UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A (AMENDMENT NO. 1)
For the fiscal year ended December 31, 2015
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: 001-33221

DELAWARE

(Mark One)

(State or other jurisdiction of incorporation or organization)

94-2875566 (I.R.S. Employer Identification No.)

4242 CAMPUS POINT COURT, SUITE 200, SAN DIEGO, CA (Address of principal executive offices)

92121 (Zip Code)

Registrant's telephone number, including area code: (858) 251-4400

HERON THERAPEUTICS, INC. (Exact name of registrant as specified in its charter)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class: Common Stock, par value \$0.01 per share

the registrant was required to submit and post such files). Yes \boxtimes No \square

Name of each exchange on which registered: The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗵 No 🗆

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes \square No \boxtimes

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 \boxtimes No \square 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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ⊠

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

Large accelerated filer |X|Accelerated filer

Non-accelerated filer \Box (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). You	s 🗆 No 🗵	
The aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant as of June \$957,876,000 based on the closing price of \$31.16 as reported by The NASDAQ Capital Market. As of February 4, 20 Company's common stock (\$0.01 par value) outstanding.		of the
Documents Incorporated by Reference		
Portions of the registrant's Definitive Proxy Statement related to its 2016 Annual Stockholders' Meeting to be held on incorporated by reference into Part III of this Annual Report on Form 10-K. Such Definitive Proxy Statement was file Commission within 120 days after the end of the fiscal year to which this report relates. Except as expressly incorpora Definitive Proxy Statement shall not be deemed to be part of this report.	d with the U.S. Securities and Exch	nange

EXPLANATORY NOTE

Heron Therapeutics, Inc. (the "Company") is filing this Amendment No. 1 (the "Amendment") to its Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "Form 10-K") filed with the Securities and Exchange Commission (the "SEC") on February 19, 2016, solely to refile Exhibit 10.36 to the Form 10-K in response to communications with the SEC's Staff regarding a request for confidential treatment made by the Company with respect to portions of this exhibit and to make related changes to the exhibit index of the Form 10-K. Certain information that previously was redacted within Exhibit 10.36 as filed with the Form 10-K has been disclosed in Exhibit 10.36 as refiled with this Amendment.

This Amendment is an exhibits-only filing solely for the purpose of filing a revised version of Exhibit 10.36 and updating the exhibit index of the Form 10-K. This Amendment does not affect any other parts of, or exhibits to, the Form 10-K, and those unaffected parts or exhibits are not included in this Amendment. Except as expressly stated in this Amendment, the Form 10-K continues to speak as of the date of the original filing of the Form 10-K, and the Company has not updated the disclosure contained in this Amendment to reflect events that have occurred since the filing of the Form 10-K. Accordingly, this Amendment must be read in conjunction with the Company's other filings made with the SEC subsequent to the filing of the Form 10-K, including amendments to those filings, if any.

Exhibit	Document Description
3.1	Certificate of Incorporation, as amended through July 29, 2009 (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, as Exhibit 3.1, filed on August 4, 2009)
3.2	Bylaws (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 22, 2016)
3.3	Certificate of Amendment of Certificate of Incorporation (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on June 30, 2011)
3.4	Certificate of Amendment of Certificate of Incorporation (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.1, filed on January 13, 2014)
4.1	Common Stock Certificate (Incorporated by reference to our Registration on Form S-3 (Registration No. 333-162968), as Exhibit 4.1, filed on November 6, 2009)
4.2	Form of Warrant to Purchase Shares of Common Stock (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.3, filed on October 22, 2009)
4.3	Amended and Restated Certificate of Designation, Preferences, and Rights of Series A Preferred Stock (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 3.C, filed on December 19, 2006)
10.1*	1997 Employee Stock Purchase Plan, as amended to date (Incorporated by reference to our Definitive Proxy on Schedule 14A, as Exhibit B, filed on April 28, 2015)
10.2	Lease Agreement between Registrant and Metropolitan Life Insurance Company for lease of Registrant's offices in Redwood City dates as of November 17, 1997 (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 1997, as Exhibit 10-E, filed on March 30, 1998)
10.3*	2002 Equity Incentive Plan dated June 13, 2002 (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-90428), as Exhibit 99.1, filed on June 13, 2002)
10.4*	Amended and Restated 2007 Equity Incentive Plan (Incorporated by reference to our Definitive Proxy on Schedule 14A, as Exhibit A, filed on April 28, 2015)
10.5*	Form of 2007 Equity Incentive Plan Stock Option Agreement (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-148660), as Exhibit 4.3, filed on January 14, 2008)
10.6*	Form of 2007 Equity Incentive Plan Restricted Stock Unit Agreement (Incorporated by reference to our Registration on Form S-8 (Registration No. 333-148660), as Exhibit 4.4, filed on January 14, 2008)
10.7*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, as Exhibit 10-O, filed on March 31, 2008)
10.8*	Form of Indemnification Agreement (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2007, as Exhibit 10-S, filed on March 31, 2008)
10.9	Securities Purchase Agreement, dated as of October 19, 2009, by and among the Registrant and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on October 22, 2009)
10.10	Registration Rights Agreement, dated as of October 22, 2009, by and among the Registrant and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on October 22, 2009)
10.11	Securities Purchase Agreement, dated as of April 24, 2011, by and among the Company and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on April 28, 2011)
10.12	Form of Senior Secured Convertible Note due 2021 (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on April 28, 2011)
10.13	Securities Agreement, dates as of April 24, 2011, by and between the Company and Tang Capital Partners, LP, as Agent for the Purchasers (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.3, filed on April 28, 2011)
10.14	Second Amendment to Lease, effective as of April 1, 2011, by and between the Company and Metropolitan Life Insurance Company (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.4, filed on April 28, 2011)
10.15*	Management Retention Agreement, dated as of April 25, 2011, by and between the Company and Michael A. Adam (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.6, filed on April 28, 2011)
10.16	Securities Purchase Agreement, dated June 29, 2011, by and between the Company and the purchasers listed on Schedule I thereto (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on June 30, 2011)
10.17	Amendment to Senior Secured Convertible Note Due 2021, dated June 29, 2011, by and between the Company and the purchasers named in the Securities Purchase Agreement, dated April 24, 2011, by and among the Company and the purchasers listed therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on June 30, 2011)
10.18	Third Amendment to Lease, effective as of July 28, 2011, by and between the Company and Metropolitan Life Insurance Company (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on August 3, 2011)
10.19	Securities Purchase Agreement, dated July 25, 2012, by and between the Company and the purchasers named therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on July 25, 2012)

10.20	Registration Rights Agreement, dated July 25, 2012, by and between the Company and the purchasers named therein (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.2, filed on July 25, 2012)
10.21*	Management Retention Agreement as of December 3, 2012, by and between the Company and Mark S. Gelder, M.D. (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2012, as Exhibit 10-AH, filed on March 1, 2013)
10.22*	Executive Employment Agreement, dated May 1, 2013, by and between the Company and Barry D. Quart, Pharm.D. (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, as Exhibit 10-AI, filed on May 10, 2013)
10.23*	Executive Employment Agreement, dated May 1, 2013, by and between the Company and Robert H. Rosen (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, as Exhibit 10-AJ filed on May 10, 2013)
10.24	Form of Non-Qualified Stock Option Agreement (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as Exhibit 10-AL, filed on August 8, 2013)
10.25*	Amendment to Management Retention Agreement, dated as of April 25, 2011, as amended May 29, 2013 (as amended, the Retention Agreement) (Incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, as Exhibit 10-AM, filed on August 8, 2013)
10.26*	Offer Letter dated November 10, 2012 between the Company and Mark S. Gelder, M.D. (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AE, filed on March 7, 2014)
10.27*	Offer Letter dated October 16, 2013 between the Company and Brian G. Drazba (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AF, filed on March 7, 2014)
10.28*	Management Retention Agreement as of October 23, 2013, by and between the Company and Brian G. Drazba (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AG, filed on March 7, 2014)
10.29*	Executive Employment Agreement, dated November 1, 2013, by and between the Company and Paul Marshall (Incorporated by reference to our Annual Report on Form 10-K for the year ended December 31, 2013, as Exhibit 10-AH, filed on March 7, 2014)
10.30*	Amendment to Executive Employment Agreement, dated May 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Dr. Barry Quart (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.1, filed on May 8, 2015)
10.31*	Amendment to Executive Employment Agreement, dated May 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Robert Rosen (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.2, filed on May 8, 2015)
10.32*	Amendment to Management Retention Agreement, dated October 23, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Brian G. Drazba (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.3, filed on May 8, 2015)
10.33*	Amendment to Executive Employment Agreement, dated November 1, 2013, as amended on April 22, 2015, by and between Heron Therapeutics, Inc. and Paul Marshall (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, as Exhibit 10.4, filed on May 8, 2015)
10.34+	SUSTOL® (granisetron, extended release) Injection Commercial Manufacturing Services Agreement – Finished Final Drug Product, dated May 27, 2015, by and between Heron Therapeutics, Inc. and Lifecore Biomedical, LLC) (Incorporated by reference to our Current Report on Form 8-K, as Exhibit 10.1, filed on May 29, 2015)
10.35*	Executive Employment Agreement, dated October 12, 2015, by and between Heron Therapeutics, Inc. and Neil Clendeninn (incorporated by reference to our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, as Exhibit 10.2, filed on November 6, 2015)
10.36+	Commercial Supply Agreement, dated December 8, 2015, by and between Heron Therapeutics, Inc. and SAFC, Inc.
23.1**	Consent of Independent Registered Public Accounting Firm (OUM & Co. LLP)
24.1	Power of Attorney (included in signature page on our Annual Report on Form 10-K for the year ended December 31, 2015, filed on February 19, 2016)
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

- * Management contract or compensatory plan, contract or arrangement.
- ** Incorporated by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on February 19, 2016
- + Confidential treatment has been requested with respect to certain portions of the exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

HERON THERAPEUTICS, INC.

Date: December 23, 2016

BY: /s/ BARRY D. QUART

Barry D. Quart, Pharm.D. Chief Executive Officer

COMMERCIAL SUPPLY AGREEMENT

EXCIPIENT

This Commercial Supply Agreement (this "Agreement"), effective as of the 8th day of December, 2015 (the "Effective Date"), is entered into by and between:

HERON THERAPEUTICS, Inc., a company incorporated under the laws of Delaware, with its principal office located at 123 Saginaw Drive Redwood City, CA ("Company"); and

SAFC, Inc., a company incorporated under the laws of the State of Wisconsin, USA, with its principal office located at 3050 Spruce Street, St. Louis, Missouri 63103, on behalf of itself and its Affiliates which provide products or services under this Agreement ("SAFC").

