	Execution Version - SEDAR+ Version
MENDED AN	ND RESTATED SUPPLY AND DISTRIBUTION AGREEMENT
MENDED AN	ND RESTATED SUPPLY AND DISTRIBUTION AGREEMENT  Dated as of May 6, 2025
MENDED AN	

# TABLE OF CONTENTS

ARTICLE 1
RULES OF CONSTRUCTION; SCHEDULES AND APPENDICES

Section 1.1	Amended and Restated Supply and Distribution Agreement	
Section 1.2	Interpretive Conventions.	
Section 1.3	Legal Review.	3
	ARTICLE 2	
AI	PPOINTMENT; EXCLUSIVITY; NON-EXCLUSIVITY; NON-COMPETE	
Section 2.1	Appointment of Vantive as Exclusive Distributor of PMX Product in Canad	
	tates of America	
Section 2.2 Section 2.3	Appointment of Vantive as Non-Exclusive Distributor of EAA Product  Non-Compete Spectral Covenant	
	ARTICLE 3	
	GOVERNANCE	
Section 3.1	JSC	5
Section 3.2	JSC Meetings	5
Section 3.3	JSC Responsibilities.	5
Section 3.4	JSC Dispute Procedure.	5
	ARTICLE 4	
	REPORTS	
Section 4.1	Reports; Data and Regulatory Submissions; and Payments	6
	ARTICLE 5	
	REGULATORY	
Section 5.1	Responsibility	6
Section 5.2	Pharmacovigilance	7
Section 5.3	Regulatory Authority Proceedings	7
Section 5.4	Product Labeling	7
Section 5.5	Vantive Responsibilities.	8
Section 5.6	Vantive's Ability to Act as Marketing Authorization Holder for EAA Produ	cts8
	ARTICLE 6	
	COMMERCIALIZATION OF PRODUCT	
Section 6.1	Standard of Care and Costs	8
Section 6.2	Promotional.	8
Section 6.3	Training	9
	ARTICLE 7	
	PURCHASE, SUPPLY AND DELIVERY OF PRODUCT	
Section 7.1	Forecast and Purchase Orders.	9

Section 7.2	Minimum Purchase Requirements for PMX Products	10
Section 7.3	Continuity of Supply.	10
Section 7.4	Shipment; Delivery; Late Deliveries	11
Section 7.5	Product Warranty; Acceptance.	12
	ARTICLE 8	
	CONSIDERATION AND PAYMENTS/INVOICING	
Section 8.1	Product Price.	
Section 8.2	Consideration.	
Section 8.3	Taxes.	
Section 8.4	Invoicing and Payment.	14
	ARTICLE 9	
	RECORDS	
Section 9.1	Records.	14
	ARTICLE 10	
	QUALITY; PRODUCT RECALL	
Section 10.1	Notices	14
Section 10.2	Quality	14
Section 10.3	Recall of Products.	15
	ARTICLE 11	
	THIRD PARTY OFFERS	
Section 11.1	Third Party Offers	16
	ARTICLE 12	
	REPRESENTATIONS AND WARRANTIES	
Section 12.1	Mutual Representations.	16
Section 12.2	Spectral Representations.	16
Section 12.3	Vantive's Representations	19
Section 12.4	Compliance.	
Section 12.5	DISCLAIMER	21
	ARTICLE 13	
	INTELLECTUAL PROPERTY RIGHTS	
Section 13.1	Trademark Licenses.	
Section 13.2	Product Rights.	
Section 13.3	Inventions and Intellectual Property Rights.	22
	ARTICLE 14	
	INDEMNIFICATION; LIMITATION OF LIABILITY	
Section 14.1	Spectral Indemnification.	
Section 14.2	Vantive's Indemnification	23

Section 14.3	Indemnification Procedure.	24
Section 14.4	IP Injunction	24
Section 14.5	Limitation of Liability	24
	ARTICLE 15	
	CONFIDENTIAL INFORMATION; PRESS RELEASE	
Section 15.1	Definition.	24
Section 15.2	Terms Confidential.	25
Section 15.3	Restrictions	
Section 15.4	Exclusions from Obligation of Confidentiality	25
Section 15.5	Equitable Remedies.	26
Section 15.6	Liability for Representatives	26
Section 15.7	Press Releases.	26
	ARTICLE 16	
	ADDITIONAL COVENANTS	
Section 16.1	Insurance.	26
	ARTICLE 17	
	TERM AND TERMINATION	
Section 17.1	Term	27
Section 17.2	Termination by Vantive.	28
Section 17.3	Termination by Spectral.	
Section 17.4	Discontinuation of Product.	28
Section 17.5	Effect of Termination or Expiration	28
Section 17.6	Accrued Claims and Survival.	29
Section 17.7	Bankruptcy	29
	ARTICLE 18	
	FORCE MAJEURE	
Section 18.1	Force Majeure.	29
Section 18.2	Notification.	30
	ARTICLE 19	
	MISCELLANEOUS PROVISIONS	
Section 19.1	Notices.	
Section 19.2	Entire Agreement.	
Section 19.3	Choice of Law.	
Section 19.4	Alternate Dispute Resolution.	
Section 19.5	Amendment; Waiver	
Section 19.6	Severability.	
Section 19.7	Relationship of the Parties.	
Section 19.8	Counterparts	
Section 19.9	Beneficiaries.	
Section 19.10	Assignment.	32

Section 19.11	Electronic Signature	33
Section 19.12	List of Schedules and Appendices.	33
	Definitions.	
Section 19.14	Other Terms.	8
	Other Terms.	

## ADDENDA

Schedule "A" Definitions
Schedule "B" Territory

Schedule "B-1" Product Specifications

Schedule "C" Product Prices

Schedule "D" Ethics & Compliance Standards for Vantive Suppliers It Is Critical That

All Vantive Suppliers Share Our Commitment to Business with Integrity

#### AMENDED AND RESTATED SUPPLY AND DISTRIBUTION AGREEMENT

THIS AMENDED AND RESTATED SUPPLY AND DISTRIBUTION AGREEMENT (this "Agreement") is effective as of May 6, 2025, (the "Effective Date") between Vantive US Healthcare LLC, a Delaware limited liability company having its principal place of business at 1 Baxter Parkway, Deerfield, IL 60015 ("Vantive"), and Spectral Medical Inc. ("Spectral"), a corporation organized and existing under the laws of Ontario, whose principal offices are located at 135 The West Mall, Toronto, Ontario, Canada M9C 1C2. Each of Vantive and Spectral is hereinafter referred to as "Party" and collectively as "Parties").

#### RECITALS

**WHEREAS**, Baxter Healthcare Corporation ("**Baxter**") and Spectral entered into a Supply and Distribution Agreement on February 3, 2020, as amended October 28, 2022, September 6, 2023 and February 1, 2024 (collectively, the "**Original Supply and Distribution Agreement**");

WHEREAS, on January 31, 2025, Baxter completed the sale of its Kidney Care segment business to Carlyle, to be carried on though Vantive and, in connection therewith, the Original Supply and Distribution Agreement was assigned by Baxter to Vantive with the consent of Spectral;

**WHEREAS,** Vantive provided Spectral with \$6,500,000.00 USD (\$6.5 million) in licensing fees and \$4,500,000.00 USD (\$4.5 million) in convertible notes maturing in November 2026;

**WHEREAS**, Vantive and Spectral entered into a senior secured promissory note, dated May 6, 2025;

**WHEREAS**, the Parties wish to amend and restate the Original Supply and Distribution Agreement on the terms set forth in this Agreement;

**WHEREAS**, Spectral manufactures, sells and distributes certain proprietary reagents, and is currently focused on developing and commercializing a treatment for septic shock utilizing Spectral's proprietary Endotoxin Activity Assay diagnostic (the "**EAA Product**"), and Spectral's licensed extracorporeal blood purification device known as the Toraymyxin Hemoperfusion Absorption Column (the "**PMX Product**");

**WHEREAS**, Vantive develops, manufactures, distributes and sells a variety of medical devices, ancillaries and disposables ("Vantive Products");

WHEREAS, Spectral has entered into an Exclusive Distribution Agreement with Toray Medical Co., Ltd., a Japanese corporation, dated November 10, 2010, pursuant to which Spectral has the exclusive right to distribute the PMX Product in Canada (the "Canadian Toray Agreement");

**WHEREAS**, Spectral entered into an original License and Material Supply Agreement with Toray Industries, Inc., a Japanese corporation ("**Toray**"), dated March 6, 2009, which has been replaced by the Amended and Restated License and Material Supply Agreement with Toray, dated June 10, 2014, pursuant to which Spectral has the exclusive right to pursue clinical testing

and commercialization of the PMX Product in the United States and Puerto Rico (the "**U.S. Toray Agreement**");

WHEREAS, under each of the Canadian Toray Agreement and the U.S. Toray Agreement, Toray has the exclusive right to manufacture the PMX Product, and has agreed to supply the PMX Product to Spectral, and Spectral agreed to purchase the PMX Product from Toray on an exclusive basis for sale in the United States and Canada, subject to an obligation under the U.S. Toray Agreement to negotiate in good faith with Spectral to transfer (whether by assignment or license) to Spectral all rights necessary to allow Spectral or a third party to manufacture the PMX Product in the event that Toray ceases to manufacture the PMX Product;

**WHEREAS**, under each of the Canadian Toray Agreement and the U.S. Toray Agreement, Spectral has the right to use sub-distributors;

WHEREAS, Spectral desires to grant exclusive distribution rights for the PMX Product to Vantive in Canada, and the exclusive distribution rights for the PMX Product in the United States, in each case subject to the terms of this Agreement;

**WHEREAS**, Spectral desires to appoint Vantive as a non-exclusive distributor of the EAA Product, subject to the terms of this Agreement;

**NOW, THEREFORE**, in consideration of the foregoing recitals and the mutual representations, warranties, covenants and agreements contained herein, the Parties hereto agree as follows:

# ARTICLE 1 RULES OF CONSTRUCTION; SCHEDULES AND APPENDICES

## Section 1.1 Amended and Restated Supply and Distribution Agreement.

The Original Supply and Distribution Agreement is amended, restated and superseded in its entirety in accordance with the terms and conditions of this Agreement;

## **Section 1.2 Interpretive Conventions.**

Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be understood to be followed by the words "without limitation." Pronouns, including "he," "she" and "it," when used in reference to any Person, shall be deemed applicable to entities or individuals, male or female, as appropriate in any given case. Standard variations on defined terms (such as the plural form of a term defined in the singular form, and the past tense of a term defined in the present tense) shall be deemed to have meanings that correlate to the meanings of the defined terms. Article, Section and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define or limit the scope, extent or intent of any provision of this Agreement. When a reference is made in this Agreement to a Recital, an Article, a Section, a Schedule or an Exhibit, such reference is to a Recital, Article or Section of, or a Schedule or Exhibit to, this Agreement, unless otherwise indicated. All references to "dollars" or "\$" shall be deemed to be references to the lawful currency of the United States.

#### Section 1.3 Legal Review.

This Agreement was negotiated by the Parties with the benefit of legal representation, and any rule of construction or interpretation otherwise requiring this Agreement to be construed or interpreted against either Party by reason of such Party having drafted this Agreement shall not apply to any construction or interpretation hereof. Subject to Section 19.6, this Agreement shall be interpreted and construed to the maximum extent possible so as to uphold the enforceability of each of the terms and provisions hereof, it being understood and acknowledged that this Agreement was entered into by the Parties after substantial and extended negotiations and with full awareness by the Parties of the terms and provisions hereof and the consequences thereof.

