HCV was 48 weeks of treatment with PegIFN in combination with RBV. However with the recent approval of two PIs, that SOC has changed to PegIFN+RBV+PI. SVRs with the PI-containing regimens are approximately 80% for genotype 1 treatment naïve patients, with about 60% of patients receiving only 24 weeks of treatment, and 30 — 90% for genotype 1 treatment experienced patients (Null Responders, Partial Responders, and Relapsers). The combination of PegIFN + RBV (dosed for only 24 weeks) is used to treat genotypes 2 and 3. SVRs with this dosing regimen are ~75% for genotype 2 and 3 patients. The recent approval of the PIs represents a major advancement in the treatment of HCV[\*\*\*].

#### 5.2 Target Product Profile

The current clinical development plan is to obtain approval for an all-oral regimen containing ALS-2200 and/or ALS-2158 to be dosed in combination with or without INCIVEK and with or without VX-222 [\*\*\*]. The Target Product Profile is shown below in Table 5.2a:

(1) Charlton M. Natural history of hepatitis C and outcomes following liver transplantation. Clin Liver Dis. 7(3):585-602, 2003

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

Table 5.2a

Target Product Profile for a regimen containing ALS-2200 and/or ALS-2158

Indication	For the treatment of chronic hepatitis C treatment naïve and treatment experienced patients with or without INCIVEK and with or without VX-222
Efficacy	[***]
Duration of Therapy	[***]
Safety, Tolerability, & Ease of Use	[***]
Contra-indications	[***]
Reproduction	[***]
Dosing	[***]

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

## 6 Preclinical program

The goal of the preclinical program will include the following:

- CMC activities to secure needed API
- Toxicology activities to enable Phase 1 studies
- Formulation activities to develop an oral dosage form (PIB)
- Complete study reports to enable regulatory submission
- Generation of Investigator's Brochures
- Regulatory filing for first in human studies
- Preparation of both compounds for studies beyond Phase 1
- CMC activities to secure needed API
- Formulation activities to develop an oral dosage form (non-PIB)
- Complete chronic toxicology studies

[\*\*\*]

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

10

## 7 Clinical Development

The overall goal of the Development Plan is to develop an all-oral regimen with SVR rates comparable to or better than the then current SOC along with better tolerability and/or convenience for patients than the then current SOC. The focus initially will be on treatment naïve and treatment experienced chronic hepatitis C patients. The clinical program is designed to translate what we expect will be the rapid and potent antiviral activity in humans for both ALS-2200 and ALS-2158 and combine one or both of them together and with or without Vertex's HCV assets, including INCIVEK and VX-222, among others[\*\*\*]. In addition, the program must, at the time of registration, result in an adequate safety database.

### 7.1 Phase 1 program

#### 7.1.1 Phase 1 SAD Study

The Phase 1 program [\*\*\*].

##### Key Assumption

[\*\*\*]

#### 7.1.2 Phase 1 MAD/VK Study

The second part of the Phase 1 program [\*\*\*].

##### Key Assumption

[\*\*\*]

#### 7.1.3 DDI (Drug-Drug Interaction) Program

The design of this study will be as follows: [\*\*\*]

##### Key Assumption

[\*\*\*]

#### 7.1.4 Conduct of the Phase 1 Study

[\*\*\*]

### 7.2 Phase 2a Program

[\*\*\*]

Key Assumption

[\*\*\*]

**7.2.1 Phase 2a Program [\*\*\*]**

- [\*\*\*]

**7.3 Phase 2b Program**

[\*\*\*]

Key Assumption

[\*\*\*]

**7.4 Phase 3 Program**

[\*\*\*]

Key Assumption

[\*\*\*]

**7.5 [\*\*\*]**

[\*\*\*]

**7.6 [\*\*\*]**

[\*\*\*]

- HIV co-infection: [\*\*\*]
- Decompensated Liver Disease/Pre-liver Transplantation: [\*\*\*]
- Post-Liver Transplant: [\*\*\*]
- Pediatrics: [\*\*\*]
- [\*\*\*]

**8 Non-Clinical Development**

**8.1 Non-Clinical Plan Overview**

[\*\*\*]