Company and SAFC are hereinafter sometimes referred to separately as a "Party" or together as the "Parties".

RECITALS

WHEREAS, Company is engaged in the research and development of pharmaceutical products;

WHEREAS, SAFC develops, manufactures and sells a broad range of biochemicals and organic chemicals globally for use in pharmaceutical development and as key components in pharmaceutical and other high technology manufacturing;

WHEREAS, Company uses the Excipient in the Finished Product, and desires to engage SAFC to manufacture the Excipient and supply the Excipient and also certain Raw Materials as requested during the term of this Agreement; and

WHEREAS, SAFC is willing to manufacture and supply to Company the Excipient and certain Raw Materials upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants and agreements contained herein, the Parties hereby agree as follows:

1. Definitions and Interpretation

1.1 "Affiliate" means any entity controlling, controlled by or under common control with either Party hereto. For purpose of this definition, "control" shall mean ownership of over fifty percent (50%) of the equity capital, the outstanding voting securities or other ownership interest of an entity, or the right to receive over fifty percent (50%) of the profits or earnings of an entity. In the case of non-stock organizations, the term "control" shall mean the power to control the distribution of profits.

- 1.2 "Analytical Methods" means the set of validated analytical methods related to the Manufacturing of the Excipient as provided by Company to SAFC, and, if applicable, methods related to Raw Materials supplied by SAFC to the Company.
- 1.3 "Applicable Law(s)" means any domestic or foreign, supranational, regional, national, state and local laws and the rules, regulations, guidelines and requirements of all Regulatory Agencies in effect from time to time applicable to SAFC with respect to the Manufacturing Process of Raw Materials or the Excipient, including without limitation in the United States (U.S.) and the European Union (EU).
- 1.4 "Batch" means the Excipient or other material as defined in the relevant Batch Record that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of Manufacturing.
- 1.5 "Batch Record" shall mean the document, proposed by SAFC and approved by Company in writing that defines the manufacturing methods, materials, and other procedures, directions and controls associated with the Manufacture and testing of Raw Materials and Excipient. The Batch Record shall also include or incorporate by reference such information as Raw Materials Specifications, in process and final or other Excipient sampling standards, test methods, specifications, equipment and instrumentation specifications and standard operating procedures, including standard operating procedures for in-process quality control testing.
- 1.6 "Biochronomer® Technology" means Heron's proprietary polymer-based bioerodible technology designed to release drugs over an extended, sustained period of time.
- 1.7 "Certificate of Analysis" means a document, which is dated and signed by a duly authorized representative of the Quality Control or Quality Assurance department of SAFC, certifying that a Batch of Excipient or an order of Raw Materials meets all Specifications.
- 1.8 "Certificate of Compliance" means a document, signed by an authorized representative of SAFC, attesting that a particular Batch of Excipient was manufactured in accordance with cGMP and Applicable Law.
- 1.9 "Commencement Date" means the date Company issues its initial binding written purchase order for the commercial supply of Excipient under Section 3.2 below.
 - 1.10 "Commercial Forecast" shall have the meaning set forth in Section 3.1 hereof.
- 1.11 "Commercially Reasonable Efforts" means the carrying out of such obligations with a level of effort and resources consistent with those commercially reasonable efforts and industry standard practices of a company performing contract manufacturing of pharmaceutical products.

- 1.12 "Compliance Level" shall have the meaning set forth in Section 2.11(b) hereof.
- 1.13 "Confidential Information" shall mean all the technical information, whether tangible or intangible, including (without limitation) any and all data, techniques, discoveries, inventions, processes, know-how, patent applications, inventor certificates, trade secrets, methods of production and other proprietary information, that either Party or any Affiliate of a Party has ownership rights to (as either owner, licensee or sub-licensee), or may hereafter obtain rights. In order for oral information to be considered to be Confidential Information hereunder, it must be identified as confidential and proprietary at the time of disclosure, or be of such type of information such that a reasonable person would believe that such information was confidential or proprietary. All written information must be conspicuously marked using words such as "confidential" or "proprietary" in order to be considered to be Confidential Information hereunder.
- 1.14 "Current Good Manufacturing Practices" or "cGMP" shall mean the standards relating to Manufacturing practices as required by the rules and regulations of Regulatory Agencies in compliance with ICH guidelines for active pharmaceutical ingredients, intermediates or bulk products as established by the principles detailed in the guidance document developed by the International Conference on Harmonization known as "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients".
- 1.15 "Deviation" shall mean excursions or nonconformity from processes, specifications, or quality systems that may affect the safety, identity, strength, purity, or quality of Excipient or any regulatory submissions for Excipient or any Raw Materials ordered by Company.
 - 1.16 "EMA" means the European Medicines Agency of the European Union.
 - 1.17 "Excipient" means ***, in all instances intended to meet the Specifications, manufactured in accord with cGMP and sold by SAFC to Company.
 - 1.18 "Failure to Supply" shall have the meaning set forth in Section 2.9(a) hereof.
- 1.19 "FCA" shall have the meaning as set forth in the 2010 edition of the International Commercial terms published by the International Chamber of Commerce, as may be amended or modified from time to time.
 - 1.20 "FDA" means the United States Food and Drug Administration, and any successor thereto.
 - 1.21 "Finished Product" means the finished dosage form of a drug product that contains Excipient or Raw Material manufactured by SAFC.

- 1.22 "For Cause Audit" means an audit of manufacturing records of the Parties by the other Party following: a) an unfavorable observations during regulatory inspections that are potentially material to the quality of the Excipient or b) a major or repeated quality excursion that may result in a failed manufacture Batch or product Recall.
 - 1.23 "Forecast" shall have the meaning set forth in Section 3.1 hereof.
 - 1.24 "Laboratory" shall have the meaning set forth in Section 4.2 hereof.
- 1.25 "Latent Defect" shall mean any nonconformity in any Batch of Excipient that was not, and could not reasonably be expected to have been, found by exercise of ordinary care in inspection and testing by the Company, provided, however, that a Latent Defect shall not include a noncomformity that could not have been avoided or prevented by SAFC by ordinary care and otherwise met all requirements for the Manufacture of Excipient. The Parties agree identification following delivery of the Excipient: (i) of a failure to follow cGMPs by SAFC, (ii) that the Certificate of Analysis is incorrect, (iii) that the Certificate of Compliance is incorrect, or (iv) a Batch record is incorrect, that results in Nonconforming Excipient is a Latent Defect.
- 1.26 "Manufacture, Manufacturing or Manufactured" means all activities related to the manufacturing of the Excipient, or any ingredient thereof in accordance with the terms and conditions of this Agreement and the Quality Agreement, which may include manufacturing the Excipient for development, or use in the manufacture of active pharmaceutical ingredients, in-process and final testing and release of the Excipient, or any component or ingredient thereof, quality assurance activities related to manufacturing and release of the Excipient and regulatory activities related to any of the foregoing.
- 1.27 "Manufacturing Process" shall mean the instructions, Specifications (as well as specifications for raw materials and packaging materials), formulae, procedures, tests and standards developed, established and described by Company for Manufacturing Excipient and/or Raw Materials.
 - 1.28 "Marks" shall have the meaning set forth in Section 11.4 hereof.
 - 1.29 "Minimum Lead Time" shall have the meaning set forth in Section 3.2(c) hereof.
- 1.30 "Nonconforming Excipient" shall mean any Excipient that does not meet the pre-approved release Specifications at the time of release and includes materials as to which any of the following apply: a) the materials have not been packaged for shipment in accordance with the instructions agreed to in writing by Company and SAFC; b) the materials do not meet Specification upon delivery to the carrier approved by Company; c) the materials shipped do not have an accurate Certificate of Compliance and/or Certificate of Analysis d) the materials were not manufactured in accord with cGMP, the Batch Record, the Specifications and the Quality Agreement or e) contains a Latent Defect. For the avoidance of doubt Nonconforming Excipient cannot be as a result of any action or inaction that occurs following delivery of Excipient or Raw Materials to Company.

- 1.31 "Nonconforming Raw Materials" shall mean any Raw Materials that do not meet the pre-approved release at the time of release and includes materials as to which any of the following apply: a) material that does not have an accurate Certificate of Analysis, or b) the material was not manufactured in accord with the Specifications and the Quality Agreement or c) the material contains a Latent Defect.
 - 1.32 "Out of Specification" or "OOS" shall mean all test results that fall outside the Specifications.
 - 1.33 "Qualified Alternate Facility" shall have the meaning set forth in Section 2.11(a) hereof.
- 1.34 "Quality Agreement" means that separate document between Company and SAFC referenced herein and attached hereto as Appendix 1 describing quality related processes, systems and commitments associated with the manufacturing and supply of the Excipient.
- 1.35 "Raw Materials" means all reagents, solvents and critical raw materials which have Specifications, and which are used in the Manufacture of the Excipient.
- 1.36 "Recall" means any action: (a) by the Company to recover title to, or possession of, quantities of Finished Product shipped to third parties or shipped to intermediates on the Company's behalf (including, without limitation, the voluntary withdrawal of the Finished Product from the market or clinical use), or (b) by the Company to effect a field correction, or (c) by any Regulatory Authority to detain or destroy any of the Finished Product.
- 1.37 "Regulatory Agency" means any and all bodies and organizations, including, without limitation, the FDA and EMA, regulating the manufacture, importation, distribution, use and sale of the, Finished Product, Excipient or Raw Materials used therein.
- 1.38 "Specifications" means the Excipient Specifications in Appendix 2, Raw Material specifications, packaging component specifications, or process intermediate specifications, as the context requires. Specifications include a list of tests, pertaining to analytical procedures, and appropriate acceptance criteria including, but not limited to, numerical limits, ranges, and qualitative analysis that establish the set of criteria to which a test article must conform to be considered acceptable for use in the manufacture of Raw Materials or Excipient. These Specifications can only be modified by agreement in writing between the Parties and in accord with the terms of the Quality Agreement
 - 1.39 "SUSTOL" means Sustol® (granisetron) Injection, extended release, as a Finished Product under this Agreement.
- 1.40 "Technology Transfer" means the transfer from SAFC or its Affiliates to Company or any third party designated by Company of the full and complete standard

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

operating procedures and tangible and intangible information that is reasonably necessary to the process of manufacturing the Excipient and/or Raw Materials, inclusive of, documents, manufacturing instructions, communications from Regulatory Authorities, know-how, licenses, stability samples, retention samples and materials (including Raw Materials Specifications) that are reasonably necessary to manufacture Excipient or Raw Materials to meet all Specifications and to comply with all Applicable Laws in connections with such transfer. This should include all information required by Regulatory Agencies that requires SAFC assistance to provide.