# ARTICLE 2 APPOINTMENT; EXCLUSIVITY; NON-EXCLUSIVITY; NON-COMPETE

# Section 2.1 Appointment of Vantive as Exclusive Distributor of PMX Product in Canada and the United States of America.

- (1) Subject to all terms and conditions of this Agreement,
  - (a) Canada. Spectral hereby appoints Vantive, with effect only if and after Vantive has paid the Upfront Exclusive Rights Payment, and Vantive hereby accepts such appointment, as Spectral's exclusive distributor of the PMX Product in Canada, with the right to distribute directly to end users or indirectly through Vantive's Affiliates and network of independent distributors and other marketing partners (collectively, "Permitted Sellers"), provided that Vantive gives written notice to Spectral of the identity of such independent distributors and marketing partners within 5 days of such appointment,
  - (b) United States of America. Spectral hereby appoints Vantive, with effect only if and after Vantive has paid the Upfront Exclusive Rights Payment, and Vantive hereby accepts such appointment, as Spectral's exclusive distributor of the PMX Product in the United States, with the right to distribute directly to end users or indirectly through Permitted Sellers, provided that Vantive gives written notice to Spectral of the identity of such independent distributors and marketing partners within 5 days of such appointment. The appointments in Section 2.1(1)(a) and Section 2.1(1)(b) are referred to collectively as the "Exclusive Distribution Rights". Vantive shall be entitled to retain the Exclusive Distribution Rights as long as it pays both Milestone Exclusivity Payments and meets the Minimum Purchase Requirements set out in Section 7.2.
  - (c) In the event that Vantive does not pay each of the Milestone Exclusivity Payments, then Spectral may terminate the Exclusive Distribution Rights and at the same time appoint Vantive as a non-exclusive distributor of the PMX Product in Canada and the United States of America. [Redacted]
  - (d) Vantive shall be responsible for the performance by the Permitted Sellers, and shall be responsible for any breach of this Agreement by the Permitted Sellers. While the Exclusive Distribution Rights are in effect, Spectral shall not grant such

rights to any other Person, and Spectral shall not, either directly or indirectly, promote, sell, market, or distribute the PMX Product in the Exclusive Territory during the Term, but may, at the sole and exclusive discretion of Vantive, provide assistance to Vantive in the marketing and promotion of the PMX Product.

- (e) In connection with Vantive's Exclusive Distribution Rights, Vantive shall not be held to a "best efforts" standard as construed by judicial precedent, but shall be required to comply with its obligations under Section 6.1 and to otherwise use commercially reasonable promotion, marketing, sales and distribution efforts, [Redacted] all based on then prevailing conditions.
- (2) Violation of Exclusive Distribution Rights. If Vantive notifies Spectral, or Spectral otherwise becomes aware, of any other Person that is, either directly or indirectly, promoting, marketing, selling or distributing the PMX Product in the Exclusive Territory, Spectral shall take all reasonable steps to cause such Person to immediately cease such activities. In case of any breach of this Section 2.1(2) by Spectral or its distributors, Vantive shall provide notice to Spectral, and, without limiting remedies otherwise available to Vantive, Spectral shall have a 30-day period in which to put in place a remediation plan to promptly cure any such breach.

# Section 2.2 Appointment of Vantive as Non-Exclusive Distributor of EAA Product.

- (1) Subject to all terms and conditions of this Agreement, Spectral hereby appoints Vantive in the Non-Exclusive Territory, and Vantive hereby accepts such appointment, as Spectral's non-exclusive distributor of the EAA Product in the Non-Exclusive Territory, either directly to end users or indirectly through its Permitted Sellers. (The foregoing appointment and license grant are referred to collectively as the "Non-Exclusive EAA Distribution Rights".)
- (2) Vantive shall be responsible for the performance by the Permitted Sellers, and shall be responsible for any breach of this Agreement by the Permitted Sellers. In connection with Vantive's Non-Exclusive EAA Distribution Rights, Vantive shall not be held to a "best efforts" standard as construed by judicial precedent, but shall be required to use commercially reasonable promotion, marketing, sales and distribution efforts that are consistent with Vantive's efforts in connection with the EAA Product that present a comparable marketing opportunity as part of Vantive's Acute Therapies business.

# Section 2.3 Non-Compete Spectral Covenant.

For the Term of this Agreement (including any extension), while Vantive has an exclusive distribution right in a particular territory, Spectral shall not, directly or indirectly, Commercialize the PMX Product in that territory (except as expressly required to fulfil Spectral's obligations under this Agreement, i.e. the importation and storage of products) or Commercialize a Competing Product, or grant any third party the right to do so, or manufacture or have manufactured the PMX Product for Commercialization by any third party in such territory.

# ARTICLE 3 GOVERNANCE

## Section 3.1 JSC.

Promptly after the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC") to facilitate dialogue between the Parties in order to share information and cooperate as reasonably necessary or advisable with respect to the activities contemplated by this Agreement, including clinical, regulatory, supply, marketing and Commercialization activities and each Party's compliance with Applicable Laws. The JSC shall be comprised of two representatives of each Party ("JSC Representatives"). The initial JSC Representatives of Vantive shall be the Vice President, Acute Marketing and Sr Director, Business Development for the Acute Therapies business unit. The initial JSC Representatives of Spectral shall be John Kellum, Chief Medical Officer and Chris Seto, Chief Executive Officer. Each Party may elect to change one or both of its JSC Representatives by express written notice to the other Party no less than five days prior to any JSC meeting.

### Section 3.2 **JSC Meetings.**

The JSC shall meet within sixty (60) days after the Effective Date and, thereafter, as agreed by the parties, but no less than once every other month for the first twelve (12) months and then at least quarterly thereafter. The location of meetings of the JSC shall take place at a location agreed by the parties. The JSC may also meet by means of a telephone conference call or videoconference. The JSC will meet in person at least once per year, alternating locations between Deerfield, Illinois, United States of America and Toronto, Ontario, Canada unless otherwise agreed. If a JSC member of a Party is unable to attend a meeting, such Party may designate a suitable alternate to attend such meeting in place of the absent member. In addition, a Party may, at its discretion, invite non-voting employees who are necessary for the purposes and responsibilities of the JSC to attend the meetings of the JSC.

## Section 3.3 JSC Responsibilities.

The Parties agree to provide mutual support as may be reasonable to facilitate each Party's performance under this Agreement. The JSC shall be a forum for consultation and coordination concerning the Commercialization of the Products, as further described in the Agreement, including at least: (a) management of performance of objectives; (b) discussion of either Party's concerns regarding the other Party's performance of its responsibilities hereunder, including discussion of any disputes between the Parties; (c) discussion of any other issue that was not foreseen as of the Effective Date; (d) attempting to resolve disputes, if any; and (e) performing such other tasks and undertaking such other responsibilities to which the parties may jointly agree. For the avoidance of doubt, the Parties acknowledge that the JSC shall have no decision-making authority and shall not have the power or authority to bind either or both Parties.

#### Section 3.4 JSC Dispute Procedure.

The Parties agree that disputes will be raised to the JSC and that the Parties will work in good faith to resolve any such dispute, if possible, prior to escalation. Either Party may convene a special meeting of the JSC for the purpose of resolving disputes. In the event a matter within

the authority of the JSC cannot be agreed by unanimous consent, the General Manager, Acute Therapies for Vantive and Chris Seto, Chief Executive Officer for Spectral (the "Senior Executives") will attempt to resolve the matter. If a resolution is not reached by the Senior Executives, the Parties will settle the matter through arbitration in accordance with Section 19.4.

# ARTICLE 4 REPORTS

## Section 4.1 Reports; Data and Regulatory Submissions; and Payments.

## (1) Seller Reports.

Within thirty (30) days of the end of each calendar quarter during the Term, Vantive will provide a written report to Spectral which sets out: [Redacted].

## (2) Spectral Clinical Trial Data and Regulatory Submissions.

Spectral shall provide Vantive with access to all PMX related clinical trial data including the EUPHRATES study and the TIGRIS Study; provided that TIGRIS Study data shall be provided only upon conclusion of the TIGRIS Study ("TIGRIS Final Data"). Additionally, Spectral shall provide Vantive with a copy of Spectral's proposed premarket notification ("Proposed Premarket Notification" or "PMA") submission to the FDA for the PMX Product.

## (3) Vantive Regulatory Submissions.

[Redacted]

# ARTICLE 5 REGULATORY

#### Section 5.1 Responsibility.

(1) Spectral shall be solely responsible, at its cost and expense, to complete the Tigris Study. Assuming that the Tigris Final Data provides a clinical basis for pursuing a Marketing Authorization for the PMX Product in the United States, Spectral shall use commercially reasonable efforts to make approval submissions and obtain Marketing Authorizations for the PMX Product in the United States as promptly as practicable after the TIGRIS Final Data is obtained, subject to any agreed plans, and to comply with pharmacovigilance and labeling requirements in respect of the Products. For the avoidance of doubt, if Vantive does not make the Initial Milestone Exclusive Rights Payment, Spectral shall have the sole and exclusive discretion as to whether to cancel the Tigris Study. If Vantive does make the Initial Milestone Exclusive Rights Payment, the discretion as to whether to cancel the Tigris study shall be mutually held by Vantive and Spectral. Spectral's responsibility for Marketing Authorizations for the PMX Product shall include preparing and submitting all Regulatory Filings and conducting all communications and interactions with the FDA and other Regulatory Authorities and taking all other action required to obtain, and at all times thereafter maintain, such Marketing Authorizations for the PMX Product, and to require Toray to maintain the Canadian Marketing Authorization for the PMX Product.

- Spectral will maintain the Marketing Authorizations for the EAA Product in Canada, the United States and the European Union.
- (2) Coordination. To the extent permitted by Applicable Laws, Spectral shall keep Vantive reasonably informed of all material communications and submissions with Regulatory Authorities relating to the Marketing Authorizations.
- (3) Spectral shall provide Vantive with access to Regulatory Filings and supporting material as needed to support negotiation of pricing and reimbursement.

## Section 5.2 Pharmacovigilance.

Spectral shall be responsible, at its cost and expense, to file all required safety reports with the FDA or other Regulatory Authorities relating to the Products in the Territories. Spectral will maintain the medical device regulation and vigilance database for the Products and will be responsible for compliance with the applicable regulations and corresponding reporting obligations. Spectral shall manage all Product-related complaints from customers, patients and commercial partners and shall be responsible for the management of, and all costs associated with, such compliance; provided, that Spectral may utilize a third party provider to perform some or all of such responsibilities, and Vantive will cooperate with the exchange of adverse event and safety information associated with use of the Products in the Exclusive Territory.

## **Section 5.3 Regulatory Authority Proceedings.**

If Spectral is subject to, or receives written notice of, an actual or threatened inspection, investigation, inquiry, import or export ban, product seizure, Enforcement Action or similar action by a Regulatory Authority with respect to a Product (whether within or outside the Territories) or Manufacturing Facility in which a Product is Manufactured, it shall notify Vantive, within two (2) Business Days after its receipt of notice, of the action. Spectral shall keep Vantive informed of the outcome of any inspection. Spectral shall inform Vantive prior to making any regulatory commitments that will be binding on or adversely impact Vantive with respect to any Product in the Exclusive Territory, including, but not limited to, any impact on supply. Vantive shall have the right to review and provide input with respect to such regulatory commitments, and Spectral shall consider such comments in good faith.

## Section 5.4 Product Labeling.

All PMX Products to be distributed by Vantive pursuant to this Agreement shall be labeled and packaged using the TORAYMYXIN™ PMX-20R brand name and trade dress in accordance with the applicable Regulatory Authority requirements. All EAA Products to be distributed by Vantive pursuant to this Agreement shall be labeled and packaged using the EAA brand name and trade dress in accordance with the applicable Regulatory Authority requirements. Spectral shall, at its expense, produce and provide to Vantive a draft copy of any and all labeling for the Products, including all artwork, labels, product inserts and packing for the Products, for Vantive's review and comment. Spectral will provide, and Vantive shall have the right to publish on its website, sample label and instructions for use ("**IFU**") for each Product. Spectral hereby grants to Vantive all rights and licenses necessary to publish the sample labels and instructions for use, solely for the purpose of publishing such label and IFU. [Redacted]

## Section 5.5 Vantive Responsibilities.

Vantive will maintain distribution records and all information needed to perform Recalls of the Products distributed by Vantive and its Permitted Sellers.

# Section 5.6 Vantive's Ability to Act as Marketing Authorization Holder for EAA Products.

With the prior written consent of Spectral, Vantive may seek Marketing Authorization for the EAA Product in any country of the world in which Spectral does not have such Marketing Authorizations, at Vantive's sole cost and expense. Spectral shall provide, at its sole cost and expense, all reasonable assistance and information required by Vantive with respect to such activities from time to time, including transferring all applicable documentation to Vantive and making available all Spectral personnel as necessary for Vantive to make applicable submissions and obtain (as part of such submission process) and maintain any such Marketing Authorization. The Parties acknowledge and agree that in each country in which Vantive has agreed to act as holder of the Marketing Authorization at any time during the Term, Vantive shall be responsible for the release of Products in such country, and shall be entitled, in its sole discretion, to make all decisions related thereto.