**9 CMC**

**9.1 Product Development Plan Overview**

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

## Exhibit C

### Press Release

#### **Vertex and Alios BioPharma Announce Exclusive Worldwide Licensing Agreement for Two Nucleotide Drug Candidates, Broadening Vertex’s Efforts to Develop New Combinations of Medicines for Hepatitis C**

*-Vertex gains worldwide rights to two distinct nucleotide analogues, ALS-2200 and ALS-2158, that act on hepatitis C polymerase-*

*-Collaboration provides multiple opportunities to develop new “all-oral” combination regimens-*

**Cambridge, MA, and South San Francisco, CA, June 13, 2011** — Vertex Pharmaceuticals Incorporated (Nasdaq: VRTX) and Alios BioPharma, Inc. today announced an exclusive worldwide licensing agreement that will add two distinct nucleotide analogues to Vertex’s hepatitis C portfolio. The compounds, which were discovered by Alios and are known as ALS-2200 and ALS-2158, have shown in *in vitro* studies to be potent inhibitors of the hepatitis C virus (HCV) polymerase, an enzyme essential for replication of the virus. The addition of these compounds provides Vertex with multiple opportunities to develop potential, new, all-oral combination regimens for chronic hepatitis C. Vertex expects ALS-2200 and ALS-2158 to enter clinical development later this year.

“We are excited to begin working with Vertex, as we believe that the Alios nucleotide analogues provide an important opportunity to improve patient care in hepatitis C,” said Lawrence M. Blatt, Ph.D., Founder and Chief Executive Officer of Alios BioPharma. “For more than a decade, Vertex has been a leader in the development of new approaches for treating hepatitis C, and together we have the potential to create an all-oral, interferon-free, combination therapy that could improve the safety, efficacy and ease of administration for patients. We look forward to initiating clinical development later this year.”

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

“The recent approval of INCIVEK was a milestone in hepatitis C care, and today’s announcement underscores our long-term commitment to further improving the treatment of this disease with new combinations of medicines,” said Peter Mueller, Ph.D., Chief Scientific Officer and Executive Vice President of Global Research and Development at Vertex. “Alios has discovered anti-HCV nucleotides that have the potential to be leading agents in hepatitis C. Based on impressive *in vitro* data, we look forward to evaluating ALS-2200 and ALS-2158 together and in combination with our approved and investigational hepatitis C medicines with the goal of creating a highly potent all-oral regimen in the years ahead.”

#### **About ALS-2200 and ALS-2158**

ALS-2200 and ALS-2158, currently in preclinical development, are highly potent nucleotide analogues that appear in *in vitro* and non-clinical studies to have a high barrier to drug resistance and the potential to be dosed once-daily. Both compounds are designed to inhibit the replication of the hepatitis C virus by acting on the NS5B polymerase. Each compound has its own unique mechanism of action, which supports the potential for developing these compounds together as a dual nucleotide regimen and as part of combination therapy regimens with Vertex’s other approved and investigational medicines for chronic hepatitis C, including INCIVEK™ (telaprevir), an FDA-approved hepatitis C protease inhibitor, and VX-222, an investigational hepatitis C non-nucleoside polymerase inhibitor. Data from *in vitro* studies showed that both ALS-2200 and ALS-2158 had a synergistic effect when combined together and with INCIVEK and VX-222. Additionally, in those *in vitro* studies, both compounds showed antiviral activity across all genotypes, or forms, of the hepatitis C virus, including genotypes more prevalent outside of the U.S. Pan-genotypic compounds for hepatitis C have the potential to be used across a broad range of people with hepatitis C worldwide.

As part of this agreement, Vertex gains worldwide rights to both compounds, further enabling the company to potentially expand development and commercialization efforts in hepatitis C to areas outside North America over the coming years. The agreement also includes a research program that will focus on the discovery of additional nucleotide analogues that act on the

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

hepatitis C polymerase. Vertex will have the option to select compounds for development emerging from the research program.