- 1.41 "Term" shall have the meaning set forth in Section 9.1 hereof.
- 1.42 "Third Party Supplier" means a manufacturer of Excipient other than SAFC.

2. Manufacture and Supply of Excipient and Raw Materials

- 2.1 <u>General Conditions of Supply</u>. During the Term, SAFC and its Affiliates shall Manufacture and supply Excipient and/or Raw Materials to Company, and Company shall purchase Excipient and/or Raw Materials from SAFC and its Affiliates in such quantities as Company may order from time to time, subject to the limitations and requirements set forth herein. Raw materials will be supplied in accord with the conditions below for Excipient except as stated in Appendix 4.
- 2.2 <u>Specifications</u>. At all times during the Term, SAFC shall Manufacture the Excipient in accordance with cGMP, the Specifications and the Quality Agreement. At all times during the Term, SAFC shall Manufacture Raw Materials in accordance with the Raw Materials Specifications and the Quality Agreement.
- 2.3 <u>Person in the Plant</u>. SAFC and/or its Affiliates shall permit Company employees, consultants and/or representatives (excluding agents of third parties which are competitors of SAFC) to be admitted to the Facility, subject to the safety and security policies of SAFC, during the Manufacturing of the Excipient and/or Raw Materials for the purposes of (i) observing the manufacturing process and (ii) reviewing all Batch Records and other documents, including, without limitation, all production logs, reagent preparation records, Deviation reports, Raw Materials testing and release data, SAFC procedures, and the like. Heron employees, consultants and/or representatives shall not be auditing the operations but shall merely observe the Manufacturing activities. All such Company employees, consultants and/or representatives pursuant to this Section 2.3 will be bound by a confidentiality agreement that is at least as stringent as the confidentiality terms set forth herein. SAFC shall consider, in good faith, any suggestions that Company or its onsite, consultants and/or representatives have regarding the design or operation of the Facility for Manufacturing and will promptly respond to Company regarding such suggestions.
- 2.4 <u>Quality Control and Release</u>. The quality control(s) and the release(s) of Excipient (including documentation) shall be done by SAFC in accordance with cGMP, the Specifications and the Quality Agreement. The quality control(s) and the release(s) of

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Raw Materials (including documentation) shall be done by SAFC in accordance with the Specifications and the Quality Agreement. Company, subject to the provisions of Section 4 of this Agreement, shall have the right to reject Excipient or Raw Materials that are Non-conforming Excipient or Raw Materials. SAFC shall retain and store remaining samples of the Excipient and critical Raw Materials as required by Applicable Law.

- 2.5 <u>Inspections</u>. Inspections of SAFC's facilities and/or its Affiliates' facilities used in the Manufacture of the Excipient and/or Raw Materials shall be conducted as specified in the Quality Agreement. Subject to the limitations and qualifications set forth in the Quality Agreement, upon prior notice of at least thirty (30) days, SAFC or its Affiliates shall permit Company's representatives (excluding agents of third parties which are competitors of SAFC) once per year, or more frequently if deemed warranted as a For Cause Audit as specified in the Quality Agreement, to visit and audit SAFC's facilities used in the Manufacture of the Excipient or Raw Materials to observe the Manufacturing thereof, to discuss with appropriate officials of SAFC and to inspect and audit records relevant to the Manufacturing of the Excipient and Raw Materials.
- 2.6 <u>Changes to Specifications and Process</u>. The Specifications shall be amended only as agreed upon in writing by Company and SAFC; provided, however, that the Parties agree to cooperate to amend or supplement the Specifications to the extent reasonably necessary to comply with changes in Applicable Laws and/or regulations or the requirements of applicable Regulatory Agencies or as Company may reasonably request from time to time (provided such request is made in good faith). SAFC shall follow the change control procedures set forth in the Quality Agreement for any proposed changes in the Manufacturing process. SAFC acknowledges that any such change(s) shall, in each case, comply with cGMP (if required), this Agreement and the Quality Agreement. In the event such amendment (whether as a result of changes in Applicable Laws or the requirements of applicable Regulatory Agencies or at Company's reasonable and good faith request or otherwise) requires additional cost or schedule adjustments for the Manufacture of the Excipient or Raw Materials hereunder, Company and SAFC shall agree in good faith on an equitable adjustment to price and/or schedule, as appropriate. Any such amended Specifications shall be reflected in and attached hereto as an amended and restated <u>Appendix 2</u>.

2.7 <u>Documentation</u>.

(a) <u>General</u>. Upon completion of Manufacture of each batch of Excipient, SAFC shall provide to Company the following documentation related to the Manufacturing of Excipient: copy of executed Batch Records, a Certificate of Analysis, Certificate of Compliance, Deviations, and any other information specified in the Quality Agreement. Upon completion of Manufacture of each order of Raw Materials, SAFC shall provide to Company the following documentation: copy of executed Batch Records, a Certificate of Analysis, notation of any Deviations and any other information specified in the Quality Agreement.

- (b) <u>Batch Records and Order Documents</u>. The Batch Records and documents related to orders of Raw Materials shall be treated as Confidential Information of Company and shall not be used or disclosed by SAFC other than for the purposes of permitting SAFC to exercise its rights or fulfil its obligations under this Agreement (including but not limited to, the provision of the Batch Record of Manufacture of Raw Materials to Company for quality review) and, where necessary, for disclosure to the relevant Regulatory Agencies in order to comply with regulatory requirements relating to the Manufacturing of Excipient or Raw Materials by SAFC or its Affiliates.
- (c) <u>Retention of Documentation</u>. All documentation related to the Manufacturing of Excipient or Raw Materials shall be archived with SAFC or its Affiliates after Manufacturing in accordance with SAFC's document retention policies and Applicable Law. Company shall be contacted at least ninety (90) days before destruction of any Excipient or Raw Materials specific records and shall be given the option to retain such documents.
- 2.8 <u>Safety</u>. Each Party shall immediately notify the other Party of any unusual health or environmental occurrence relating to Excipient or Raw Materials. Each Party shall advise the other Party immediately of any safety or toxicity problems of which it becomes aware regarding Excipient or Raw Materials.
- 2.9 <u>Proprietary Rights.</u> All inventions related specifically to (i) the Excipient or (ii) those Raw Materials proprietary to Company listed and identified as proprietary on Appendix 4. ("Proprietary Raw Materials"), pursuant to the services provided under this Agreement by SAFC or its Affiliates to Company, conceived or reduced to practice during the Term, and as a result of this Agreement, whether or not patentable, and whether or not invented solely by or on behalf of Company or jointly by or on behalf of Company and SAFC shall be owned solely by the Company. All know-how related specifically to the Excipient or Proprietary Raw Materials Manufactured and supplied by SAFC or its Affiliates to Company, arising during the Term, and as a result of this Agreement, whether arising as a result of the activities by or on behalf of Company alone or by or on behalf of Company and SAFC jointly, shall be owned solely by Company. SAFC shall cooperate in vesting ownership of the foregoing inventions and know-how in Company including, but not limited to, delivering such acknowledgements, assignments, and conveyance documents as Company shall request.
- 2.10 <u>Process Improvements</u>. Upon request from either Party, SAFC shall prepare, from time to time, a plan which details the agreed services necessary to implement improvements or changes to the processes involved in the Manufacture of Excipient or Raw Materials Manufactured and supplied by SAFC or its Affiliates to Company, or where new or additional equipment is being used in such Processing. The scope and price of any such a work plan should be agreed in writing by the Parties and set forth in a separate statement of work referring to and falling under the terms of this Agreement. The Price of such additional work shall be consistent with similar previously performed work and/or industry standards. Should the parties make process

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improvements that result in a reduction in the cost of the Excipient or Raw Materials ordered by Company from SAFC or its Affiliates, the Parties will share equally in such savings after the cost of the implementation has been credited to the Party or Parties that paid for such process improvement.

2.11 Purchase Commitment.

(a) During the Term and upon the terms and subject to the conditions of this Agreement and as long as SAFC can demonstrate to Company's reasonable satisfaction, based on capacity availability, Batch size and other commercially reasonable requirements, that SAFC has in place an acceptable alternate Manufacturing facility at which SAFC is capable of manufacturing the Excipient and/or necessary Raw Materials for the Manufacture of the Excipient in compliance with this Agreement and the Quality Agreement ("Qualified Alternate Facility"), Company agrees to purchase from SAFC, its and its Affiliate's annual worldwide requirements of the Excipient for use in SUSTOL. If SAFC does not have a Qualified Alternate Facility, then during the Term and upon the terms and subject to the conditions of this Agreement, Company agrees to purchase from SAFC, not less than *** of its and its Affiliate's annual worldwide requirements of the Excipient for use in SUSTOL unless there is a Failure to Supply pursuant to Section 2.12(a).

(b) If during the Term SAFC reasonably believes that Company is not purchasing Excipient at the level required by this Section 2.11 (the "Compliance Level"), it will provide Company with written notice requesting that Company provide sufficient documentation demonstrating compliance with the Compliance Level. Company shall have sixty (60) days after such notice to provide documentation responsive to the request, and which illustrates solely the Company's annual requirements for Excipient, and that amount purchased from SAFC. If Company provides such documentation and such documentation does not demonstrate, to SAFC's reasonable satisfaction Company's compliance with the Compliance Level, then, in the event that Company does not agree with SAFC's findings, Company and SAFC shall mutually agree on an acceptable independent third party auditor to review Company's books and records solely to determine whether Company met the Compliance Level. Such third-party auditor will be required to sign a standard form of confidentiality agreement for the benefit of Company. The cost of the independent third party shall be borne by Company if the independent third party determines reasonably that Company was out of compliance with the Compliance Level, otherwise by SAFC. If pursuant to this Section 2.11(b) Company is deemed or determined to be out of compliance with the Compliance Level, then SAFC may adjust pricing by not more than the per cent (%) shortfall in the Compliance Level as determined by the independent third party. Any adjusted pricing hereunder would remain in effect until such time as Company demonstrates compliance with the Compliance Level.