# ARTICLE 6 COMMERCIALIZATION OF PRODUCT

#### Section 6.1 Standard of Care and Costs.

Vantive shall use commercially reasonable efforts, as defined in Section 2.1(1)(e), to Commercialize the Products entirely on its own behalf and at its own expense and in compliance with all Applicable Laws and the Marketing Authorizations.

## Section 6.2 Promotional.

## (1) Marketing Plan; Promotional Materials.

Vantive shall have sole responsibility and control over, and will bear all costs and expenses of, the marketing materials and strategy for the Products. All marketing materials shall be consistent with the approved claims and technical characteristics provided by Spectral for use by Vantive. Within thirty (30) days after the grant of the first Approval for the PMX Product and, as soon as practicable, after the execution of this Agreement for the EAA Product, Spectral shall provide Vantive with copies of the approved package insert for the Products. Vantive shall then promptly, based on the above, create, develop and format promotional materials used for the Commercialization of the Products. Vantive will provide such promotional materials to Spectral for Spectral's review.

#### (2) Legal Compliance.

Vantive shall be responsible for ensuring compliance with Applicable Laws and Marketing Authorizations for all promotional materials and training developed by Vantive for the Products (collectively, the "Marketing Materials"), and shall not use any Marketing Materials or make any product claims for the Products that fail to comply with Applicable Laws and the

Marketing Authorizations. However, notwithstanding anything contained in this Agreement to the contrary, in no event shall Vantive's failure to satisfy its obligation contained in this Section 6.2(2) constitute a breach under this Agreement for which Spectral shall have the right to terminate this Agreement. [Redacted]

## (3) Ownership.

Vantive shall own all copyright in and to all Marketing Materials, and, to the extent reasonably requested by Vantive, Spectral shall, at Vantive's cost and expense, execute all documents and take all actions reasonably requested by Vantive to vest title to such Marketing Materials in Vantive. In no event shall this Section 6.2(3) be interpreted to confer any rights or interest to Vantive in the Spectral Trademarks or any other IP Rights of Spectral, except and only to the extent expressly otherwise provided for in Section 13.1 of this Agreement. Spectral shall not have the right to use any of the content contained in the Marketing Materials, except with the express written consent of Vantive, which consent may be granted or withheld at Vantive's sole discretion. In the event of termination or expiration of this Agreement, Spectral will not use identical copies of the Marketing Materials, but may reproduce the product claims and technical characteristics that are derived from the Marketing Authorizations.

## Section 6.3 Training.

Spectral shall cooperate with Vantive in the establishment of any necessary training programs, including technical sales training, system for real-time technical advice regarding the Products, and customer field support (e.g., effective response to product complaints and warranty claims), for Vantive's marketing and sales personnel and for opinion leaders, physicians and other healthcare professionals in the Territory. The frequency, timing, location, content and other material aspects of such training shall be determined jointly by Vantive and Spectral. [Redacted]

# ARTICLE 7 PURCHASE, SUPPLY AND DELIVERY OF PRODUCT

#### Section 7.1 Forecast and Purchase Orders.

#### (1) Forecasts.

Vantive shall provide Spectral, on or before the last day of each calendar quarter a written non-binding rolling twelve (12)-month forecast (each a "Rolling Forecast"), specifying [Redacted]. The Parties acknowledge and agree that the Initial Forecast is for planning purposes only, may not be accurate and shall be non-binding.

- (2) Purchase Orders and Limits.
  - (a) [Redacted]
  - (b) [Redacted]
- (3) Inconsistent Terms.

Purchases of the Products pursuant to this Agreement shall be upon the terms and conditions specified in this Agreement and such terms and conditions shall govern all purchases hereunder and shall take precedence over any inconsistent, conflicting or additional language as may exist on Purchase Orders, invoices, confirmations, order acknowledgments or other forms or communications of either Vantive or Spectral, except for quantities, delivery dates and shipping instructions, or unless otherwise expressly agreed in writing by both Parties.

## **Section 7.2 Minimum Purchase Requirements for PMX Products**

(1) Minimum Purchase Requirement.

[Redacted]

(2) Adjustment to Minimum Purchase Requirements.

[Redacted]

(3) Failure to Achieve Minimum Purchase Requirements.

[Reacted]

## Section 7.3 Continuity of Supply.

(1) Responsibility.

Vantive acknowledges and agrees that Toray has the sole right to Manufacture the PMX Product, and it is the expectation of all Parties that PMX Product supplied under this Agreement will be Manufactured by Toray. Spectral shall be solely responsible for the Manufacture and supply the EAA Products. Spectral shall Manufacture the EAA Product and cause Toray to Manufacture the PMX Products in compliance with the applicable Product Warranty, Marketing Authorizations and Applicable Laws and Vantive shall not be responsible for any Manufacturing costs.

(2) Disaster Recovery and Business Continuity Program.

At all times during the Term, Spectral will maintain and adequately support a disaster recovery and business continuity program ("Disaster Recovery and Business Continuity Program") that ensures the continuous operation and, in the event of an interruption, the recovery of all material business functions needed to meet Spectral's obligations under this Agreement. The Parties will prepare a disaster recovery plan for the PMX Products as part of the Joint Steering Committee activities.

(3) Manufacturing Capacity.

[Redacted]

(4) Delivery of Products by Air

[Redacted]

(5) Safety Stock.

[Redacted]

(6) Failure to Supply.

[Redacted]

- (7) Cessation of Manufacture of PMX Product by Toray
  - (a) In the event that Toray ceases to manufacture the PMX Product, Spectral will negotiate in good faith with Toray to transfer (whether by assignment or license) to Spectral all IP Rights necessary to allow Spectral or a third party to begin manufacture of the PMX Product. If Vantive has exclusive rights to the PMX Product under this Agreement at that time, Spectral agrees in the first instance to negotiate in good faith with Vantive regarding Vantive manufacturing the PMX Product.

## (8) [Redacted]

## Section 7.4 Shipment; Delivery; Late Deliveries.

(1) Shipping.

Spectral shall or shall cause Toray to inspect, package, label, store and ship the Product in compliance with the Product Warranty and the applicable Firm Purchase Orders (including the quantity and desired delivery date specified therein) and in accordance with commercial and industry practice. Each Product shall be shipped from a Manufacturing Facility (the "Point of Shipment") using a carrier selected by Vantive to a destination designated by Vantive in the applicable Accepted Order (the "Point of Destination").

### (2) Delivery.

Delivery of Product shall be EXW (Incoterms 2010) Point of Shipment (Incoterms 2010), and in accordance therewith: (i) Spectral shall deliver the Product to the Point of Shipment; (ii) Vantive shall bear the costs of freight, transportation, shipping and insurance from the Point of Shipment to the Point of Destination; (iii) a bill of lading will be furnished to Vantive with respect to each shipment; (iv) title and risk of loss shall pass to Vantive upon acceptance of the Product by Vantive at the Point of Shipment; (v) Spectral shall be deemed to have delivered the Product on the date of delivery to the Point of Shipment (the "Date of Delivery"); and (vi) Vantive, at its own expense, shall clear Product for export and obtain any export licenses with respect thereto, and, at its own expense, shall clear Product for import into the Territory and obtain any import licenses with respect thereto. Spectral shall provide Vantive with any information required to clear Product for export and/or import.

## (3) Expedited Shipping.

Except due to Vantive's act or omission, for any Product that is delivered twenty (20) or more Business Days after the delivery date specified in a Firm Purchase Order and confirmed by Spectral, Spectral shall pay for expedited shipping to Vantive's customers.

## Section 7.5 Product Warranty; Acceptance.

# (1) Warranty for Product.

- (a) Spectral represents and warrants to Vantive and its Permitted Sellers that the Products delivered to Vantive hereunder will be produced in accordance with and conform in all respects to the Product Specifications, has been manufactured, handled, packaged and stored in accordance with Applicable Laws, the relevant quality agreements, and the Marketing Authorizations, and will be free from any defects (including design, engineering, material, manufacture and label defects) for the term ending on the expiration date of the sterility defined on the label of each PMX Product or EAA Product (collectively, "Product Warranty"). In addition, Spectral represents and warrants to Vantive that the Products delivered to Vantive hereunder will be free of liens, security interests or encumbrances of any nature imposed by or through Spectral.
- (b) Spectral shall not be responsible for the quality of any Products when: (i) such Products have been stored by Vantive in improper conditions; (ii) when the Products are used without following the instructions for use provided by Spectral and/or Toray; (iii) when the Products are used with improper or defective components; (iv) when the labels on the Products have been removed, defaced or altered; and (v) when the Products have been improperly repaired or reformed.

## (2) Inspection.

Vantive shall within thirty (30) days following the delivery of a shipment of Product by Spectral (i) visually inspect such shipment and (ii) review the relevant documentation submitted to Vantive, and shall notify Spectral of any non-conformance of the shipment to the Product Warranty ("Non-Conforming Product") to the extent discovered by Vantive. In such notification, Vantive shall specify in reasonable detail such non-conformance.

#### (3) Latent Defects.

Within thirty (30) days after Vantive's discovery that a shipment of Product or portion thereof contains a Latent Defect, Vantive shall notify Spectral of such Latent Defect, specifying in reasonable details such Latent Defect.

#### (4) Remedies.

If either (a) Vantive has notified Spectral that a shipment of Product(s) or any portion thereof is non-conforming with the Product Warranty or (b) a Recall is required due to Spectral's breach of the Product Warranty, then Spectral shall use commercially reasonable efforts to promptly manufacture, release and supply to Vantive the quantity of Product equivalent to the quantity of Non-Conforming Product(s) at no cost to Vantive. In circumstances where Spectral

has not replaced any Non-Conforming Product within two (2) months, at Vantive's option, Spectral shall provide Vantive with a refund for the Non-Conforming Product(s). Vantive shall, at Spectral's cost and expense, either return to Spectral such Non-Conforming Product or the non-conforming portion thereof or destroy such Non-Conforming Product, as directed by Spectral within its sole discretion.

# ARTICLE 8 CONSIDERATION AND PAYMENTS/INVOICING

#### **Section 8.1** Product Price.

- (1) [Redacted]
- (2) [Redacted]
- (3) Product Price per Unit. Vantive shall pay for each Unit of Product delivered to Vantive hereunder the applicable Product Price set forth on attached Schedule "C" (for each Product, the "**Product Price**" and collectively, the "**Product Prices**"), which pricing may be revised by mutual agreement of the Parties throughout the Term.

#### Section 8.2 Consideration.

- (1) The Parties acknowledge that on February 4, 2020, Baxter paid to Spectral the sum of \$5,000,000.00 USD (\$5 million) pursuant to Section 8.2(1) of the Original Supply and Distribution Agreement (the "**Upfront Exclusive Rights Payment**").
- (2) The Parties acknowledge that on February 16, 2024, Baxter paid to Spectral the further sum of \$1,500,000.00 USD (\$1.5 million) pursuant to Section 8.2(2) of the Original Supply and Distribution Agreement (the "Initial Milestone Exclusive Rights Payment"), as partial consideration for a grant of exclusive distribution rights for the PMX Product in the United States.
- (3) Within ninety (90) days of regulatory approval of the PMA for PMX in the United States, Vantive shall have the right to make a second exclusive rights payment to Spectral (the "Second Milestone Exclusive Rights Payment"), in the amount specified below, as the second part of the consideration for a grant of exclusive distribution rights for the PMX Product in the United States. For the avoidance of doubt, the determination of whether to make the Second Milestone Exclusive Rights Payment shall be at Vantive's sole discretion. The amount of the Second Milestone Exclusive Rights Payment shall be \$[Redacted] if the Relative Mortality Benefit is [Redacted] or greater and \$[Redacted] if the Relative Mortality Benefit is less than [Redacted].

#### Section 8.3 Taxes.

Product Prices do not include any applicable sales, use, gross receipts, excise, value-added, or any similar transaction or consumption taxes imposed on the supply of Products to Vantive under this Agreement ("**Taxes**"). Vantive shall be liable for such Taxes and shall pay such

Taxes that are properly invoiced to Vantive. Spectral and Vantive shall each be responsible for taxes imposed on its own income, property or capital.