**Future Development Plans:** Alios and Vertex plan to initiate clinical development of each compound in the fourth quarter of 2011, which is expected to include studies of the compounds in healthy volunteers followed by short-duration safety and viral kinetic studies in people with hepatitis C. The goal of the first clinical studies of these compounds is to generate data to enable the initiation of Phase 2 studies as early as the end of 2012. These Phase 2 studies are expected to evaluate multiple combination regimens of ALS-2200, ALS-2158, INCIVEK and VX-222. The combination studies would be designed to



generate sustained viral response (SVR or viral cure) data. Additional details on the clinical development program for ALS-2200 and ALS-2158 will be provided later in 2011 upon initiation of the first clinical study.

### **Terms of the Transaction**

As part of the agreement, Alios will receive a \$60 million up-front payment from Vertex for the worldwide rights to ALS-2200 and ALS-2158. Vertex is responsible for development costs related to ALS-2200 and ALS-2158 and will also provide research funding to Alios. In addition, Alios would be eligible to receive research and development milestone payments up to \$715 million if both compounds are approved. Vertex expects to pay approximately \$35 million in development milestones in 2011. Alios is also eligible to receive up to \$750 million in sales milestones on sales of all approved medicines under the collaboration. The agreement also includes tiered royalties on product sales.

### **Important Information About INCIVEK™ (telaprevir) tablets**

#### **Indication**

INCIVEK™ (telaprevir) is a prescription medicine used with the medicines peginterferon alfa and ribavirin to treat chronic (lasting a long time) hepatitis C genotype 1 infection in adults with stable liver problems, who have not been treated before or who have failed previous treatment.

It is not known if INCIVEK is safe and effective in children under 18 years of age.

#### **IMPORTANT SAFETY INFORMATION**

INCIVEK should always be taken in combination with peginterferon alfa and ribavirin. Ribavirin may cause birth defects or death of an unborn baby. Therefore, you should not take

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

3

---

INCIVEK combination treatment if you are pregnant or may become pregnant, or if you are a man with a sexual partner who is pregnant.

INCIVEK and other medicines can affect each other and can also cause side effects that can be serious or life threatening. There are certain medicines you cannot take with INCIVEK combination treatment. Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

INCIVEK can cause serious side effects including rash and anemia. The most common side effects of INCIVEK include itching, nausea, diarrhea, vomiting, anal or rectal problems, taste changes and tiredness. There are other possible side effects of INCIVEK, and side effects associated with peginterferon alfa and ribavirin also apply to INCIVEK combination treatment. Tell your healthcare provider about any side effect that bothers you or doesn't go away.

You are encouraged to report negative side effects of prescription drugs to the FDA at 1-800-FDA-1088 OR 1-800-332-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You may also report side effects to Vertex at 1-877-824-4281.

Please see full Prescribing Information for INCIVEK including the Medication Guide, available at [www.INCIVEK.com](http://www.INCIVEK.com).

#### **About Hepatitis C**

Hepatitis C is a serious liver disease caused by the hepatitis C virus, which is spread through direct contact with the blood of infected people and ultimately affects the liver.(1) Chronic hepatitis C can lead to serious and life-threatening liver problems, including liver damage, cirrhosis, liver failure or liver cancer. (1) Though many people with hepatitis C may not experience symptoms, others may have symptoms such as fatigue, fever, jaundice and abdominal pain.(1)

Unlike HIV and hepatitis B virus, chronic hepatitis C is curable.(2) However, approximately 60 percent of people with genotype 1 chronic hepatitis C do not achieve SVR,(3),(4),(5) or viral cure,(6) after treatment with 48 weeks of pegylated-interferon and ribavirin alone. If treatment is not successful and a person does not achieve a viral cure, they remain at an increased risk for progressive liver disease.(7),(8)

More than 170 million people worldwide are chronically infected with hepatitis C.(6) In the United States, nearly 4 million people have chronic hepatitis C and 75 percent of them are unaware of their infection.(9) Hepatitis C is four times more prevalent in the United States compared to HIV.(9) Genotype 1 is the most common form of HCV in the United States, accounting for around 70 percent of cases.(13) However, different forms are more common in other parts of the world. The majority of people with hepatitis C in the United States were born between 1946 and 1964, accounting for two of every three people with chronic hepatitis C.(10) Hepatitis C is the leading cause of liver transplantations in the United States and is reported to contribute to 4,600 to 12,000 deaths annually.(11),(12) By 2029, total annual medical costs in the United States for people with hepatitis C are expected to more than double, from \$30 billion in

*Portions of this exhibit, indicated by the mark “[\*\*\*],” have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

4

---

2009 to approximately \$85 billion.(9)

#### **About Vertex**

Vertex creates new possibilities in medicine. Our team discovers, develops and commercializes innovative therapies so people with serious diseases can lead better lives. Vertex scientists and our collaborators are working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, epilepsy and other life-threatening diseases.