2.12 Delay; Third Party Supplier.

- (a) If SAFC is or will be unable, for any reason (including an event of Force Majeure under Section 11.17 hereof), to supply the Excipient in accordance with the quantities and/or delivery dates specified by Company in a purchase order received by SAFC (provided that such quantities are within the Forecast and such delivery dates meet the Minimum Lead Time requirements herein) ("Failure to Supply"), SAFC shall promptly notify Company in writing of such circumstance. Within thirty (30) days of such Failure to Supply, SAFC shall notify Company of the cause of such failure and shall propose a plan of remediation. Further, SAFC will use commercially reasonable efforts to initiate a Technology Transfer to support the manufacture of Excipient by a Third Party Supplier. Each company will bear its own costs related to such Technology Transfer.
- (b) If such Failure to Supply will continue or does continue for a period of ninety (90) or more consecutive days, and SAFC is unable in its then current facility or any Qualified Alternate Facility to Manufacture the Excipient in quantities necessary to cure the Failure to Supply, then Company may, at its discretion and upon written notice to SAFC and without being deemed to be in breach of Section 2.8 of this Agreement, Manufacture or have Manufactured by a Third Party Supplier that quantity of Excipient required by Company that SAFC is or may be unable to supply. In such event, SAFC will use commercially reasonable efforts to complete a Technology Transfer to support the manufacture of Excipient by a Third Party Supplier or the Company, which shall mean providing all documentation, access to records, and other necessary support, provided any additional third-party costs incurred by SAFC to support such Technology Transfer will be at the Company's cost. Further, if Company at such time is receiving its annual worldwide commitment from SAFC, then following the Failure to Supply Company will only be required to purchase *** of its annual supply of the Excipient for use in the Finished Product from SAFC following the Failure to Supply.
- (c) SAFC shall promptly notify Company when SAFC can resume supply of Excipient in accordance with this Agreement and provide Company with a firm date for delivery of the Excipient in accordance with Company's needs. Upon receipt of notice the annual commitment will return to at least *** per cent of the Company's annual worldwide requirements for the Excipient for the Finished Product.

2.13 Exclusivity.

During the Term and for an additional period of either:

- (i) *** years if:
 - (1) SAFC terminates this Agreement; or
 - (2) Company terminates this Agreement for material breach in accordance with Section 9.2(a);

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(ii) *** years if the Company terminates this Agreement for reasons unrelated to SAFC performance or nonperformance;

without considering other limitations with respect to the use of Heron's proprietary technology, SAFC shall not Manufacture any product that uses or relies on Heron's proprietary Biochronomer Technology for itself or for or on behalf of any Third Party.

3. Forecasts, Release, Purchase Orders, Delivery and Storage

3.1 Forecasts. Within (30) thirty days following the Effective Date Company shall determine its initial estimated purchases of the Excipient from SAFC under this Agreement and shall deliver to SAFC a written, rolling twelve (12) month forecast (the "Forecast") of such estimated quantities. The Forecast shall cover each of the next succeeding four (4) calendar quarters. The first calendar quarter shall be binding on Company, the second calendar quarter is also binding, but can be increased or decreased by up to two (2) Batches from the preceding forecast for such quarter, and the following two calendar quarters shall be non-binding. After delivery of the initial Forecast, the Forecast shall be updated by Company on a calendar quarterly basis, which update shall include the next successive calendar quarter added to the last period of the previous Forecast. Although the third and fourth calendar quarters of the Forecast are non-binding, Company understands that SAFC shall use the Forecast for planning purposes (including scheduling of production campaigns, Raw Material acquisitions and investment in equipment and other resources) in order to make available the production capacity required to Manufacture and supply the forecasted amounts and provide replacement Batches of the Excipient, if required, within the time frames specified therein.

3.2 Commercial Supply; Purchase Orders.

- (a) To initiate SAFC's Manufacture and supply of commercial quantities of the Excipient under this Agreement, Company must issue a binding written purchase order for its initial purchase of Excipient at least ninety (90) days prior to the first scheduled shipment of Excipient thereunder or such shorter time as may be agreed upon by the Parties in writing.
- (b) All purchase orders for Excipient hereunder shall be in complete Batches equal to the size of the current manufacturing batch size agreed between the Parties in Appendix 3.
- (c) All purchase orders subsequent to the initial purchase order for commercial supply must be issued at least ninety (90) days prior to the scheduled shipment of Excipient thereunder or such shorter time as may be agreed upon by the Parties in writing. The minimum number of days between the date of a purchase order and the shipment of Excipient under this Section 3.2(c) and Section 3.2(a) above shall be referred to hereinafter as the "Minimum Lead Time".

- (d) Within fourteen (14) days of receipt of a purchase order, SAFC shall notify Company in writing of its acceptance of the purchase order. If SAFC fails to respond within fourteen (14) days of receipt of the purchase order, the purchase order shall be deemed accepted, but only to the extent that any amount ordered is not in excess of the Forecast and that the requested delivery date satisfies the Minimum Lead Time.
- (e) If a purchase order exceeds the Forecast or does not meet the Minimum Lead Time, SAFC may accept such purchase order, but will be required only to use Commercially Reasonable Efforts to fill such excess or accommodate such shorter lead-time.
- (f) For each such purchase of Excipient, the purchase order shall specify: (i) an identification of the Excipient ordered; (ii) quantity requested; (iii) the requested delivery date; and (iv) shipping instructions and address.
- (g) Each purchase order is a contract for the purchase of such Excipient under the terms and conditions set forth in this Agreement, to the exclusion of any additional or contrary terms set forth in any purchase order, unless otherwise explicitly agreed to in writing by the Parties.
- 3.3 <u>Release of Excipient</u>. SAFC shall notify the Company when (i) the Manufacture of Excipient is complete, (ii) all Manufacturing records have been reviewed, (iii) all testing is completed, reviewed, and Excipient meets Specifications (as evidenced by a Certificate of Analysis), (iv) all Deviations, if any, have been adequately reviewed and approved by the Company, and (v) Excipient has been released by SAFC in accordance with the Quality Agreement, and a Certificate of Compliance is issued. SAFC shall make efforts to ensure that release is targeted for four (4) weeks after Manufacturing is complete. If this target release date cannot be achieved for a Batch, SAFC shall notify Company of the reason. In the event the target release date cannot be achieved for reasons that are outside of SAFC's or its Affiliates' control (e.g. a Force Majeure event), and the target release date for a Batch of Excipient is late by thirty-five (35) days: (a) on the first occurrence of such late release during a calendar year, there shall be no late penalty; (b) on the second occurrence of such late release during a calendar year, there will be a reduction in the purchase price for such Batch of ten per cent (10%) of the purchase price. The Company will be responsible for dispositioning product in accordance with procedures detailed in the Quality Agreement.
- 3.4 <u>Delivery, Title and Risk of Loss</u>. All Excipient supplied by SAFC or its Affiliates hereunder shall be supplied FCA SAFC's shipping point. Delivery of the Excipient to the carrier at such SAFC shipping point shall constitute delivery to Company. Title to and risk of loss for the Excipient sold hereunder shall pass to the Company or its designee when the Excipient is delivered to the carrier at SAFC's shipping point. SAFC and its Affiliates reserve the right to make delivery in instalments of multiple Batches, all such instalments to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries.

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- 3.5 <u>Packaging</u>. SAFC and its Affiliates will preserve, package, handle, and pack all Excipient and Raw Materials so as to protect the Excipient and Raw Materials from loss or damage, in conformance with standard commercial practices, the Specifications, the Quality Agreement, government regulations and other applicable standards.
- 3.6 Raw Material Inventory. Prior to receipt of the first Forecast, the Parties shall meet and agree upon the quantities of Raw Materials SAFC shall have in inventory, in order to ensure that Forecast is delivered and maintain continuity supply during the applicable time frames. Thereafter, the parties shall engage at least quarterly to review Raw Materials requirements and inventory on hand, as well as the status of those suppliers from which Raw Materials are obtained, or, if manufactured by SAFC or its Affiliates the status of the relationship with respect thereto. Company agrees to reimburse SAFC for all costs related to any Raw Materials that expire or are otherwise unusable due to Company not ordering the quantities of Excipient in the Forecast, provided SAFC shall use Commercially Reasonable Efforts to ensure that any such excess Materials do not expire or become unusable (e.g., through the appropriate rotation of its Raw Materials inventory and reprocessing of Raw Material).
- 3.7 <u>Purchase of Raw Materials.</u> Company may also purchase Raw Materials from SAFC or its Affiliates as required for SAFC's Manufacture of Excipient at the Price in Exhibit 3 under the terms of the Agreement.
- 3.8 <u>Storage</u>. SAFC and its Affiliates shall hold all Excipient and Raw Materials under the storage conditions established pursuant to the Quality Agreement and, with respect to Excipient, in accordance with cGMP.

4. Rejection, Defects and Non-Conforming Goods

- 4.1 Nonconforming Goods. Within thirty (30) days from the date SAFC delivers Excipient to Company (or to a third party designated by Company) after Excipient release, Company shall have the right to determine whether such Excipient is Nonconforming Excipient. Any claim by Company that Excipient is Nonconforming Excipient shall be made in writing to SAFC or its Affiliates as applicable within such thirty (30) day period and shall be accompanied by a detailed report of analysis prepared by or on behalf of Company. If the Excipient contains a Latent Defect, then the thirty (30) day time period referred to herein shall not apply; provided that (i) Company notifies SAFC or its Affiliate promptly upon having reason to know of such Latent Defect (but in any event no later than ninety (90) days prior to the expiration of the Batch and (ii) the limitation on remedy and liability set out in Section 4.3 below shall apply with respect thereto.
- 4.2 <u>Disagreement Concerning Fulfilment of Requirements</u>. In the event of a disagreement concerning Nonconforming Excipient, Company and SAFC shall agree on an independent testing laboratory or quality expert on matters of compliance with cGMP, if applicable or Applicable Law of recognized standing in the industry selected by Company

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and approved by both Parties ("Laboratory") to determine whether any such Excipient was Nonconforming Excipient. The findings of the Laboratory shall be binding. The expenses related to such testing shall be borne by SAFC only if the testing confirms that the material is Nonconforming Excipient (unless the nonconformity was attributable to Company's negligence or wilful misconduct) and otherwise by Company. During any period that the Parties are in dispute regarding the conformity of the Excipient, SAFC, or as applicable its Affiliates shall, if requested by Company, replace such quantity of Excipient. Company shall pay for the original shipment of Excipient within thirty (30) days of requesting a replacement batch and shall pay for the replacement shipment of Excipient unless the Laboratory confirms the nonconformity of the original shipment, provided, however, that the Company is only obligated to pay for Excipient that is Non-conforming Excipient if the reason for the nonconformity is undetermined or is determined to be due to the fault of the Company or its contractors or licensees.