## Section 8.4 Invoicing and Payment.

- (1) General.
  - (a) Upon shipment of Product, Spectral shall be entitled to submit an invoice therefor to Vantive, [Redacted]
- (2) Disputed Payments.

Vantive may escrow any amounts due hereunder if Vantive (a) in good faith disputes the amount claimed by Spectral to be due hereunder, or Spectral fails to provide with its invoices any required documentation and (b) provides Spectral with notice of such dispute or missing documentation within thirty (30) days after the date of Vantive's receipt of the applicable invoice. Documentation shall mean the Purchase Order number, Spectral's order number, the invoice date, the ship-to name and address, the Vantive Code(s) shipped and the quantities shipped. Vantive's notice of disputed payment shall include a written description of the nature of the disputed claim. Spectral and Vantive will cooperate in good faith to investigate any lost or misdirected shipments of Products.

## ARTICLE 9 RECORDS

#### Section 9.1 Records.

The Parties shall keep sufficient records regarding their respective activities under this Agreement, including true and accurate books and records and reasonable supporting documentation which may be necessary for determining the Parties' compliance with their obligations under this Agreement. Such books and records shall be kept for a period of at least four (4) calendar years after expiration of the Term or termination of this Agreement, unless a longer period is required under the Parties' document retention policies or by Applicable Laws.

# ARTICLE 10 QUALITY; PRODUCT RECALL

#### Section 10.1 Notices.

Spectral shall promptly notify Vantive in writing of any material issues relating to the safety or efficacy of the Products of which Spectral is aware.

## Section 10.2 Quality.

(1) Quality Agreement for Toray Product.

[Redacted]

(2) Quality Agreement for EAA Products.

#### [Redacted]

## (3) Batch Records.

Spectral covenants that records which include information relating to the manufacturing, packaging and quality operations for each lot of Products will be prepared at the time the manufacturing thereof occurs, in accordance with all Applicable Laws. Spectral shall keep batch records for each lot of Products for the period of time required by the Applicable Law.

## (4) Compliance with Laws.

The Parties' obligations set forth in this ARTICLE 10 are intended to comply with Applicable Law in both Territories. The requirements of this ARTICLE 10 shall therefore be construed and interpreted to comply with all such laws, rules and regulations. To the extent provisions of this ARTICLE 10 do not adequately reflect any such law, rule or regulation, such provisions shall be revised via a written amendment to this Agreement signed by both Parties, to the extent reasonably necessary to make such provisions legal and valid in accordance with such laws, rules and regulations.

#### Section 10.3 Recall of Products.

### (1) Administration of Product Recall.

Any recall or market withdrawal or other corrective action (as defined in the relevant quality agreements) related to the Products in both Territories (collectively a "Recall") shall be administered by Spectral (including, without limitation, contacts to the FDA), and Vantive shall provide to Spectral or its designee all reasonable assistance. Vantive shall execute the Recall by completing the actions required by the appropriate Regulatory Authority. Recall letters, if required by the appropriate Regulatory Authority, shall be prepared jointly by Vantive and Spectral, but Spectral shall have the final say over the wording of any such letters.

## (2) Recall Decision.

If either Party intends to perform a Recall of Products in either Territory, then such issue shall be first discussed and agreed upon with the other Party promptly. In the event that the Parties cannot agree about a Recall, Spectral shall be entitled to make the final decision about such Recall. Without limiting the foregoing, a Recall shall be performed in the event of any of the following conditions: (a) a Recall is requested by a Regulatory Authority in a Territory, (b) Products pose a clear and present danger to patient safety or (c) Vantive is the holder of the Marketing Authorizations and determines that a Recall is required.

#### (3) Recall Expenses.

The Recall Expenses associated with any Recall shall be borne by Spectral, except to the extent such Recall is required as a result of Vantive's act or omission. "**Recall Expenses**" means all out of pocket costs directly associated with a Recall, including costs (i) of notifying customers, (ii) of examining the Products, (iii) associated with the return shipment and destruction of

Recalled Product, (iv) associated with the shipment of Products in replacement of Recalled Product, and (v) associated with the Products tracking and reporting.

## ARTICLE 11 THIRD PARTY OFFERS

## **Section 11.1** Third Party Offers

[intentionally deleted]

# ARTICLE 12 REPRESENTATIONS AND WARRANTIES

# **Section 12.1** Mutual Representations.

Each Party hereby represents and warrants to the other Party that, as of the date hereof:

## (1) Organization; Good Standing.

It is a corporation or other form of legal entity duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or organization, and has all requisite corporate or equivalent power and authority to conduct its business and engage in the transactions provided for in this Agreement.

## (2) Authority; Binding Obligation.

The execution, delivery and performance by it of this Agreement, and the consummation by it of the transactions contemplated hereby and thereby, have been duly authorized and approved by all necessary corporate or equivalent action on its part. This Agreement has been duly executed and delivered by it and constitutes its legal, valid and binding obligation, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency or other laws relating to or affecting creditors' rights generally and by general equity principles.

#### (3) No Conflicts.

Its execution and performance of this Agreement will not violate any Applicable Laws, Orders, corporate or equivalent organizational documents, contracts or agreements by which it is bound.

#### (4) Consents.

It is not obligated to obtain any approvals, exemptions or consents from, or to provide any notices to, any Governmental Authority or Third-Party to enter into and perform its obligations under this Agreement, except for the Marketing Authorizations.

#### Section 12.2 Spectral Representations.

(1) Spectral hereby represents and warrants to Vantive that, as of the date hereof:

## (a) Grant of Rights.

Spectral has the legal and valid right to grant the rights being granted to Vantive pursuant to this Agreement. Spectral has not granted to any Third-Party the right to Commercialize the PMX Product in the Exclusive Territory. Spectral has not entered into any contract, commitment or agreement or granted any license or right that would conflict with the rights granted to Vantive under this Agreement.

### (b) No Actions.

Spectral has not received any notice of, and to Spectral's knowledge there are not, any material unresolved actions, citations, adverse inspectional observations, adverse decisions, adverse Orders, product recalls, adverse information requests, untitled letters, warning letters, or any similar notices or communications, written or oral, from any Regulatory Authority applicable to the Products. There are not facts or circumstances known to Spectral that Spectral could reasonably expect to give rise to any matters referred to in the preceding sentence. No Governmental Authority has commenced or, to Spectral's knowledge, intends to commence, any action to enjoin or restrict Spectral's production of the Product at any of its Manufacturing Facilities.

# (c) Manufacturing and Audit Rights.

Spectral represents and warrants that Spectral and Toray are parties to: (i) a Clinical Supply and Quality Agreement dated August 20, 2019, which governs supply of PMX Product for the TIGRIS Study; and (ii) a Commercial Quality Agreement dated October 2, 2017, which shall be amended and restated after Spectral obtains Marketing Authorizations for the PMX Products in the United States. Spectral also represents and warrants that the current quality agreements with Toray: (i) require Toray to manufacture the PMX Products in compliance with cGMPS and all Applicable Laws; (ii) provide Spectral with audit rights for PMA, EAA quality program under MDSAP; and (iii) provides for inspection of Toray's manufacturing facilities by the FDA.

# (d) Compliance with Regulatory Laws.

Neither Spectral nor any of its owners undertakes the direct or indirect sales and marketing promotion of Vantive products to sources of federal health care program business, including individuals and entities in a position to recommend or refer federal health care program business. Spectral further warrants that no owner, investor or manager of Spectral controls any third party's purchasing decisions with respect to the Products, or Vantive products and services. In the event of any subsequent ownership, investment, management or employment structure of Spectral changes these representations, Spectral will notify Vantive within five (5) Business Days and any such changes shall be a basis for Vantive to terminate this Agreement upon not less than 90 days' written notice to Spectral.

#### (e) No Field Actions.

The Products have not been the subject of a Field Action, whether at the request of a Regulatory Authority or otherwise, anywhere in the world. Spectral is not considering any Field Action with respect to the Products, and there are no factors or circumstances that could give rise

to any such Field Action. To the knowledge of Spectral, no Field Action with respect to the Products (i) is required to be implemented by Spectral in order to comply with any Regulatory Law; or (ii) has been requested or ordered by any Regulatory Authority, health care professional or consumer group.

### (f) Debarment.

Neither Spectral nor any of its Affiliates, nor, to Spectral's knowledge, any of their respective officers, directors, subcontractors, agents, principals, or employees (collectively, "Spectral Parties") is or has ever been debarred under any FDA Law or on the U.S. Department of Health and Human Service's List of Excluded Individuals/Entities or the U.S. General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs. To Spectral's knowledge, no Spectral Party has employed (or used any contractor or consultant that employs) any Person who is (i) debarred under any FDA Law or under investigation by the FDA for debarment thereunder, or (ii) included on the U.S. Department of Health and Human Service's List of Excluded Individuals/Entities or the U.S. General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs. Spectral further represents and warrants that it has no knowledge of any circumstances which may affect the accuracy of the foregoing representations and warranties, including FDA investigations of or debarment proceedings against the Spectral Parties, and Spectral agrees to immediately notify Vantive should it become aware of any such circumstances.

# (g) General Compliance.

Each of Spectral and its Affiliates is, and has been, during the five-year period prior to the date hereof, in compliance in all material respects with all Applicable Laws and Orders applicable to it or by which any of its property or assets is bound or affected. Neither Spectral nor any of its Affiliates has (i) been subject to any Order or Proceeding with respect to any material actual or alleged non-compliance with Applicable Law, (ii) made any voluntary disclosure to any Governmental Authority with respect to any material actual or potential non-compliance with Applicable Law or (iii) been the subject of any criminal Proceeding or convicted of any felony or misdemeanor.

# (h) Anti-Corruption Compliance.

(a) Neither Spectral nor any of its Affiliates, nor, to Spectral's knowledge, any Person acting for or on their behalf, has, directly or indirectly: (i) used or agreed to use any funds for unlawful contributions, gifts, entertainment or expenses relating to any governmental action or inaction or political activity; (ii) made or agreed to make, or attempted to make or agree to make, any unlawful payment to any Government Official or violated any provision of any Anti-Corruption Law; (iii) taken any action that would constitute a violation of any Anti-Corruption Law; (iv) made or agreed to make, or attempted to make or agree to make, any other unlawful payment; or (v) taken any action in furtherance of making an offer, payment, gift, promise to pay, or authorization of the giving of anything of value, to any Government Official (or to any Person while knowing or having reason to know that all or some portion of the consideration remitted to that Person will be offered, given, or promised to a Government Official), for the purpose of (A)

influencing any act, decision, or failure to act by a Government Official in his or her official capacity; (B) inducing such Government Official to use his or her influence to affect any act or decision of a Governmental Authority; (C) obtaining, retaining or directing any business; or (D) pursuing the issuance of any Order or any other commercial or regulatory benefits.

- (b) To Spectral's knowledge, no Government Official is a principal, owner, officer, employee or agent of any entity in which Spectral has an interest, and no Government Official has any material financial interest in the business of Spectral.
- (2) Ethics & Compliance Standards.

While performing its or their obligations under this Agreement, Spectral and employees of Spectral will comply with Ethics & Compliance Standards for Vantive's Suppliers, attached hereto as Schedule "D", a copy of which Spectral acknowledges having received, read and understood. Spectral warrants that it has not given to any employee or agent of Vantive, nor has it received from any employee or agent of Vantive any commissions, payments, gifts, kickbacks, lavish or extensive entertainment, or other things of value in connection with this Agreement. Spectral acknowledges that giving of any such payments, gifts, entertainment, or other things of value is strictly in violation of Ethics & Compliance Standards for Vantive's Suppliers and may result in the cancellation of this Agreement. Supplier shall notify Vantive of any requests or actions from Vantive employees or agents that could result in potential violations of Ethics & Compliance Standards for Vantive's Suppliers by contacting Vantive's Ethics & Compliance Helpline at: Vantive.ethicspoint.com.