Founded more than 20 years ago in Cambridge, MA, we now have ongoing worldwide research programs and sites in the U.S., U.K. and Canada.

For more information and to view Vertex's press releases, please visit [www.vrtx.com](http://www.vrtx.com).

## About Alios BioPharma

Alios BioPharma is a biotechnology company located in South San Francisco, California, that is developing novel medicines aimed at the treatment of viral diseases. Alios has an innovative team of highly experienced scientists and clinical researchers who are developing direct acting antiviral agents against several human viral pathogens of public health importance including, Hepatotropic viruses, Respiratory viruses and other chronic, acute and emerging viral diseases. Additionally, Alios is developing molecular activators of an interferon induced, broad spectrum antiviral innate immune pathway called RNase-L. The overall goal for the Alios therapeutic platform is to maximize patient benefits in areas of high unmet medical need through optimization of potency, safety and tolerability.

INCIVEK™ is a trademark of Vertex Pharmaceuticals Incorporated.

## Special Note Regarding Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, including statements regarding (i) Vertex broadening its efforts to develop new combinations of medicines for hepatitis C; (ii) multiple opportunities to develop new "all-oral" combination regimens; (iii) the expectation that clinical development of ALS-2200 and ALS-2158 will begin in 2011; (iv) the potential to create an all-oral, interferon-free, combination therapy that could improve the safety, efficacy and ease of administration for patients; (v) Vertex's long-term commitment to further improving the treatment of Hep C with new combinations of medicines; (vi) the anti-HCV nucleotides having the potential to be leading agents in hepatitis C; (vii) the goal of creating a highly potent all-oral regimen in the years ahead; (viii) the potential for development of these compounds together as a dual nucleotide regimen and as part of combination therapy regimens with INCIVEK (telaprevir) and VX-222; (ix) the potential to expand development and commercialization efforts in hepatitis C to areas outside North America over the coming years; (x) Alios' future research program and Vertex's option to select compounds that may emerge from the research program; (xi) all of the

*Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.*

---

statements under the caption "Future Development Plans;" (xii) Vertex's responsibility for development and research funding; and (xiii) potential development and commercialization milestones and royalty payments. While the Company believes the forward-looking statements contained in this press release are accurate, there are a number of factors that could cause actual events or results to differ materially from those indicated by such forward-looking statements. Those risks and uncertainties include, among other things, that the outcomes for our planned clinical trials and studies may not be favorable, that there may be varying interpretations of data produced by one or more of our clinical trials, that the Company may not obtain the benefits it expects to obtain from this transaction for a variety of reasons including the possibilities that the Company may not be able to successfully develop combination therapies involving INCIVEK and/or VX-222 and the drug candidates that the Company is acquiring in this transaction; and that *in vitro* data regarding ALS-2200 and ALS-2158 may not be predictive of results that may be obtained from clinical trials, and the other risks listed under Risk Factors in Vertex's annual report and quarterly reports filed with the Securities and Exchange Commission and available through the Company's website at [www.vrtx.com](http://www.vrtx.com). The Company disclaims any obligation to update the information contained in this press release as new information becomes available.

(VRTX - GEN)

---

(1) Centers for Disease Control and Prevention. Hepatitis C Fact Sheet: CDC Viral Hepatitis. Available at: <http://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf>. Accessed March 21, 2011.

(2) Pearlman BL and Traub N. Sustained Virologic Response to Antiviral Therapy for Chronic Hepatitis C Virus Infection: A Cure and So Much More. *Clin Infect Dis*. 2011 Apr;52(7):889-900.