- 4.3 Remedies for Non-Conforming Product. If SAFC is notified within the notice period set forth in Section 4.1 that any Excipient delivered to Company is Nonconforming Excipient, SAFC or its Affiliates shall replace, at its own cost, the nonconforming Excipient with substitute Excipient that conforms to the Excipient Requirements within a commercially reasonable period not to exceed ninety (90) days from the date that Company notifies SAFC or its Affiliates of such non-conformity (unless the nonconformity is attributable to Company's negligence or wilful misconduct). Pursuant to written directions from SAFC or its Affiliates, Company shall either return the Non-conforming Excipient to SAFC or its Affiliates or destroy it, in each case, at SAFC's or its Affiliates' expense. If Company is directed, and agrees, to destroy Nonconforming Excipient, SAFC or its Affiliates shall pay to Company the documented out-of-pocket cost (without mark-up) of such destruction within thirty (30) days of such request following which Company will follow SAFC's or its Affiliates instructions regarding destruction. Company shall provide SAFC or its Affiliates, if requested a certificate certifying such destruction following completion. Except as provided for under Section 6.6 hereof regarding SAFC's indemnification obligations for third party claims, the remedy described in this Section 4.3 shall be Company's sole remedy and SAFC's and its Affiliates only liability for Nonconforming Excipient.
- 4.4 <u>Deviations and OOS</u>. At the request of either Party, the other Party and its Affiliates shall cooperate in the investigation and response to any Excipient complaints concerning Deviations and OOS, which may relate to SAFC's or its Affiliates role in the Manufacture of Excipient (in addition to complying with the corresponding provisions in the Quality Agreement).

5. Sales Prices and Terms of Payment

5.1 <u>Currency</u>. Except as otherwise expressly indicated, all references to "\$" or to "dollars" in this Agreement shall be read as referring to the legal tender of the United States of America.

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- 5.2 <u>Sales Prices</u>. The sales prices for Excipient Manufactured under this Agreement and released by SAFC's quality assurance department shall be the sales price designated on Appendix 3, after taking into account the credit for previous purchases of Raw Materials as detailed on Appendix 3. The sales prices are to be understood as packaged and ready for further processing at the facility of Company or of a third party designated in writing by Company, excluding costs of shipping, insurance and freight and further excluding applicable sales or other taxes (which will be applied as set forth in Section 5.6 hereof). All prices are quoted in United States Dollars.
- 5.3 Invoices and Payments. SAFC shall invoice Company after final release by the Company of the Excipient. Following final release of the Excipient, or request for shipment by Company, SAFC shall have not more than thirty (30) days to ship the Excipient unless Company has requested SAFC to store such Excipient. The Company shall have up to the time of final release to request either the shipment of the Excipient to Company or for storage by SAFC. Company shall make all payments in accordance with the invoices and Appendix 3. Further, all payments made hereunder are due within thirty (30) days from the date of the invoice. Payments shall be made in accordance with the instructions on the invoice. All payments hereunder shall be made in United States Dollars. If the Company requests that SAFC not ship Excipient upon release by Company, then SAFC shall store the Excipient for Company, and Company shall execute SAFC's standard Bill and Hold Letter Agreement passing title to and risk of loss of the Excipient to Company and authorizing SAFC to invoice Company for the Excipient upon final release by Company. In addition, if Company does not request shipment of stored Excipient within ninety (90) days of final release, then Company agrees to pay SAFC its standard storage fee for customer product stored on site at an SAFC facility. Unless SAFC is notified sooner of the final release or withholding of final release by Company of any Batch of Excipient, such Batch shall be deemed for purposes of invoicing and shipment to be finally released by Company thirty (30) days after SAFC's delivery of the completed Batch Records and other documents specified in the Quality Agreement for such Batch to Company. If Company withholds final release of any Batch of Excipient, Company shall provide in its notice to SAFC a written description of the specific defects in the Batch Record which caused Company to withhold final release of such Batch.
- 5.4 <u>Overdue Payments</u>. Company shall pay interest on all past-due amounts at a rate of interest equal to the lesser of 1.0% per month or the maximum rate permitted by Applicable Law.

5.5 Price Adjustment.

(a) Notwithstanding any other provision of this Agreement to the contrary, each year of the Term following the first year of the Term, with sixty (60) days prior written notice to Company, and in addition to any other price adjustment that may be permitted by this Agreement or otherwise agreed to by the Parties, SAFC may adjust the pricing applicable to Company's purchases of the Excipient for such year by an amount not to exceed the percentage increase in the U.S. Producer Price Index, PCU325412325412, Industry: Pharmaceutical preparation manufacturing,

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Product: Pharmaceutical preparation manufacturing, Base Date: 198106 (or any similar successor index) as reported by the U.S. Department of Labor Bureau of Labor Statistics from the Effective Date to the time of such written notice to Company reflecting such price increase. SAFC may also adjust the pricing applicable to the Company's purchases of Excipient hereunder by the documented increase in the price of raw materials received by SAFC from unrelated third parties and not manufactured by SAFC or its Affiliates for the Company.

5.6 Taxes.

- (a) If Company must withhold from any payment to SAFC or its Affiliates under this Agreement any taxes required to be withheld by Company under the Applicable Laws of any country, state, territory or jurisdiction, such amount shall be paid to the appropriate taxing authorities. Upon request, Company shall provide SAFC and its Affiliates with documentation of such withholding as is reasonably available to allow SAFC and its Affiliates to document such tax withholdings for purposes of claiming tax credits and similar benefits.
- (b) Any use tax, sales tax, excise tax, duty, custom, inspection or testing for, or any other tax, fee or charge of any nature whatsoever imposed by, any governmental authority, on or measured by the transaction between Company and SAFC or its Affiliates shall be paid by Company in addition to any other amounts due hereunder.

6. Recall, Warranties, Indemnification and Insurance

6.1 Recall.

- (a) Company shall be responsible for conducting any Recall arising out of or related to this Agreement (including without limitation any Recall of any Finished Product). SAFC and its Affiliates shall fully cooperate with and give all reasonable assistance to the Company to the extent the Recall relates to the Excipient, or as necessary to respond to inquiries from Regulatory Agencies. Further, SAFC and/or its Affiliates shall be responsible for the direct costs associated therewith to the extent that such recall is a result of SAFC's or its Affiliates failure to manufacture the Excipient or Raw Materials to its Specifications, or if such Recall directly results from a material breach of SAFC's or its Affiliates obligations hereunder, and/or of the Quality Agreement and/or from its gross negligence or wilful misconduct (in which case SAFC and/or its Affiliates shall be responsible for the direct costs and expenses associated with such Recall); provided, however, that to the extent such Recall or similar action is also due to Company's breach of its representations, warranties or obligations hereunder or under the Quality Agreement or from Company's or its Affiliates' or licensees' (if any) negligence or wilful misconduct, then SAFC's and its Affiliates liability for such Recall shall be reduced proportionately by the damages or losses attributable to Company. Otherwise, Company shall bear all expenses associated with any Recall. In the event of such Recall or similar action, each Party shall use commercially reasonable efforts to mitigate the costs associated therewith.
- (b) In the case of a disagreement as to the existence or level of Nonconforming Excipient or Nonconforming Raw Materials in connection with a Recall under Section 6.1(a) above, then the matter shall be referred to the Laboratory in accordance with Section 4.2 above. The decision of the Laboratory shall be final and binding on the Parties.

- 6.2 <u>Adverse Event Reporting</u>. Company shall be responsible for all reporting to Regulatory Authorities of Adverse Events. If SAFC becomes aware of any Adverse Events, it shall report all information in its possession regarding such event to Company as soon as practicable in order to allow Company to fulfil its regulatory reporting obligations within the time frames required by the Regulatory Agency(ies) and Applicable Laws after becoming aware of such information, and shall cooperate with Company as necessary to report such event to the Regulatory Agency(ies).
 - 6.3 SAFC Representations, Warranties and Covenants. SAFC hereby represents and warrants on behalf of itself and its Affiliates as follows:
 - (a) (i) The execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which SAFC or its Affiliates is a party or SAFC's or its Affiliates constituent documents, (ii) SAFC and its Affiliates are not prohibited or limited by any law or agreement (to which it is a party) from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by SAFC or its Affiliates as applicable;
 - (b) The Excipient shall be Manufactured and shipped in compliance with cGMP, the Specifications, and all other Applicable Laws, rules and regulations;
 - (c) All Excipient delivered by SAFC hereunder will conform to the Quality Agreement and the Specifications; and
 - (d) It is not debarred and has not and will not use, in performing its obligations under this Agreement in any capacity, the services of any person debarred under subsections 306(a) or (b) of the Generic Drug Enforcement Act of 1992.
 - (e) The Batch Records, executed Batch Records and written procedures maintained by SAFC will accurately reflect in all material regards the processes and procedures followed by it in the Manufacturing of the Excipient, and the records and written procedures maintained by its Affiliates will accurately reflect in all material regards the processes and procedures followed by it in the Manufacturing of the Raw Materials.