## Section 12.3 Vantive's Representations

Vantive hereby represents and warrants to Vantive that, as of the date hereof:

- (1) Debarment. Neither Vantive nor any of its Affiliates, nor, to Vantive's knowledge, any of their respective officers, directors, subcontractors, agents, principals, or employees (collectively, "Vantive Parties") is or has ever been debarred under any FDA Law or on the U.S. Department of Health and Human Service's List of Excluded Individuals/Entities or the U.S. General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs. To Vantive's knowledge, no Vantive Party has employed (or used any contractor or consultant that employs) any Person who is (i) debarred under any FDA Law or under investigation by the FDA for debarment thereunder, or (ii) included on the U.S. Department of Health and Human Service's List of Excluded Individuals/Entities or the U.S. General Services Administration's Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs. Vantive further represents and warrants that it has no knowledge of any circumstances which may affect the accuracy of the foregoing representations and warranties, including FDA investigations of or debarment proceedings against the Vantive Parties, and Vantive agrees to immediately notify Spectral should it become aware of any such circumstances.
- (2) Anti-Corruption Compliance.

- Neither Vantive nor any of its Affiliates, nor, to Vantive's knowledge, any Person (a) acting for or on their behalf, has, directly or indirectly: (i) used or agreed to use any funds for unlawful contributions, gifts, entertainment or expenses relating to any governmental action or inaction or political activity; (ii) made or agreed to make, or attempted to make or agree to make, any unlawful payment to any Government Official or violated any provision of any Anti-Corruption Law; (iii) taken any action that would constitute a violation of any Anti-Corruption Law; (iv) made or agreed to make, or attempted to make or agree to make, any other unlawful payment; or (v) taken any action in furtherance of making an offer, payment, gift, promise to pay, or authorization of the giving of anything of value, to any Government Official (or to any Person while knowing or having reason to know that all or some portion of the consideration remitted to that Person will be offered, given, or promised to a Government Official), for the purpose of (A) influencing any act, decision, or failure to act by a Government Official in his or her official capacity; (B) inducing such Government Official to use his or her influence to affect any act or decision of a Governmental Authority; (C) obtaining, retaining or directing any business; or (D) pursuing the issuance of any Order or any other commercial or regulatory benefits.
- (b) To Vantive's knowledge, no Government Official is a principal, owner, officer, employee or agent of any entity in which Vantive has an interest, and no Government Official has any material financial interest in the business of Vantive.

## Section 12.4 Compliance.

## (1) Compliance.

Spectral has complied in all material respects with all Applicable Laws with respect to the development, Manufacture and Commercialization of the Product. Each Party and its Affiliates and their respective employees and agents shall comply in all material respects with all Applicable Laws that pertain to its activities under this Agreement and, except as otherwise provided herein, shall bear the entire cost and expense of such compliance. Without limitation of the foregoing, each Party agrees that, in connection with this Agreement, it shall not: (i) knowingly use in any capacity the services of any Person who is debarred or subject to debarment by the FDA or is otherwise prohibited by any Governmental Authority from participating in any government health program; and (ii) make, give, provide, offer, or promise, directly or indirectly, any payment, benefit or other incentive to any Government Official or other Person in order to influence the acts of such Person in his or its official capacity or to induce such Person to use his or its influence with a Governmental Authority to obtain or retain business or gain an improper advantage in any manner that would be in violation of any Anti-Corruption Law.

## (2) Conflicts.

The Parties shall not, directly or indirectly, take any action (including the grant of any right, the assignment or transfer or any asset or the undertaking of any obligation) that is in conflict with any provision of this Agreement.

#### Section 12.5 DISCLAIMER.

EACH PARTY AGREES AND ACKNOWLEDGES THAT, EXCEPT AS SET FORTH IN THIS AGREEMENT (INCLUDING, FOR THE AVOIDANCE OF DOUBT, ANY SCHEDULES, EXHIBITS OR ANNEXES HERETO), NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, IMPLIED, EXPRESS OR STATUTORY, ARISING BY OPERATION OF LAW OR OTHERWISE, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS ALL SUCH REPRESENTATIONS AND WARRANTIES, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ARISING FROM COURSE OF PERFORMANCE.

## ARTICLE 13 INTELLECTUAL PROPERTY RIGHTS

#### Section 13.1 Trademark Licenses.

- (1) Each Party hereby grants to the other a nonexclusive, royalty-free license under the Licensed Trademarks of the grantor Party solely for the purpose of exercising the grantee's rights and performing the grantee's obligations under this Agreement. The licensee shall not have the right to grant sublicenses (except that Vantive shall have the right to grant sublicenses to Permitted Sellers) and its use of the Licensed Trademarks, including the goodwill generated therefrom, shall inure solely to the benefit of the licensor. Each Party, to the extent it is the licensee of the other Party's Licensed Trademarks, shall:
  - (a) comply with all reasonable instructions of the licensor as to the form and manner in which the Licensed Trademarks are used, including any instructions as to quality, style and graphic integrity;
  - (b) not make any addition to, deletion from or other modification to the Licensed Trademarks;
  - (c) prior to the production of packaging, labeling or other materials bearing any of the Licensed Trademarks, provide the licensor a reasonable opportunity to review and approve the presentation of the Licensed Trademarks;
  - (d) not adopt, use or register as its own any Trademarks, designs or other indicia that are confusingly similar to, or that dilute, the Licensed Trademarks;
  - (e) not use the Licensed Trademarks other than pursuant to this Agreement; and
  - (f) cease all use of the Licensed Trademarks upon the termination or expiration of this Agreement.

#### Section 13.2 Product Rights.

In the event that Spectral assigns, licenses or otherwise transfers any Product IP Rights licensed to Vantive hereunder, Spectral will ensure that: (a) such assignment, license or transfer is subject to all the rights and licenses granted to Vantive under this Agreement, (b) such assignment, license or transfer does not in any way conflict with the terms of this Agreement, and

(c) the obligations of this Agreement with respect to such assigned, licensed or transferred Product Rights shall be binding upon such assignee. Upon making any such assignment, license or transfer, Spectral shall give Vantive written notice of such assignment as soon as reasonably possible, but in no event later than thirty (30) days after the effective date of such transaction, and provide to Vantive a copy of the underlying agreement pursuant to which such assignment, license or transfer has been made, subject to reasonable redactions to protect commercially sensitive information.

## Section 13.3 Inventions and Intellectual Property Rights.

# (1) Ownership.

As between the Parties, each Party shall have sole ownership of all IP Rights: (i) owned by that Party prior to the Effective Date of this Agreement; (ii) which comes into existence through work efforts unrelated to the performance of this Agreement ("Background IP"); and/or (iii) any other IP Rights conceived, created, reduced to practice, or invented solely by its employees and contractors in the performance of its obligations under this Agreement ("Forward IP"). Notwithstanding the foregoing, Spectral shall have sole and exclusive ownership of all Forward IP that constitutes improvements to its proprietary Products, technologies or Product IP Rights and that incorporates such proprietary Products, technologies or Product IP Rights (the "Product Improvement Rights"). For the avoidance of doubt, such Product Improvement Rights exclude any improvements created, developed or derived from Vantive's "Study Materials" (as defined in the Collaborative Research Agreement – Tigris Subgroup Study dated August 22, 2023 between Baxter and Spectral, and subsequently assigned to Vantive). Spectral and Vantive shall jointly own all other Forward IP jointly invented by Spectral and Vantive; provided that Vantive's rights in any such jointly owned Forward IP covering Products shall be, and is, subject to the exclusivity grants herein.

#### (2) Assignment of Product Improvement Rights.

Vantive hereby assigns to Spectral any right, title and interest in and to the Product Improvement Rights as may be necessary to effect the foregoing ownership allocations, and Vantive agrees to undertake such further acts as may be necessary to evidence such assignment. To the extent that Product Improvement Rights created for or on behalf of Vantive are not vested in Vantive upon creation, Vantive hereby agrees to ensure that such rights are assigned to Vantive, and then to effect assignment from Vantive to Spectral of any right, title and interest in and to the Product Improvement Rights as may be necessary to effect the foregoing ownership allocations.

## (3) Prosecution. [intentionally deleted]

## (4) Defense.

In the event that any Third Party files suit against Vantive and/or Spectral alleging infringement of any IP Rights applicable to any Product, Spectral shall be responsible for defending such action at Spectral's own expense; provided, however, that Vantive must fully cooperate with Spectral, and may retain separate counsel at its sole expense if it elects to do so. Spectral shall keep Vantive fully informed regarding all aspects of the infringement litigation and

shall consult with Vantive on all issues of litigation strategy (though Spectral shall have the final decision regarding such strategy). Notwithstanding the foregoing sentence, Spectral shall not settle such litigation except with Vantive's express written consent if the result thereof would be that the sum of the payments Vantive must pay to Spectral and the Third Party (on a per-unit-sold basis) is greater than the per-unit payment otherwise due to Spectral hereunder. In the event Spectral is unsuccessful in defending such litigation and Vantive is enjoined against continuing to Commercialize any Product under this Agreement, in addition to any remedies provided elsewhere herein Vantive may elect to terminate this Agreement with respect to such Product or to declare the Agreement tolled (but not terminated) for the duration of such injunction.

## (5) Control of Litigation.

Notwithstanding the foregoing paragraph, in the event of any challenge to the validity or enforceability of any Background IP or Forward IP owned by Vantive, Vantive shall have control of any litigation or administrative proceeding to defend against such challenge, and shall bear the costs and expenses of the same. Spectral shall cooperate in the defense of such challenge as reasonably requested by Vantive and at Vantive's sole expense.

# ARTICLE 14 INDEMNIFICATION; LIMITATION OF LIABILITY

## Section 14.1 Spectral Indemnification.

Spectral shall indemnify and hold harmless Vantive and its Affiliates, as well as their respective officers, shareholders, directors and employees, agents, successors and assigns, against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees and expenses of litigation) resulting from any third party claims made or third party suits arising from or related to (i) a claim of infringement, misappropriation or misuse of third party IP Rights resulting directly from the manufacture, use, or Commercialization of the Product; or (ii) Spectral's wrongful act, omission or negligence in connection with the performance of Spectral's obligations under the Agreement or (iii) breach by Spectral of any of its representations, warranties or obligations under this Agreement. This indemnity shall not apply to the extent such claims, liabilities or causes of action are caused by the fault, breach of contract, tort (including negligence and strict liability) of Vantive.

#### Section 14.2 Vantive's Indemnification.

Vantive shall indemnify and hold harmless Spectral and its Affiliates, as well as their respective officers, shareholders, directors and employees, agents, successors and assigns, against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees and expenses of litigation) resulting from any third party claims made or third party suits arising from or related to (i) Vantive's wrongful act, omission or negligence in connection with the performance of Vantive's obligations under the Agreement, [Redacted] or (ii) breach by Vantive of any of its representations, warranties or obligations under this Agreement. This indemnity shall not apply to the extent such claims, liabilities or causes of action are caused by the fault, breach of contract, tort (including negligence and strict liability) of Spectral.

#### Section 14.3 Indemnification Procedure.

As a condition to any indemnity hereunder, the Party seeking indemnity (the "Indemnified Party") shall give the other Party (the "Indemnifying Party") prompt written notice of any claim which may be subject to indemnity hereunder and all right, power and assistance as may be necessary for the Indemnifying Party to investigate, defend and/or settle the claim; provided however, the Indemnifying Party shall not settle the claim in a manner that would require the Indemnified Party to admit liability or incur financial obligation without the Indemnified Party's prior written consent. The Indemnifying Party has no obligation to indemnify the Indemnified Party for any settlement made without the Indemnifying Party's prior written consent.

## Section 14.4 IP Injunction.

[Redacted]

## Section 14.5 Limitation of Liability.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, NEITHER PARTY (OR ITS RESPECTIVE OFFICERS, SHAREHOLDERS, DIRECTORS AND EMPLOYEES, AGENTS, SUCCESSORS AND ASSIGNS) SHALL BE LIABLE TO THE OTHER PARTY FOR ANY LOSS OF PROFIT, BUSINESS REVENUE, OR INCIDENTAL DAMAGES, INDIRECT DAMAGES, SPECIAL DAMAGES, CONSEQUENTIAL LOSS OR DAMAGES OR PUNITIVE DAMAGES HOWSOEVER ARISING OUT OF OR RELATING IN ANY WAY TO THIS AGREEMENT. THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO: (i) THE PARTIES' OBLIGATIONS IN RESPECT TO RECALL EXPENSES PURSUANT TO SECTION 10.3(3); (ii) A BREACH OF ARTICLE 15 (Confidential Information; Press Release); (iii) SPECTRAL'S BREACH OF SECTION 2.1(2) (Violation of Exclusive Distribution Rights) or (iv) THE PARTIES OBLIGATIONS UNDER SECTIONS 14.1-14.4 (Indemnification).