(3) Manns MP, McHutchison JG, Gordon SC, et al. Peginterferon alfa-2b plus ribavirin compared with interferon alfa-2b plus ribavirin for initial treatment of chronic hepatitis C: a randomised trial. *Lancet*. 2001;358:958-965.

(4) Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. *N Engl J Med*. 2002;347:975-982.

(5) McHutchison JG, Lawitz EJ, Shiffman ML, et al; IDEAL Study Team. Peginterferon alfa-2b or alfa-2a with ribavirin for treatment of hepatitis C infection. *N Engl J Med*. 2009;361:580-593.

(6) Ghany MG, Strader DB, Thomas DL, Seeff, LB. Diagnosis, management and treatment of hepatitis C; An update. *Hepatology*. 2009;49 (4):1-40.

(7) Morgan TR, Ghany MG, Kim HY, Snow KK, Lindsay K, Lok AS. Outcome of sustained virological responders and non-responders in the Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis (HALT-C) trial. *Hepatology*. 2008;50(Suppl 4):357A (Abstract 115).

(8) Veldt BJ, Heathcote J, Wedmeyer H. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. *Annals of Internal Medicine*. 2007; 147: 677-684.

(9) Institute of Medicine of the National Academies. Hepatitis and liver cancer: a national strategy for prevention and control of hepatitis B and C. Colvin HM and Mitchell AE, ed. Available at: <http://www.iom.edu/Reports/2010/Hepatitis-and-Liver-Cancer-A-National-Strategy-for-Prevention-and-Control-of-Hepatitis-B-and-C.aspx>. Updated January 11, 2010. Accessed March 21, 2011.

(10) Pyenson B, Fitch K, Iwasaki K. Consequences of hepatitis C virus (HCV): Costs of a baby boomer epidemic of liver disease. Available at: [http://www.natap.org/2009/HCV/051809\\_01.htm](http://www.natap.org/2009/HCV/051809_01.htm). Updated May 2009. Accessed March 21, 2011. This report was commissioned by Vertex Pharmaceuticals, Inc.

(11) Volk MI, Tocco R, Saini S, Lok, ASF. Public health impact of antiviral therapy for hepatitis C in the United States. *Hepatology*. 2009;50(6):1750-1755.

(12) Davis GL, Alter MJ, El-Serag H, Poynard T, Jennings LW. Aging of hepatitis C virus (HCV)-infected persons in the United States: A multiple cohort model of HCV prevalence and disease progression. *Gastroenterology*. 2010;138:513-521.

(13) Blatt LM, Mutchnick MG, Tong MJ, et al. Assessment of hepatitis C virus RNA and genotype from 6807 patients with chronic hepatitis in the United States. *J Viral Hepat*. 2000; 7:196-202.

**Vertex Contacts:**

Investors:

Michael Partridge, 617-444-6108

Lora Pike, 617-444-6755

Matthew Osborne, 617-444-6057

or

Media:

Zachry Barber

617-444-6992 or [mediainfo@vrtx.com](mailto:mediainfo@vrtx.com)

**Alios Contact:**

John Donovan, Chief Business Officer

650-635-5504 or [jdonovan@aliosbiopharma.com](mailto:jdonovan@aliosbiopharma.com)

Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.7**

**Alios Patent Rights**

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**Schedule 1.8**

**ALS-2158**

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

Portions of this exhibit, indicated by the mark "[\*\*\*]," have been redacted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.



## CERTIFICATION

I, Jeffrey M. Leiden, certify that:

1. I have reviewed this Amendment No. 2 to the Quarterly Report on Form 10-Q/A of Vertex Pharmaceuticals Incorporated; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: March 2, 2012

/s/ JEFFREY M. LEIDEN

---

Jeffrey M. Leiden  
*Chief Executive Officer*  
*(principal executive officer)*

---

## CERTIFICATION

I, Ian F. Smith, certify that:

1. I have reviewed this Amendment No. 2 to the Quarterly Report on Form 10-Q/A of Vertex Pharmaceuticals Incorporated; and
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Date: March 2, 2012

/s/ IAN F. SMITH

---

Ian F. Smith  
*Executive Vice President and Chief Financial Officer*  
*(principal financial officer)*

---