- (f) Each Certificate of Analysis will reflect the results of the tests conducted on the sample of Excipient or Raw Materials to which it relates.
- (g) SAFC and/or its Affiliates as applicable will have obtained and maintained in effect all such approvals and permits as may be required under Applicable Laws, rules, regulations and requirements to operate the Manufacturing facility for the Excipient or the Raw Materials for the purposes of Manufacturing Excipient and Raw Materials under the Quality Agreement and under this Agreement.
- 6.4 <u>Company Representations</u>, <u>Warranties and Covenants</u>. Company represents and warrants that (i) the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which Company is a party or Company's constituent documents, (ii) Company is not prohibited or limited by any law or agreement to which it is a party from entering into this Agreement and (iii) the performance of this Agreement will not create any conflict with any other business or activity engaged in by Company.
- 6.5 <u>Disclaimer</u>. 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 WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT.
- 6.6 <u>Company Indemnification</u>. Company shall indemnify, defend and hold harmless SAFC, its Affiliates and its or their directors, officers and employees from all actions, losses, demands, damages, fines, penalties, costs and liabilities arising from any third party claim (including reasonable attorneys' fees) to which SAFC is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:
 - (a) any breach by Company of any of its obligations or representations and warranties under this Agreement;
 - (b) any negligent act or omission or willful misconduct by Company, its Affiliates or its or their directors, officers, employees, agents or subcontractors;
 - (c) SAFC following any of Company's procedures as described in the Analytical Methods, the Manufacturing Process or the Specifications;
 - (d) Company's incorporation of the Excipient or the Raw Materials into the Finished Product;
 - (e) the labeling, marketing, distribution or sale by Company of the Finished Product;

- (f) the use of the Excipient in a use other than that for which it is described in a regulatory filing by Company, or of the Finished Product; or
- (g) the infringement by the Finished Product and/or the Excipient of any intellectual property or other proprietary rights of any third party.
- 6.7 <u>SAFC</u> Indemnification. SAFC shall indemnify, defend and hold harmless Company, its Affiliates and its or their directors, officers and employees from all actions, losses, demands, costs and liabilities arising from any third party claim (including reasonable attorney's fees) to which Company is or may become subject insofar as they arise out of or are alleged or claimed to arise out of:
 - (a) any breach by SAFC of any of its obligations or representations and warranties under this Agreement or the Quality Agreement; or
 - (b) any negligent act or omission or willful misconduct by SAFC, its Affiliates or its or their directors, officers, employees, agents or subcontractors.
- 6.8 <u>Limitation on Indemnification</u>. Provided, however, that neither Party shall have the obligation to indemnify, defend, and/or hold harmless the other Party, its Affiliates and its or their directors, officers and employees for any and all actions, losses, demands, damages, fines, penalties, costs and liabilities to the extent that such Party has an obligation to indemnify the other Party with respect to such actions, losses, demands, damages, fines, penalties, costs and/or liabilities pursuant to Section 6.6 or Section 6.7 above.
- 6.9 <u>Indemnification Procedure</u>. Either Party intending to seek indemnification from the other Party under Sections 6.5 or 6.6 above, as the case may be, shall give the other Party prompt notice of any such claim or lawsuit (including a copy thereof) served upon it and shall fully cooperate with the other Party and its legal representatives in the investigation of any matter which is the subject of indemnification. Such Party seeking indemnification shall not unreasonably withhold its approval of the settlement of any claim, liability or action covered by the above indemnification provisions. Notwithstanding the foregoing, the failure to give timely notice to the indemnifying Party shall not release the indemnifying Party from any liability to the Party seeking indemnification to the extent the indemnifying Party is not prejudiced thereby.
- 6.10 <u>Company Insurance</u>. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for five (5) years after the expiration or termination of this Agreement, Company shall obtain and maintain commercial product liability insurance with limits of not less than \$10,000,000 per occurrence for product liability. With respect to all insurance coverage required under this Section 6.8, (i) Company shall, promptly upon SAFC's request, furnish SAFC with certificates of insurance evidencing such insurance and (ii) in the event of any reduction in coverage, termination or cancellation of any such policy shall provide no less than thirty (30) days' prior written notice of reduction in coverage, termination or cancellation.

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

6.11 SAFC Insurance. Without limiting its liability under this Agreement (except as may be otherwise expressly provided in this Agreement), during the Term and for five (5) years after the expiration or termination of this Agreement, SAFC shall obtain and maintain product liability insurance (including through self-insurance) with limits of not less than \$10,000,000 per occurrence for general liability and product liability. With respect to all insurance coverage required under this Section 6.9, SAFC shall, promptly upon Company's request, furnish Company with certificates of insurance evidencing such insurance or other similar evidence if self-insured.

7. Regulatory Matters; Quality; Compliance with Laws

- 7.1 Regulation of Manufacturing Process. If SAFC or its Affiliates are required by the FDA, EMA, or any other Regulatory Agency to validate or re-validate Manufacturing processes that will impact the Manufacturing of Excipient or Raw Materials as the case may be, SAFC or its Affiliates shall notify Company and consult with Company regarding the required activities, provided, however, that if such requested changes are solely related to the Excipient, SAFC shall inform the Company promptly and the requested changes will be discussed and agreed to between the parties. SAFC or its Affiliates shall be responsible for the costs of any such validation or re-validation that is required due to the non-compliance of the SAFC Manufacturing facility with cGMPs or Applicable Law applicable generally to manufacturing in SAFC's facility; otherwise any such costs that are specific to the Manufacturing of the Excipient or Raw Materials shall be borne by Company.
- 7.2 <u>Correspondence</u>. SAFC and its Affiliates will notify Company (pursuant to the Quality Agreement) promptly upon receipt of any correspondence from a Regulatory Agency, which relates to the Excipient or Raw Materials. In addition, SAFC shall provide to the Regulatory Agencies all documents and information requested by such authority, and shall submit to all inquiries, audits and inspections by the Regulatory Agencies.
- 7.3 <u>Quality Agreement</u>. Within one (1) month following the execution of this Agreement, the Parties shall execute a revised Quality Agreement in substantially the form attached to this Agreement as Appendix 1. In the event of a conflict between the terms of this Agreement and the Quality Agreement, this Agreement shall control except with respect to matters relating to compliance with cGMPs as specified in the responsibility matrix and related regulations, in which case, the Quality Agreement will control.
- 7.4 <u>Records.</u> SAFC and its Affiliates shall maintain all quality assurance manufacturing records, Batch Records, executed Batch Records and other records directly related to the Manufacture of Excipient or Raw Materials required by any applicable Regulatory Agency, in a secure area reasonably protected from fire, theft and destruction.

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- 7.5 <u>Regulatory Documents and Support.</u> SAFC and its Affiliates shall provide to Company such documentation as may be requested by a Regulatory Agency and necessary support, including copies of documents, required for regulatory filings by Company.
- 7.6 Regulatory Inspections. SAFC and its Affiliates shall reasonably accommodate requests made on behalf of Company by a Regulatory Agency to inspect the Manufacturing facility and or any Qualified Alternate Facility. SAFC and its Affiliates shall reasonably accommodate GMP audits or other required audits by Company in preparation for such inspections if necessary. SAFC and its Affiliates shall use commercially reasonable efforts to support such audits. To the extent practicable, SAFC and its Affiliates shall inform Company of such any inspections directly or indirectly related to the Excipient or Raw Materials and shall permit two (2) representatives to be present during those portions of such inspections that relate to the Excipient or Raw Materials. SAFC and its Affiliates shall promptly provide the Company with information reasonably requested by Company and information requested by a governmental or Regulatory Agency in the course of an inspection related to or affecting the Excipient or Raw Materials. SAFC and its Affiliates shall provide Company with a summary of the observations made by Regulatory Agencies and the plan to correct any deficiencies related to the Excipient or Raw Materials and those areas of the Facility that are directly related to the manufacture of the Excipient or Raw Materials following each inspection.
- 7.7 Access to Facilities. Company and/or its' designees will have routine access (subject to SAFC's standard safety, security and confidentiality policies and procedures) on no more than three months' prior written notice, to SAFC's and its Affiliates manufacturing facilities at mutually agreeable times for the purpose of auditing SAFC's and its Affiliates compliance with cGMP regulations as defined and/or Applicable Law, and for overall compliance with the relevant legislation, and with respect to the manufacture of Excipient or Raw Materials on Company's behalf; provided, however, if a For Cause Audit, is required by Company, SAFC or its Affiliates as applicable will allow Company or its designees to access SAFC and its Affiliates manufacturing facilities with ten (10) days notice at no cost. Except with respect to For Cause Audits, routine audits will be limited to one (1) audit every calendar year at no cost and will be conducted by a reasonable number of employees or representatives of Company or its designees who are subject to the same requirements of confidentiality as Company.
- 7.8 <u>Compliance with Laws; Authorizations</u>. In performing this Agreement, each Party shall (i) comply with all Applicable Law and regulations and (ii) obtain all releases, licenses, permits or other authorization required by any governmental body or authority.

8. Confidentiality; Intellectual Property License

8.1 <u>Confidentiality Obligations of SAFC</u>. In the course of the performance of this Agreement, Company may, from time to time, disclose Confidential Information of Company to SAFC or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, SAFC and its Affiliates shall: (i) maintain in confidence and not

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disclose the Confidential Information of Company to any third party, except on a need-to-know basis to SAFC's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with SAFC's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of Company for any purpose other than the performance of SAFC's and/or its Affiliates' obligations hereunder.

- 8.2 <u>Confidentiality Obligations of Company</u>. In the course of the performance of this Agreement, SAFC and its Affiliates may, from time to time, disclose Confidential Information of SAFC to Company or its Affiliates. Except as expressly permitted otherwise by the terms of this Agreement, Company shall: (i) maintain in confidence and not disclose the Confidential Information of SAFC and its Affiliates to any third party, except on a need-to-know basis to Company's (or its Affiliates') employees and agents to the extent such disclosure is reasonably necessary in connection with Company's (or its Affiliates') activities as expressly authorized by this Agreement and upon obligations of confidentiality similar to those set forth herein; and (ii) not use or grant the use of the Confidential Information of SAFC and its Affiliates for any purpose other than the performance of Company's obligations hereunder.
- 8.3 Exceptions. The provisions of Sections 8.1 and 8.2 above shall not apply to any Confidential Information of the disclosing Party that can be shown by competent evidence by the receiving Party:
 - (a) To have been known to or in the possession of the receiving Party without any separate obligation of confidentiality before the date of its actual receipt from the disclosing Party;
 - (b) To be or to have become readily available to the public other than through any act or omission of any Party in breach of any confidentiality obligations owed to the disclosing Party;
 - (c) To have been disclosed to the receiving Party, other than under an obligation of confidentiality, by a third party which is not known to the receiving Party to have had an obligation to the disclosing Party not to disclose such information to others; or
 - (d) To have been subsequently independently developed by the receiving Party without use of or reference or access to the disclosing Party's Confidential Information.
- 8.4 <u>License</u>. During the Term, Company hereby grants to SAFC a royalty-free, non-exclusive license under any know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the Excipient or the Manufacture of the Excipient that are owned or controlled by Company and that are necessary for SAFC's performance of its obligations under this Agreement,

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but only for such purposes and only to the extent useful for SAFC to perform its obligations under this Agreement. During the Term, Company hereby grants to Affiliates of SAFC, as applicable, a royalty-free, non-exclusive license under any know-how, trade secrets, copyrights, designs, databases, discoveries, improvements and/or inventions (whether patentable or not) related to the Manufacture of the Raw Materials that are owned or controlled by Company and that are necessary for such party's performance of its obligations under this Agreement, but only for such purposes and only to the extent useful for such party to perform its obligations under this Agreement.