# ARTICLE 15 CONFIDENTIAL INFORMATION; PRESS RELEASE

#### Section 15.1 Definition.

All information and materials that are marked as "Confidential" by the disclosing Party (or which are disclosed in circumstances in which it could reasonably be assumed that such information was confidential) and which are disclosed or made available by either Party or its Affiliates to the other Party or its Affiliates relating to this Agreement, including customer requirements, lists, preferences and methods of operation; any know-how, data, process, or technique of either Party relating to such Party's products; and any research project, work-in-process, future development, scientific, engineering, or manufacturing information, designs, drawings, management information reports and other computer-generated reports, plans or strategies, and business acquisition plans, whether in written, verbal, electronic, graphic or other visual form (including a physical prototype, physical sample, photograph, video tape, or sound recording), as the case may be, at any time prior to the Effective Date, during the Term of this Agreement, and for five (5) years following the termination or expiration of this Agreement, shall be deemed "Confidential Information" and the exclusive property of the disclosing Party.

#### Section 15.2 Terms Confidential.

The Parties agree that the specific pricing and minimum purchase requirement terms of this Agreement shall be considered Confidential Information of both Parties and shall not be disclosed to a third party except (i) in the case of Spectral, to Toray, in connection with Spectral's obligations under the Canadian Toray Agreement and the U.S. Toray Agreement; (ii) as required by Applicable Laws, including the rules or regulations of the U.S. Securities and Exchange Commission, and the Canadian securities regulatory authorities, or similar agency in other country, or of any stock exchange, including Nasdaq and the Toronto Stock Exchange; (iii) as provided for in Section 15.3 or Section 15.4 or (iv) to a third party with whom Vantive or Spectral is in due diligence relating to a merger, an acquisition or a financing, and provided that such third party is subject to obligations as to non-disclosure, use of care and restricted use of at least as stringent as those provided for hereunder, and the Party so disclosing such Confidential Information to such a third party shall be responsible and liable for any breach of such obligations by such third party.

#### Section 15.3 Restrictions.

Except as expressly otherwise provided for in this Agreement, a Party and its Representatives receiving Confidential Information from the other Party: (i) shall during the Term and for five (5) years thereafter, not disclose any Confidential Information received from the other Party or its Affiliates other than in connection with its performance under this Agreement, (ii) shall use the same degree of care to prevent any access to any such Confidential Information as used for the protection of similar materials of its own and (ii) not use such Confidential Information other than for the purpose of the implementation of this Agreement. Notwithstanding the foregoing, either Party (or its Affiliates) may disclose Confidential Information received from the other Party (or its Affiliates) to the receiving Party's directors, officers, employees, subcontractors, legal representatives or agents (its "Representatives"), as the case may be, requiring such information or materials to perform this Agreement, provided that such persons agree to use and maintain the confidentiality of any such Confidential Information in accordance with this Agreement. Each Party shall promptly notify the other Party upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information.

### Section 15.4 Exclusions from Obligation of Confidentiality.

The restrictions set forth in Section 15.2 shall not apply to any Confidential Information that: (a) at the time of disclosure hereunder is or thereafter become available to the public through no fault of the receiving Party, as shown by the receiving Party's written or electronic records; (b) was known to, or was otherwise in the possession of the receiving Party or any of its Affiliates prior to the receipt of such Confidential Information from the other Party, as shown by the receiving Party's written or electronic records; (c) is obtained by the receiving Party from a source other than the disclosing Party and other than one who would be breaching a commitment of confidentiality to that disclosing Party by disclosing the Confidential Information to the receiving Party, as shown by the receiving Party's written or electronic records, or (d) is developed by the receiving Party independently of any disclosure made hereunder, as evidenced by the receiving Party's written or electronic records. If either Party receives a subpoena or other validly issued administrative or judicial process requesting the Confidential Information of the other Party (or is otherwise required by Applicable Law, rule, regulation or stock exchange rules to divulge such

Confidential Information), the receiving Party shall promptly notify the disclosing Party and tender to the disclosing Party the defense of such demand. If requested by the disclosing Party to whom the defense of such a demand has been tendered, the receiving Party shall cooperate (at the expense of the disclosing Party) in the disclosing Party's defense of such demand. Unless the demand shall have been timely limited, quashed, or extended, the receiving Party shall thereafter be entitled to comply with such demand.

## Section 15.5 Equitable Remedies.

Each Party acknowledges that if it breaches its obligations under this ARTICLE 15, the other Party may suffer immediate and irreparable harm, it being acknowledged that monetary remedies may not be adequate. Accordingly, if a court of competent jurisdiction should find that a Party has breached any such obligations, such Party shall not oppose the entry of an appropriate order compelling performance by such Party and restraining it from any further breaches.

# Section 15.6 Liability for Representatives.

Each Party shall be responsible and liable in the event of any breach of the terms and conditions of this ARTICLE 15 by its Representatives and/or their respective officers, directors and employees.

#### Section 15.7 Press Releases.

Unless otherwise required by law, rule, regulation, applicable stock exchange rules or court order, neither Party shall issue press releases or otherwise disclose to the public the terms of this Agreement, or the transactions contemplated by this Agreement, without the other Party's prior written consent (assuming reasonable advance notice).

# ARTICLE 16 ADDITIONAL COVENANTS

### Section 16.1 Insurance.

## (1) Spectral's Coverage.

During the Term, Spectral shall maintain general and umbrella liability insurance covering their premises and operations of not less than \$10,000,000 per occurrence/aggregate for bodily injury (including death) and property damage. Spectral will also provide product liability insurance of at least \$5,000,000 per occurrence/aggregate for bodily injury (including death) and property damage. Spectral shall name Vantive as additional insured and provide at least thirty (30) days' advance written notice to Vantive of cancellation or material adverse change in coverage Within thirty (30) calendar days after the Effective Date and annually thereafter, Spectral shall provide to Vantive satisfactory proof of insurance in the form of a certificate of insurance.

## (2) Vantive's Coverage.

During the Term, Vantive shall maintain insurance or self-insurance of the following types for General Liability Insurance with combined limits of not less than \$10,000,000 per occurrence/aggregate for bodily injury, including death, and property damage. Within thirty (30) days after the Effective Date, Vantive shall provide to Spectral satisfactory proof of insurance or self-insurance in the form of a certificate of insurance or self-insurance.

## (3) Additional Terms.

By requiring insurance, each Party represents that the coverage and limits may not necessarily be adequate to protect the other. Failure of a Party to have insurance coverage, inability to obtain insurance coverage, or any inadequacy of insurance coverage shall not relieve or decrease the other Party's obligations or liabilities under this Agreement.

## ARTICLE 17 TERM AND TERMINATION

#### Section 17.1 Term.

Unless earlier terminated by Spectral or Vantive as provided herein, the term of this Agreement shall commence upon the Effective Date and shall continue in effect for ten (10) years following the date that the Marketing Authorization for the PMX Products in the United States is obtained (the "Initial Term"). Thereafter, the term of this Agreement shall automatically renew for two additional five-year periods (each, a "Renewal Term"), unless either Party notifies the other Party in writing of its intent not to renew this Agreement no less than seven (7) months prior to the end of the Initial Term of the then-current Renewal Term, as the case may be. Initial Term and any Renewal Terms shall be collectively referred to herein as the "Term."

#### (1) Termination for Cause.

#### (a) Termination for Material Breach.

Each Party may terminate this Agreement if the other Party has breached a material term or condition of this Agreement, and such breach has not been cured within sixty (60) days after receipt of written notice of such breach from the non-defaulting Party.

#### (b) Termination for Insolvency.

Each Party may immediately terminate this Agreement if (each referred to as an "Insolvency Event"): (a) the other Party files a voluntary petition or acquiesces in or fails to contest an involuntary petition under any bankruptcy, insolvency or similar law; (b) an involuntary petition is filed against the other Party under any bankruptcy, insolvency or similar law and is not dismissed within 90 days; (c) the other Party is adjudged bankrupt; (d) a court assumes jurisdiction of the assets of the other Party under a federal reorganization act; (e) a trustee or receiver is appointed by the court for all or a substantial portion of the assets of the other party; (f) the other party becomes insolvent or suspends its business; (g) the other Party makes an

assignment of all or substantially all of its assets for the benefit of its creditors; or (h) the other Party shall propose or be a party to any dissolution or liquidation or is dissolved or liquidated.

### (2) Persisting Force Majeure.

The Party to whom a Force Majeure Event has not occurred may terminate this Agreement with immediate effect by giving written notice to the Party to whom a Force Majeure Event has occurred. Termination under this provision may only occur where the Force Majeure Event materially prevents the Party to whom a Force Majeure Event has occurred from performing a material provision of this Agreement for a period of time exceeding one hundred and eighty (180) days. Such termination right shall be exercised prior to the later of (i) thirty (30) days after the expiration of the 180-day period, or (ii) the date on which the Party to whom a Force Majeure Event has occurred resumes the performance of its obligations.

# (3) Extended Supply Failure.

Vantive may, on a Product-by-Product basis with respect to any one or more Products that has been subject to an Extended Supply Failure, terminate this Agreement upon delivery of a written notice to such effect to Spectral, which termination shall be effective sixty (60) days from the date of the notice and which, for the avoidance of doubt, shall not restrict or limit any of Vantive's rights.

## Section 17.2 Termination by Vantive.

Vantive may terminate this Agreement, without prejudice to any remedy or claim it may have against Spectral, if the Approval for the PMX Product is withdrawn by the Regulatory Authorities in the US or Canada.

#### Section 17.3 Termination by Spectral.

[Redacted]

### **Section 17.4** Discontinuation of Product.

[Redacted]

#### **Section 17.5 Effect of Termination or Expiration.**

Upon expiration or termination of this Agreement for any reason whatsoever, the Parties shall have the specific rights and obligations set forth as follows:

## (1) Last Buy Right.

[Redacted]

## (2) Transfer of Remaining Inventory.

During the one-year period commencing on the effective date of termination or expiration of this Agreement, Vantive may sell-off the Remaining Inventory.

(3) Recovery of Milestone Exclusivity Payments.

[Redacted]

#### Section 17.6 Accrued Claims and Survival.

(1) Accrued Claims.

No expiration or termination of this Agreement shall relieve either Party from any liability which, at the time of such expiration or termination has already accrued to such Party, prior to such expiration or termination.

- (2) Survival.
  - (a) In the event of expiration or termination of this Agreement, the following provisions shall survive expiration or termination of this Agreement: ARTICLE 8 (Consideration and Payments/Invoicing); ARTICLE 9 (Records); ARTICLE 10 (Quality; Product Recall); ARTICLE 13 (Intellectual Property Rights); ARTICLE 14 (Indemnification; Limitation of Liability); ARTICLE 15 (Confidential Information; Press Release); Section 17.5 (Effect of Termination or Expiration); and ARTICLE 19 (Miscellaneous Provisions).

All other provisions, including all rights and obligations thereunder, shall terminate and be of no further force and effect (except to the extent necessary with respect to the liabilities accrued prior to expiration or termination of this Agreement pursuant to ARTICLE 15 (Confidential Information; Press Release)).

## Section 17.7 Bankruptcy

All rights and licenses now or hereafter granted by Spectral to Vantive pursuant to this Agreement, including the license granted to Vantive in Section 2.1, are, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon the disclaimer, resiliation or rejection of this Agreement by or on behalf of Spectral following the occurrence of any Insolvency Event with respect to Spectral, Spectral agrees that Vantive, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The foregoing provisions of this Section are without prejudice to any rights Vantive may have arising under the Bankruptcy Code or other Applicable Law.

# ARTICLE 18 FORCE MAJEURE

## Section 18.1 Force Majeure.

Notwithstanding any other provision of this Agreement, Spectral and Vantive shall each be excused for any delay or default in performing any of their respective obligations hereunder if such delay or default is caused by conditions which are beyond its reasonable control including, but not limited to, acts of God, government restrictions (including import and export restrictions), wars, terrorism, destruction of facilities by fire, earthquake, storm or other casualty, epidemic, or

failure of public utilities or common carrier (each a "Force Majeure Event"), including (for the avoidance of doubt) Force Majeure Events affecting Toray's ability to manufacture and/or ship PMX Products.