9. Term and Termination

- 9.1 <u>Term</u>. The initial period of this Agreement shall commence as of the Effective Date and shall continue in full force and effect until the fifth (5th) yearly anniversary of the Commencement Date, unless earlier terminated as provided in Sections 9.2 and 9.3 below. Thereafter the Agreement shall be renewed automatically for additional three (3) year periods, unless cancelled by one of the Parties upon at least twelve (12) months prior written notice. Such initial period and any renewal period shall be referred to herein as the "Term".
 - 9.2 <u>Termination</u>. Notwithstanding the provisions of Section 9.1 above, the Parties may terminate this Agreement in the event of either of the following:
 - (a) <u>Termination for Material Breach</u>. Either Party may terminate this Agreement by written notice at a date set in the notice (allowing at least one hundred and twenty (120) days for cure, except for default in payment obligations that are the subject of a good faith dispute for which the cure period is sixty (60) days) in the event of a material breach of this Agreement by the other Party; provided that the breaching Party fails to cure such breach within one hundred and twenty (120) days from the date of such notice; and further provided that the cure period for failure to pay an invoice when due (which is a material breach of this Agreement) is sixty (60) days.
 - (b) Termination by Company. The Company may terminate this Agreement, upon ninety (90) days' notice, under the following circumstances: (i) SAFC delivers two Batches that are determined to be Non-conforming Excipient during any twelve (12) month period, which are not replaced by SAFC with conforming Batches of Excipient within sixty (60) days following notification from the Company that such Batches are Non-conforming Excipient; (ii) three (3) or more Batches of Excipient, which are conforming Excipient, are delivered within any twelve (12) month period more than sixty (60) days after the delivery date established for the order (excluding Batches covered under (i) above, which are replacement Batches); or (iii) SAFC rejects any validly placed order for reasons other than Force Majeure.
 - (c) <u>Insolvency</u>. If either Party shall become insolvent or shall make or seek to make an arrangement with, or an assignment for the benefit of creditors,

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or if proceedings in voluntary or involuntary bankruptcy shall be instituted by, on behalf of or against such Party, or if a receiver or trustee of such Party's assets shall be appointed, or bankruptcy proceedings begin, the other Party may terminate this Agreement, as may be permitted by the Applicable Laws, with immediate effect.

9.3 Rights and Obligations Upon Termination.

- (a) <u>Technology Transfer</u>; <u>Return of Inventory and Confidential Information</u>. In the event of any termination, SAFC and its Affiliates as applicable shall return to Company: (i) all Company property at Company's expense, unless such termination shall have been as a result of a breach of this Agreement by SAFC or its Affiliates in accordance with Section 9.2(a), in which case such property shall be returned at SAFC's or its Affiliates' expense, except and solely to the extent required to be retained by law or to comply with such Party's continuing obligations hereunder or for purposes of dispute resolution or litigation; (ii) all Confidential Information of Company (except and solely to the extent required to by retained by law or to comply with SAFC's continuing obligations hereunder or for purposes of dispute resolution or litigation) and shall make no further use of such Confidential Information without the prior written consent of Company and (iii) shall reasonably cooperate with the Company in supporting a Technology Transfer to a Third Party supplier, provided, however, that in the event termination is due to a default by the Company, SAFC's obligations shall be solely to provide all records and other data related to the Manufacturing or Excipient or Raw Materials in its possession.
- (b) <u>Payments.</u> Termination of this Agreement shall not release either Party from the obligation to make payment of all amounts then or thereafter due and payable. Upon termination of this Agreement by SAFC pursuant to Section 9.2(a), Company shall take delivery and pay for all Excipient or Raw Materials that is subject to an open purchase order, pay all monies due and owing pursuant to this Agreement and reimburse SAFC and its Affiliates for its costs for all material, work in process, finished Excipient or Raw Materials and all other outstanding inventory (meaning all raw materials that are specifically required and purchased by SAFC for the manufacture of the Excipient) to the extent that such items were reasonably acquired by SAFC or its Affiliates to meet its obligations hereunder in a timely manner, and make such other payments to SAFC or its Affiliates as may be set forth in <u>Appendix 3</u> hereto.
- 9.4 <u>Surviving obligations</u>. Termination or expiration of this Agreement shall not affect any accrued rights or obligations of either Party. The terms of Sections 2.7(b), 2.7(c), 2.13, all of 4, 5.3, 5.4, 5.6, 6.1, 6.3 through 6.11, 8.1 through 8.3, 9.3, 9.4, all of 10 and all of 11 of this Agreement shall survive termination of this Agreement.

10. Governing Law; Dispute Resolution

- 10.1 <u>Governing Law</u>. This Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of New York, USA, without regard to its conflict of law provisions. The U.N. Convention on International Sales of Goods shall not apply to this Agreement.
- 10.2 <u>Good Faith Meeting</u>. In the event of any dispute arising between the Parties concerning this Agreement, Company and SAFC and its Affiliates agree that in the first place they shall meet for good faith discussions in an attempt to negotiate an amicable solution.

10.3 Arbitration.

- (a) Any dispute arising between the Parties out of or in connection with this Agreement, or the interpretation, breach or enforcement thereof that cannot be amicably resolved pursuant to Section 10.2 above within two (2) months as from the first appearance of such dispute shall be finally settled by arbitration as set forth in this Section 10.3.
- (b) The arbitration shall be conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that both Parties are domestic United States companies or in accordance with the International Arbitration Rules of the American Arbitration Association in effect at the time of the arbitration to the extent that one of the Parties is not a domestic United States company, except, in each instance, as such rules may be modified herein or by mutual agreement of the Parties.
 - (c) The seat of the arbitration shall be New York City, New York, USA, and it shall be conducted in the English language.
- (d) The arbitration shall be conducted by three arbitrators. The Party initiating arbitration ("Claimant") shall appoint an arbitrator in its request for arbitration ("Request"). The other Party ("Respondent") shall appoint an arbitrator within thirty (30) days of receipt of the Request and shall notify the Claimant of such appointment in writing. If within thirty (30) days of receipt of the Request by the Respondent, either Party has not appointed an arbitrator, then that arbitrator shall be appointed by the American Arbitration Association. The first two arbitrators appointed in accord with this provision shall appoint a third arbitrator within thirty (30) days after the Respondent has notified Claimant of the appointment of the Respondent's arbitrator or, in the event of a failure by a Party to appoint, within thirty (30) days after the American Arbitration Association has notified the Parties and any arbitrator already appointed of its appointment of an arbitrator on behalf of the Party failing to appoint. When the third arbitrator has accepted the appointment, the two arbitrators making the appointment shall

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promptly notify the Parties of the appointment. If the first two arbitrators appointed fail to appoint a third arbitrator or so to notify the Parties within the time period prescribed above, then the American Arbitration Association shall appoint the third arbitrator and shall promptly notify the Parties of the appointment. The third arbitrator shall act as Chair of the tribunal.

- (e) The arbitral award shall be in writing, state the reasons for the award, and be final and binding on the Parties. The award may include an award of costs, including reasonable attorneys' fees and disbursements. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets.
 - (f) Notwithstanding Section 10.1 hereof, the arbitration and this Section 10.3 shall be governed by Title 9 (Arbitration) of the United States Code.
- (g) The Parties agree that the arbitration shall be kept confidential and that the existence of the proceeding and any element of it (including but not limited to any pleadings, briefs or other documents submitted or exchanged, any testimony or other oral submissions, and any awards) shall not be disclosed beyond the tribunal, the American Arbitration Association, the Parties, their counsel and any person necessary to the conduct of the proceeding, except as may be lawfully required in judicial proceedings relating to the arbitration or otherwise.

11. Miscellaneous

- 11.1 <u>Conditional Effectiveness</u>. The effectiveness of this Agreement is conditioned upon Company and SAFC duly executing and delivering the Quality Agreement.
- 11.2 <u>Publicity</u>. Any public announcement or similar publicity with respect to this Agreement will be issued, if at all, at such times and in such manner as shall be mutually agreed in writing by the Parties. Notwithstanding the foregoing, any disclosure of this Agreement required by Applicable Law shall not be prohibited.
- 11.3 <u>Use of Names</u>. SAFC and its Affiliates shall not use the name of Company or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of Company. Company shall not use the name of SAFC or its Affiliates or the names of their employees, or representatives or Affiliates in any advertising materials or in any publication without prior written consent of SAFC. Notwithstanding the foregoing, Company shall be entitled to identify SAFC and its Affiliates as the source of the Excipient in any regulatory submission without SAFC's prior written consent, and either Party may provide such disclosure as may be required by Applicable Law.
- 11.4 Marks. Each Party reserves all rights to any name, trademark, service mark or logo ("Marks") it may have or hereafter acquire. Neither Party shall by this Agreement

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obtain any right, title or interest in or to any Marks of the other Party or its Affiliates. Accordingly, neither Party shall use any Marks confusingly similar to or likely to cause confusion with the Marks of the other or of any other person or entity. Each use by a Party of any Marks of the other Party, whether in advertising or marketing materials, websites, company announcements or offering circulars, informational materials, public events, or otherwise, shall be subject to the prior written approval of the other Party.

11.5 Limitation of Liability.

- (a) NOTWITHSTANDING ANYTHING HEREIN (OR IN ANY RELATED AGREEMENT OTHER THAN A PROPERLY EXECUTED AMENDMENT) TO THE CONTRARY, EXCEPT WITH RESPECT TO A BREACH OF ARTICLE 8 OR FRAUD BY A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (SUCH AS LOST PROFITS) OR ANY SPECIAL OR PUNITIVE DAMAGES ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, WHETHER BASED ON CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE AND REGARDLESS OF WHETHER ANY PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
- (b) NOTWITHSTANDING ANYTHING HEREIN (OR IN ANY RELATED AGREEMENT OTHER THAN A PROPERLY EXECUTED AMENDMENT) TO THE CONTRARY, EXCEPT IN THE CASE OF THE GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT OF SAFC, THE MAXIMUM AGGREGATE LIABILITY OF SAFC TO COMPANY FOR ANY CAUSE OF ACTION (OR RELATED CAUSES OF ACTION) ARISING OUT OF OR RELATED TO THIS AGREEMENT AND/OR THE DELIVERY OF THE EXCIPIENT SHALL NOT EXCEED THE AMOUNT ACTUALLY PAID BY COMPANY TO SAFC PURSUANT TO THIS AGREEMENT FOR THE EXCIPIENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRECEDING THE CLAIM GIVING RISE TO THE LIABILITY.
 - (c) The foregoing limitations in Section 11.5(a) and (b) above shall survive notwithstanding any failure of essential purpose of a limited remedy.

11.6 Assignment; Successors; Subcontractors; Third-Party Beneficiaries.

(a) Neither Party may assign or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of the other Party, which will not be unreasonably withheld, except that (i) either Party may assign, in whole or in part, without such consent any of its rights or obligations under this Agreement to any Affiliate of such Party, provided that any such assignment to an Affiliate shall not relieve the assignor as the primary obligor hereunder and/or (ii) either Party may assign in connection with the merger, consolidation or sale of the stock or substantially all of the assets of the business responsible for the performance of this Agreement, other than to a competitor of the other Party hereto with respect to the Finished Product, in which case such Party in question shall have the right to withhold consent to such assignment.

- (b) Subject to the preceding subsection (a), this Agreement will apply to, be binding in all respects upon, and inure to the benefit of the successors and permitted assigns of the Parties.
- (c) Notwithstanding any other provisions of this Agreement to the contrary, SAFC or its Affiliates may use one or more subcontractors (including, without limitation, any Affiliate of SAFC) in the performance of its obligations hereunder with written permission of Company, such approval not to be unreasonably withheld, as long as it exercises appropriate diligence in the selection of such subcontractors and remains primarily liable for the performance of its obligations hereunder. With respect to any work performed by any Affiliate of SAFC in connection with this Agreement, the Parties agree and acknowledge that SAFC shall include the work performed by its Affiliate and the related charges, with reasonable accompanying detail, on those invoices submitted to the Company by SAFC in the regular course. Such work will be subject to the terms and conditions of this Agreement irrespective of the source of the invoice.
- (d) Nothing expressed or referred to in this Agreement will be construed to give any person other than the Parties any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement. This Agreement and all of its provisions and conditions are for the sole and exclusive benefit of the Parties to this Agreement and their successors and assigns.
- 11.7 <u>Transactions Outside Scope of Agreement</u>. Other than as expressly provided for otherwise in this Agreement, this Agreement shall in no way limit or restrict the ability of either Party or any Affiliate of such Party to offer its products or services to any other person.
- 11.8 No Transfer of Rights. No transfer, grant or license of rights under any patent or copyright or to any intellectual property, proprietary information and/or trade secret is made or is to be implied by this Agreement except as may be expressly stated otherwise herein.
- 11.9 <u>Independent Contractors</u>. The Parties undertake to carry out this Agreement as independent contractors. No franchise, partnership, joint venture or relationship of principal and agent is intended by this Agreement. Neither Party is authorized, in the name of or on behalf of the other Party, to incur any obligation, receive any benefit or right or otherwise bind the other Party. All employees, agents, representatives and contractors of a Party are solely those of such Party and no acts thereof will be binding upon the other Party.
- 11.10 <u>Waiver</u>. The failure or the delay of any Party hereto to enforce at any time any provision of this Agreement shall not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce such provision. No waiver of any breach of this Agreement shall be held to constitute a waiver of any other or subsequent breach of this Agreement.

- 11.11 <u>Severability</u>. Should any provision of this Agreement become void or be cancelled, then the other provisions shall remain in full force and effect. If a provision of this Agreement should be void or should be declared void, then the Parties will attempt to replace it by another valid provision or will leave the provision unreplaced by mutual consent. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.
 - 11.12 Appendices. All appendices attached hereto are hereby incorporated in and made a part of this Agreement as if fully set forth herein.
- 11.13 Entire Agreement. This Agreement, including all appendices hereto, contains the final, complete and exclusive agreement of the Parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter.
- 11.14 <u>Amendment</u>. This Agreement shall not be deemed or construed to be modified, amended, rescinded, cancelled or waived, in whole or in part, except by written amendment signed by the Parties hereto.
- 11.15 Notices. All notices, consents, waivers and other communications under this Agreement must be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt), (ii) sent by facsimile (with written confirmation of transmission), (iii) when received by the addressee if sent by registered or certified mail (return receipt requested) or if sent by an internationally recognized overnight delivery service, in each case to the appropriate addresses and facsimile numbers set forth below (or to such other addresses and facsimile numbers as a Party may designate by notice to the other Party):

If to Company: Heron Therapeutics, Inc.

Attention: SVP, Technical Operations

123 Saginaw Drive

Redwood City, California 94063 Telephone: 650-366-2626

Fax: 650-365-6490

With a copy to: Heron Therapeutics, Inc.

Attention: General Counsel:

123 Saginaw Drive

Redwood City, California 94063

Fax: 650-365-6490

Facsimile No.: 650-365-6490

If to SAFC: SAFC, Inc.

645 Science Drive Madison, WI 53711 Attention: Site Director Facsimile No.: 608-233-6873

Pursuant to 17 CFR 20.24b-2, confidential information has been omitted in places marked "***" and has been filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Application with the Commission.

With a copy to: SAFC

3050 Spruce Street St. Louis, Missouri 63103 Attention: Legal Department Facsimile No.: 314.286.8005

- 11.16 <u>Section Headings</u>; <u>Construction</u>. The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. Unless otherwise expressly provided, the word "including" does not limit the preceding words or terms.
- 11.17 <u>Force Majeure</u>. Any events that cannot be prevented by SAFC or its Affiliates, such as fire, flood, war, strike, civil unrest, terrorism, natural catastrophes, government acts and regulations, and other events beyond SAFC's or its Affiliates reasonable control, will free SAFC and its Affiliates for the duration of the event from its obligations under this Agreement. As soon as there is an indication of an event of force majeure, SAFC or its Affiliates will advise Company within ten (10) days or as soon as practical of the effect of such event on this Agreement and about the measures to be taken to mitigate such effect. The Parties are obligated to mitigate damages and to resume the fulfilment of the contractual obligations as quickly as possible.
- 11.18 Expenses. Except as otherwise expressly provided in this Agreement, in the appendices hereto or in any agreement or other document expressly referenced herein and forming a part hereof, including the Quality Agreement, each Party to this Agreement will bear its respective expenses incurred in connection the performance of its obligations hereunder. In the event of termination of this Agreement, the obligation of each Party to pay its own expenses will be subject to any rights of a Party arising from a breach of this Agreement by the other.
- 11.19 <u>Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.
- 11.20 <u>Governing Language</u>. The validity, interpretation, construction and performance of this Agreement shall be in accordance with the English language. If this Agreement is translated into another language and there is a conflict between the non-English version and the English version, then the English version shall control.

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IN WITNESS WHEREOF, the Parties intending to be bound by the terms and conditions hereof have caused this Agreement to be signed effective as of the Effective Date by their duly authorized representatives.

SAFC, INC. HERON THERAPEUTICS, INC.

By: /s/ Patrick S. Klipstine By: /s/ Paul Marshall

Name: Patrick S. Klipstine Name: Paul Marshall

Title: Director, Operations

Title: SVP Tech Ops

12/18/15

APPENDIX 1

QUALITY AGREEMENT

Quality Agreement between Company and SAFC and its Affiliates, as amended, supplemented or restated from time to time (actual version).

[Redacted in its entirety—29 pages omitted]

APPENDIX 2

SPECIFICATIONS

The Specifications for the Excipient with be as per the then current version of the controlled document: FPS 200-658 (SPEC-MAD-FPS-005916) or successor document agreed in writing by the Parties.

**

[Redacted in its entirety—5 pages omitted]

APPENDIX 3

PRICING

Annual Commitment (Batches)*	*Price per l	Kg of ***	 Price/Batch **)
1-4 Batches	\$	***	\$ ***
5-15 Batches	\$	***	\$ ***
>15 Batches	\$	***	\$ ***

^{*} Assumes batch sizes between *** kgs.

Pricing is per kg predicated on targeted Batch size of approximately *** of Excipient. Only full Batches may be ordered, not increments. If an approved process change results in a different target Batch size, the per unit prices will be recalculated and negotiated in good faith.

Volume pricing will apply based on the Contract Year's four-quarters forecast as of Jan 1st of each year, beginning January 1st 2016 ("Contract Year"). In the event the Forecast changes during the Contract Year whether by increase or decrease, the per kg pricing will be recalculated at the end of the year as of December 31st, applicable to all Excipient to have been delivered and accepted during the Contract Year, as follows:

- (a) In the event the actual number of Batches purchased was less than the forecast for the Contract Year, Heron will pay to SAFC the difference between the price per unit paid, and the applicable per unit price based on actual Batches purchased. Such invoice and payments will be per the terms of the Agreement.
- (b) In the event the actual number of Batches purchased for the Contract Year exceeds the forecast, SAFC will either refund to Heron, or credit to outstanding Firm Orders, at SAFC's option, the difference between the price per unit paid by Heron, and the applicable per unit price based on actual Batches purchased unless it is the final year of the contact in which case SAFC will refund to Heron such amount.

Pre-purchased Raw Materials

Heron has purchased inventories of the Proprietary Raw Materials *** and *** that are presently stored at SAFC as agreed between the parties 23rd October 2013.

SAFC will provide a credit off the commercial price per kg of the price sated above when the purchased inventory is used. The amount of such credit is outlined in the table below. When these inventories are consumed or their usefulness has been excluded due to quality requirements necessary to make *** to established specifications, the pricing for *** will revert to the established per kg price outlined above.

<u>Item</u> ***	Credit/kg of ***
***	\$ ***
***	\$ ***

APPENDIX 4

PROPRIETARY RAW MATERIALS

All defined terms have the meaning assigned to them in the Supply Agreement.

Chemical Name: *** Structure: ***
Specification: ***

Name: *** Structure: ***
Specification: ***

List of Proprietary Raw Materials

Purchase and Delivery of Proprietary Raw Materials

Raw Materials can be purchased at the Price indicated below and the Price adjusted per Section 5.5. Orders should be placed for the standard batch sizes indicated below at least ninety (90) days prior to delivery. The Raw Material will be shipped in accord with shipment instructions provided in writing by the Company at the time of order placement. The Raw Materials will be delivered matching the Specifications indicated above along with a Certificate of Analysis, executed Batch Records, analytical test results, and copies of Raw Material Specifications for such Batch of Raw Materials.

All other terms will be as per the appropriate Section of this Agreement.

Price: \$***
Standard batch size: ***

Price: \$***
Standard batch size: ***

SECTION 302 CERTIFICATION

I, Barry D. Quart, certify that:

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

Date: December 23, 2016 /s/ Barry D. Quart

Barry D. Quart, Pharm.D. Chief Executive Officer (As Principal Executive Officer)

SECTION 302 CERTIFICATION

I, Brian G. Drazba, certify that:

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

Date: December 23, 2016 /s/ Brian G. Drazba

Brian G. Drazba Vice President, Finance and Chief Financial Officer (As Principal Financial and Accounting Officer)