#### Section 18.2 Notification.

The Party affected by a Force Majeure Event pursuant to Section 18.1 shall notify the other Party as soon as reasonably practicable in writing of any such Force Majeure Event and the underlying reasons for the delay or default. The Party to whom the Force Majeure occurred shall then in good faith seek a resolution of the delay or failure to perform and to remove the Force Majeure Event and shall use commercially reasonable diligence to remove or mitigate any such causes of non-performance.

### ARTICLE 19 MISCELLANEOUS PROVISIONS

#### Section 19.1 Notices.

All notices and other communications required under this Agreement shall be in writing and shall be deemed to have been given if delivered by hand, or sent by courier, electronic facsimile transmission (provided that in case of electronic or facsimile transmission, a confirmation copy of the notice shall be delivered by hand or sent by U.S. Mail within two days of transmission), addressed:

#### To Vantive:

Vantive US Healthcare LLC 1 Baxter Parkway, Deerfield, IL 60015 Attention: [Redacted]

## To Spectral:

Spectral Medical Inc. 135 The West Mall Toronto, Ontario M9C 1C2 Attention: [Redacted] Facsimile: [Redacted]

Email: [Redacted]

until notice of a change in address or addressee is given as provided in this Section. All notices given in accordance with this Section shall be effective, if delivered by hand or by courier, at the time of delivery, and, if communicated by facsimile or other electronic transmission, at the time of confirmation of such transmission.

## **Section 19.2 Entire Agreement.**

This Agreement, including the attached Schedules and Appendices is the entire agreement between the Parties hereto with respect to the subject matter hereof, there being no prior written or oral promises or representations not incorporated herein.

#### Section 19.3 Choice of Law.

This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware excluding (a) its conflicts of laws principles, and (b) the United Nations Conventions on Contracts for the International Sale of Goods.

## **Section 19.4** Alternate Dispute Resolution.

Any and all disputes, claims or controversies ("Disputes") arising out of or relating to this Agreement, including without limitation, any Dispute as to the existence, validity, performance, breach or termination of this Agreement, shall be resolved in the following manner. A Party must first send written notice of the Dispute to the other Party for attempted resolution by negotiation between the respective JSC representatives. If the JSC representatives fail to meet or if they do not reach resolution of the Dispute within 30 days after such notice is received (all references to "days" in this provision are to calendar days), then the matter shall be escalated by the Parties to their respective Senior Executives for the purpose of mediating the Dispute within 14 days from the expiration of the above 30-day period. If the mediation fails to resolve all Disputes or if the mediation has not been scheduled within 14 days from the above 30-day period's expiration, either Party may initiate arbitration with respect to the matters submitted to negotiation and mediation by filing a written demand for arbitration. Notwithstanding the foregoing, to the extent a party is seeking injunctive relief either party may immediately bring a proceeding seeking preliminary injunctive relieve in a court having jurisdiction, and this relief shall remain in effect until the parties reach a resolution or so long as the arbitrator(s) feel as appropriate.

Any and all Disputes not resolved as provided for above, shall be settled by final and binding arbitration administered by the International Institute for Conflict Prevention and Resolution ("CPR") in accordance with the CPR's Rules for Administered Arbitration by three arbitrators, of whom each party shall designate one, with the third arbitrator to be designated by the two party-appointed arbitrators. The proceedings shall be confidential, and the place of arbitration shall be New York, New York. Judgment on the award rendered by the Arbitrators may be entered in any court having jurisdiction thereof.

#### Section 19.5 Amendment; Waiver.

No amendment or modification of the terms of this Agreement shall be binding on either Party unless reduced to writing and signed by an authorized representative of the Party to be bound. The waiver by either Party of any particular default by the other Party shall not affect or impair the rights of the Party so waiving with respect to any subsequent default of the same or a different kind; nor shall any delay or omission by either Party to exercise any right arising from any default by the other affect or impair any rights which the non-defaulting Party may have with respect to the same or any future default.

#### Section 19.6 Severability.

In the event that any of the provisions of this Agreement is held to be invalid, illegal, void or otherwise unenforceable in any jurisdiction by reason of any rule of law, administrative decision, judicial decision, public policy or otherwise, such provision shall be ineffective in such jurisdiction to the extent of such invalidity, illegality, voidness or unenforceability without affecting, impairing or invalidating the remaining provisions, if any, of this Agreement. Any such invalid, illegal, void or otherwise unenforceable provisions shall be replaced by valid and enforceable substitute provisions which are as similar as possible to such invalid, illegal, void or otherwise unenforceable provisions in terms of economic and other commercial effect upon the Parties.

#### Section 19.7 Relationship of the Parties.

By virtue of this Agreement, neither Party establishes the other as its agent (except as otherwise expressly provided), partner, joint venturer, or legal representative, and neither Party has express or implied authority.to bind the other Party in any manner whatsoever (except as otherwise expressly provided). Each Party shall be responsible for the acts and omissions of its subcontractors, including Third Party Manufacturers.

#### Section 19.8 Counterparts.

For convenience of the Parties hereto, this Agreement may be executed in one or more counterparts, each of which shall be deemed an original for all purposes.

#### Section 19.9 Beneficiaries.

This Agreement is solely for the benefit of the Parties hereto and their respective successors and permitted assigns and shall not confer upon any other Person any remedy, claim, liability, reimbursement or other right in excess of those existing without reference to this Agreement.

#### Section 19.10 Assignment.

The terms and conditions of this Agreement shall inure to the benefit of, and be binding upon, Spectral, Vantive and their respective successors by operation of law and permitted assigns. Both Spectral and Vantive may assign or otherwise transfer this Agreement and its rights and obligations thereunder without the consent of the other party, provided that the assignee agrees to abide by all of its terms and conditions. Spectral agrees to promptly notify Vantive in writing of any Change of Control Event, such notice to occur no later than the effective date of such Change of Control Event. In the event Spectral is acquired by a Vantive Competitor or assigns any rights under this Agreement to a Vantive Competitor, in accordance with the Change of Control Event definition, Vantive has the right to immediately terminate this Agreement, upon one hundred and eighty (180) days' notice.

#### Section 19.11 Electronic Signature.

A manual signature on this Agreement or other documents to be delivered pursuant to this Agreement, an image of which shall have been transmitted electronically, will constitute an original signature for all purposes. The delivery of copies of this Agreement or other documents to be delivered pursuant to this Agreement, including executed signature pages where required, by electronic transmission will constitute effective delivery of this Agreement or such other document for all purposes.

#### Section 19.12 List of Schedules and Appendices.

Below are schedules and appendices to this Agreement, which are hereby incorporated by reference into this Agreement and form an integral part of this Agreement.

Schedule "A" - Definitions

Schedule "B" - Territory

Schedule "C" - Product Prices

Schedule "D" - Vantive Ethics and Compliance Standards

Schedule "E" - Licensed Trademarks

**IN WITNESS WHEREOF**, Vantive and Spectral have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

VANTIVE US HEALTHCARE LLC	SPECTRAL MEDICAL INC
---------------------------	----------------------

By: "Gavin Campbell"	By: "Chris Seto"
Name:Gavin Campbell	Name:Chris Seto
Title: President - Acute Therapies	Title: Chief Executive Officer

#### Schedule "A" Definitions

#### Section 19.13 Definitions.

"Act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as amended from time to time.

"Affiliate" means any Person controlled by, controlling or under common control with a Party. For purposes of this definition, the term "control" means the direct or indirect power to direct the management of a Person, whether through the ownership of voting securities (as in the case of a subsidiary), by contract, or otherwise; and the terms "controlling" and "controlled" have meanings correlative to the foregoing.

"**Agreement**" has the meaning set forth in the introductory paragraph.

"Anticipatory Supply Failure" has the meaning set forth in Section 7.3(6).

"Anti-Corruption Law" means, with respect to a Party, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and all other anti-corruption or anti-bribery Applicable Laws of any jurisdiction that is applicable to the business of such Party.

"Applicable Laws" means all international, national, federal, state, provincial and local laws, statutes, codes, rules, regulations, ordinances, orders, decrees or other pronouncements of any governmental, administrative or judicial authority having the effect of law and having jurisdiction over the Products, as they apply to the Parties' respective activities under this Agreement, including without limitation, (i) all federal, state and local laws and regulations in each jurisdiction within the Territory; (ii) cGMPs; and (iii) all applicable environmental health and safety laws.

"Binding Forecast" has the meaning set forth in Section 7.1(1).

"Binding Forecast Period" has the meaning set forth in Section 7.1(1).

"Business Day" means any day other than Saturday, Sunday or a legal holiday (i.e., a day when banks are closed or are authorized to be closed in Toronto or Illinois).

"Calendar Year" means a period of one year beginning on January 1 and ending on December 31.

"cGMPs" means: (i) current Good Manufacturing Practices required by the FDA and as set forth from time to time by the Act or FDA regulations, policies or guidelines (including without limitation 21 CFR 210 and 211) in effect at a particular time governing the manufacture, handling, storage and control of the Finished Product in the United States, and (ii) the corresponding requirements of each applicable Regulatory Authority in the Territory.

"Change of Control Event" means (i) the acquisition of ownership, directly or indirectly, beneficially or of record, by any Person or group (within the meaning of the Securities

Exchange Act of 1934 and the rules of the Securities and Exchange Commission there under as in effect on the date hereof) consisting of or including a Vantive Competitor, of equity interests representing more than fifty percent (50%) of the aggregate ordinary voting power represented by the issued and outstanding equity interests of Spectral or (ii) the acquisition of direct or indirect control of Spectral by any Person or group consisting of or including a Vantive Competitor.

"Commercialization" means any and all activities directed to the offering for sale and sale of the Products, including activities related to importing, marketing, promoting, advertising, distributing, storing, selling and providing support for the Products. When used as a verb, "Commercialize" means to engage in Commercialization.

"Competing Product" means, with respect to the PMX Product, an extracorporeal blood purification device that removes endotoxins; and with respect to the EAA Product means a diagnostic to identify the level of endotoxin in a patient.

"Confidential Information" has the meaning set forth in Section 15.1.

"Contract Year" means the time period commencing on the effective date, and ending twelve months thereafter, and each successive 12-month period thereafter.

"**Date of Delivery**" has the meaning set for in Section 7.4(2).

"Disaster Recovery and Business Continuity Program" has the meaning set forth in Section 7.3(2).

"Effective Date" has the meaning set forth in the introductory paragraph.

"Enforcement Action" means: (i) an advisory, administrative, or judicial action, as those actions are described in Chapters 4, 5 and 6, respectively, of FDA's Regulatory Procedures Manual (e.g., a warning or untitled letter) or a similar action initiated by a Governmental Authority alleging or asserting noncompliance with Applicable Law; (ii) a request to attend a Regulatory Meeting, as that term is defined in Chapter 10-3 of FDA's Regulatory Procedures Manual, with the FDA or a similar meeting requested by a foreign Governmental Authority; or (iii) import alert or any detention or refusal in connection with the importation of any Products into any jurisdiction, seizure of any product in any jurisdiction or any similar action by any Governmental Authority or (iv) significant inspectional observations or other agency findings or actions that result in a Regulatory Agency withdrawing Marketing Authorizations for any Products.

"Exclusive Distribution Rights" has the meaning set forth in Section 2.1(1)(b).

"Exclusive Territory" shall be Canada and, upon payment of all of the Milestone Exclusivity Payments, the United States of America.

"Extended Supply Failure" means any of the following: (i) Spectral fails to deliver an Anticipatory Supply Failure Withdrawal Notice to Vantive within one hundred and fifty (150) days after the delivery of any Anticipatory Supply Failure Notice; (ii) Spectral fails

to deliver the entire quantity of any Product in the amount, and by one hundred and fifty (150) days after the requested Date of Delivery, specified in any Firm Purchase Order; (iii) in any twelve-month period Spectral fulfills two or more Accepted Orders for the same Product with such Product that does not comply with its Product Warranty in amounts equal to twenty percent (20%) or more of the quantity of such Product included in each of such Accepted Orders; (iv) Spectral has failed to deliver any Product in excess of one hundred and fifty (150) consecutive days beyond the requested Date of Delivery in an Accepted Order for such Product.

#### "Failure to Supply" means any one following events:

- (i) Spectral's inability to supply, for reasons other than a Force Majeure or Vantive's failure to meet the Forecasting Conditions, at least seventy-five percent (75%) of the quantity of Units for Finished Product in Firm Purchase Orders issued pursuant to this Agreement that Spectral would be required to fill under this Agreement, and such failure continues for a period of 90 consecutive days; or
- (ii) a Regulatory Authority in the Territory takes any action, including the issuance of any injunction that could reasonably be expected to disrupt Spectral's ability to fulfill its obligations under Section 7.4 for a period of more than ninety (90) days.

"Failure to Supply Trigger Date" has the meaning set forth in Section 7.3(6).

"FDA" means the United States Food and Drug Administration.

"Field Action" means any action by a Party that meets the criteria of "recall," "correction," "removal", "market withdrawal", or "stock recovery" under 21 CFR §7.3, or any similar field or customer action as defined by applicable regulatory law.

"Firm Purchase Order" means a Purchase Order submitted by Vantive in accordance with Section 7.1(2) and confirmed by Spectral, stating the confirmed quantities of Product and delivery date.

"Force Majeure Event" has the meaning set forth in Section 18.1.

"**Forecasting Conditions**" means, as applicable, Vantive's delivery of the Rolling Forecasts in accordance with Section 7.1(1).

"Government Official" means any (i) officer, employee or agent of any Governmental Authority; (ii) any official, employee or agent of a public international organization; (iii) any Person acting in an official capacity on behalf of such government, instrumentality or public international organization; (iv) any political party official or candidate for political office; or (v) a member of a royal family.

"Governmental Authority" means any instrumentality, subdivision, court, administrative agency, department, commission, official or other authority of any country, state,

province, municipality or other governmental or political subdivision, any quasigovernmental or private body exercising any regulatory or other governmental authority of any kind, or any arbitrator, court or tribunal of competent jurisdiction.

"**Indemnified Party**" has the meaning set forth in Section 14.3.

"Indemnifying Party" has the meaning set forth in Section 14.3.

"Initial Milestone Exclusive Rights Payment" has the meaning set forth in Section 8.2(2).

"Initial Term" has the meaning set forth in Section 17.1.

"Insolvency Event" has the meaning set forth in Section 17.1(1)(b).

"IP Rights" shall mean all intellectual property or proprietary rights of any description including (a) rights in any patent, patent application (including any provisionals, continuations, divisions, continuations-in-part, but only for subject matter supported pursuant to 35 U.S.C. § 112 by the foregoing), extensions, renewals, reissues, revivals and reexaminations, any PCT applications, and all foreign counterparts, industrial design, (b) trade secrets, (c) inventions, discoveries, improvements, modifications, know-how, technique, methodology (whether or not protectable by patent), or trade secret or copyright.

"JSC" has the meaning set forth in Section 3.1.

"JSC Representatives" has the meaning set forth in Section 3.1.

"Latent Defect" means a failure of the Product(s) to conform to the Product Warranty that was not discovered by Vantive by its inspection of the Product.

"Licensed Trademarks" means, with respect to each Party, those Vantive Trademarks and Spectral Trademarks set forth below its name on Annex E.

"Manufacture or Manufacturing" means all of the operations to make, test, release, package, store, label and ship the Product, including: (i) the receipt, handling and storage of the raw materials; (ii) the manufacturing, packaging, labeling, storing and shipping of the Product; and (iii) the quality assurance and quality control testing (including release) of the Product.

"Manufacturing Facility" means, for each Product, any of the manufacturing facilities where Spectral, Toray or their contractor will Manufacture such Product, and any other location provided Spectral delivers prior notice of such location to Vantive.

"Marketing Authorizations" shall mean all approvals, clearances, licenses, permits registrations or authorizations by a Regulatory Authority that are necessary to Commercialize a Product in a particular Territory.

"Marketing Materials" has the meaning set forth in Section 7.2(3).

"Milestone Exclusivity Payments" the Initial Milestone Exclusive Rights Payment and the Second Milestone Exclusive Rights Payment.

"Minimum Purchase Requirements" has the meaning set forth in Section 7.2(1).

"**Non-Conforming Product**" has the meaning set forth in Section 7.5(2).

"Non-Exclusive Territory" shall be the jurisdictions worldwide in which Spectral has the appropriate Marketing Authorizations to sell the EAA Product (which as of the Effective Date are Canada, the United States of America and the European Union), and any other country in which the Parties agree that Vantive may seek Marketing Authorization to sell the EAA Product.

"Non-Exclusive EAA Distribution Rights" has the meaning set forth in Section 2.2(1).

"Non-Exclusive PMX Distribution Rights" has the meaning set forth in Section 2.1(1)(b).

"Order" means any award, decision, injunction (whether temporary, preliminary or permanent), judgment, stipulation, order, ruling, subpoena, writ, decree, consent decree or verdict entered, issued, made or rendered by any court, administrative agency, arbitrator or other Governmental Authority.

"Party" or "Parties" has the meaning set forth in the introductory paragraph.

"Permitted Sellers" has the meaning set forth in Section 2.1(1)(a).

"Person" means an individual, corporation, partnership, limited liability company, unincorporated syndicate, unincorporated organization, trust, trustee, executor, administrator or other legal representative, governmental authority or agency, or any group of Persons acting in concert.

"PrismaFlex and PrisMax" mean Continuous Renal Replacement Therapy (CRRT) devices and ancillaries manufactured by Vantive.

"**PrisMax Sub-Study**" means a subgroup study of the Tigris Study using the PrisMax System Version 3 and Prismaflex HP-X.

"Proceeding" means any action, arbitration, audit, hearing, proceeding, litigation, or suit (whether civil, criminal, administrative or investigative) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Authority or arbitrator.

"**Product(s)**" shall mean the PMX Product and/or the EAA Product.

"Product Improvement Rights" has the meaning set forth in Section 13.3(1).

"**Product IP Rights**" shall mean with respect to each Product, all IP Rights that specifically pertain to the design, manufacture and/or use of any such Product.

"**Product Price**" has the meaning set forth in Section 8.1.

"Product Specifications" means collectively, (i) design and functionality specifications relating to the Product as agreed by the Parties in Schedule "B-1" and as may be provided in product documentation and instructions for use, and (ii) any specifications for manufacturing, testing, storing, packaging, shipping, or labeling the Product set forth in any approved application for Approval and any supplements and amendments thereto.

"**Product Warranty**" has the meaning set forth in Section 7.5(1)(a).

"**Proposed Premarket Notification**" or "**PMA**" shall have the meaning ascribed to it in Section 4.1(2).

"Purchase Order" has the meaning set forth in Section 7.1(2).

"**Recall**" has the meaning set forth in Section 10.3(1).

"Recall Expenses" has the meaning set forth in Section 10.3(3).

"Regulatory Authority" means, with respect to each country or jurisdiction in the Territory, any regulatory authority, entity, group, bureau, agency, commission, council or other government entity involved in granting Marketing Authorizations, or in administering Applicable Laws in that country or jurisdiction, including the FDA, Health Canada, Competent Notified Body, TGA and Med safe.

"Regulatory Filings" mean all applications, notifications, requests and other documents that may be filed with a Regulatory Authority by a Party seeking approval to engage in development, Manufacturing or Commercialization activities with respect to the Product in the Territory or seeking any regulatory designation or status with respect to the Product in the Territory, and all related correspondence to or from Regulatory Authorities, as well as all supplements and amendments to the foregoing, and together with any and all supporting documentation related to the foregoing, including summaries of product characterization, product circulars, advertising and promotion documents, patient product information, packaging components, periodic safety update reports, risk management plans, adverse event files, reports, and analyses and complaint files, reports, and analyses.

"Regulatory Submissions" mean any premarket filings, submissions, licenses, listings and clearances made to the applicable Regulatory Authorities to clear the Products for Commercialization in the Territory.

"Remaining Inventory" shall mean (a) Vantive's inventory of Products existing as of the date of expiration or termination of this Agreement, and (b) any other Products that are (i) in transit to Vantive as of the date of expiration or termination of this Agreement, or (ii) in accordance with a Binding Forecast, past the point in the manufacturing process when such Products could have been used other than as part of the Vantive Codes.

"Renewal Term" has the meaning set forth in Section 17.1.

"Relative Mortality Benefit" shall mean the following calculation, using the TIGRIS Study results as submitted to the FDA: (placebo mortality – treatment mortality) x 100 placebo mortality.

"Representatives" has the meaning set forth in Section 15.3.

"**Rolling Forecast**" shall have the meaning set forth in Section 7.1(1).

"SAMI Device" means a Continuous Renal Replacement Therapy device commercialized by Spectral under the brand name the "SAMI CRRT System" or the "SAMI System", and utilized in a sub-study of the Tigris Study that seeks regulatory approval of the PMX Product in the United States.

"Second Milestone Exclusive Rights Payment" has the meaning set forth in Section 8.2(3).

"Senior Executives" shall have the meaning ascribed to them in Section 3.4.

"Shortfall Units" means the difference between Vantive's Minimum Purchase Requirements, as may be adjusted pursuant to Section 7.2(2), and the actual or anticipated number of Units of Product purchased (or to be purchased) by Vantive during the Contract Year.

"Spectral" has the meaning set forth in the introductory paragraph.

"Spectral Trademarks" means any registered or unregistered trademarks, service marks, trade names, trade dress, logos or other designations that, from time to time, Spectral approves for use by Vantive in connection with the Products.

"Taxes" has the meaning set forth in Section 8.3.

"**Term**" has the meaning set forth in Section 17.1.

"Territory(ies)" means, collectively, Exclusive Territory and Non-Exclusive Territory.

"Third Party Manufacturer" means any the Persons that render Spectral device sub-assembly components or services (e.g. manufacturing, sterilization, packaging, etc.) in connection with the Product.

"TIGRIS Final Data" shall have the meaning ascribed to it in Section 4.1(2).

"TIGRIS Study" means the clinical trial sponsored by Spectral Diagnostics (US) Inc. entitled Safety and Efficacy of Polymyxin B Hemoperfusion (PMX) for Endotoxemic Septic Shock in a Randomized, Open-Label Study (ClinicalTrials.gov Identifier: NCT03901807).

"**Unit**" shall mean an individual finished Product.

"Upfront Exclusive Rights Payment" has the meaning set forth in Section 8.2(1).

"Vantive" has the meaning set forth in the introductory paragraph.

"Vantive Codes" means the product codes for the Product.

"Vantive Competitor" means [Redacted].

"Vantive Trademarks" means any other registered or unregistered trademarks, service marks, trade names, trade dress, logos or other designations owned by Vantive (or Vantive International) that, from time to time, Vantive approves for use by Spectral in connection with the Product.

#### Section 19.14 Other Terms.

Terms defined in other Sections of this Agreement will have the meanings therein provided.

#### Schedule "B" Territory

PMX Product - United States and Canada

EAA Product - the jurisdictions worldwide in which Spectral has the appropriate Marketing Authorizations to sell the EAA Product (which as of the Effective Date are Canada, the United States of America and the European Union), and any other country in which the Parties agree that Vantive may seek Marketing Authorization to sell the EAA Product.

In addition to the rights granted to Vantive in Section 5.6, Vantive may request that Spectral seek Marketing Authorizations in new countries. Spectral will consider these requests in good faith, and the Parties will engage in good faith negotiations on cost sharing related to expanding into these countries. If Spectral receives Marketing Authorizations in new countries, Vantive shall be given nonexclusive rights to EAA in those countries.

## Schedule "B-1" Product Specifications

The Product Specifications for the Toray Product will be set out in the PMA package to be approved by the FDA, which package will be made available to Vantive, and all successive updates or amendments, each of which will also be made available to Vantive.

The Product Specifications for the EAA Product are outlined in the 510(k) package (K183176) approved by the FDA on March 12, 2019, which package will be made available to Vantive, and all successive updates or amendments, each of which will also be made available to Vantive.

## Schedule "C" Product Prices

[Redacted]

## Schedule "D" Ethics & Compliance Standards for Vantive Suppliers

[Redacted]

### Schedule "E" Licensed Trademarks

# Spectral Trademarks

SPECTRAL

TORAYMYXIN

EAA

ENDOTOXIN ACTIVITY ESSAY

#### **Vantive Trademarks**

VANTIVE

PRISMAX

PRISMAFLEX