
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event Reported): November 15, 2022

Amphastar Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

001-36509
(Commission File Number)

33-0702205
(IRS Employer Identification
Number)

11570 6th Street
Rancho Cucamonga, California
(Address of Principal Executive Offices)

91730
(Zip Code)

Registrant's telephone number, including area code: **(909) 980-9484**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AMPH	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01. Entry into a Material Definitive Agreement

On November 15, 2022 (the “Effective Date”) Amphastar Nanjing Pharmaceuticals, Inc. (“ANP”), a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. (the “Company”), entered into a supply agreement (the “Agreement”) with Nanjing Letop Biotechnology Co., Ltd. (“Letop”). Pursuant to the Agreement, Letop will manufacture and deliver chemical intermediates (“Intermediates”) for ANP according to the requirements of the purchase orders confirmed by Letop (collectively, the “Transaction”). ANP is entitled to decide the quantity of the Intermediates that it purchases from Letop at its own discretion, and ANP has no obligation to purchase any minimum quantity of the Intermediates from Letop. ANP will retain ownership of all confidential information ANP shares with Letop during the term of this Agreement. Each of ANP and Letop have made customary representations, warranties and covenants in the Agreement. This Agreement will remain in full force and effect for a period of three (3) years from the Effective Date.

Payments under the Agreement will be made in Chinese yuan. The total cost of the Agreement to ANP for the three (3) year period of the agreement shall not exceed approximately \$1.5 million, with payments adjusted based on actual currency exchange rates.

As previously disclosed in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021, Henry Zhang is an immediate family member of Dr. Jack Zhang, Chief Executive Officer, President, and Director of the Company, Dr. Mary Luo, Chairman, Chief Operating Officer, and Director of the Company. Henry Zhang beneficially owns a majority of the equity interest in Letop, and the Agreement with Letop represents a related party transaction. Accordingly, the independent and disinterested members of the Audit Committee of the Board of Directors of the Company evaluated and approved the Transaction and entry into the Agreement following their review of applicable considerations.

The foregoing is a brief description of the material terms of the Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the copies of the Agreement, a copy of which is filed as Exhibit 10.1 hereto and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1*	Supply Agreement by and between Amphastar Nanjing Pharmaceuticals, Inc. and Nanjing Letop Biotechnology Co., Ltd. dated November 15, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Certain confidential information contained in this Exhibit was omitted by means of marking such portions with brackets because the identified confidential information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

Date: November 18, 2022

AMPHASTAR PHARMACEUTICALS, INC.

By: /S/WILLIAM J. PETERS

William J. Peters

Chief Financial Officer, Executive Vice President and
Treasurer

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS ([***]), HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

SUPPLY AGREEMENT

供应协议

This Supply Agreement (this “**Agreement**”) is entered into by and between the following parties on November 15, 2022 (the “**Effective Date**”):

本供应协议 (“本协议”) 由以下双方于 2022 年 11 月 15 日 (“生效日”) 签订：

(1) **Amphastar Nanjing Pharmaceuticals, Inc.**, a limited liability company duly incorporated and validly existing under the laws of PRC, with the unified social credit code: [***] (the “**Customer**”);
and

(1) 美药星（南京）制药有限公司，一家根据中国法律注册并存续的有限责任公司，社会统一信用代码为：[***] (“买方”)；及

(2) **Nanjing Letop Biotechnology Co., Ltd.**, a limited liability company duly incorporated and validly existing under the laws of PRC, with the unified social credit code: [***] (the “**Supplier**”).

(2) 南京乐韬生物科技有限公司，一家根据中国法律注册并存续的有限责任公司，社会统一信用代码为：[***] (“供应方”)。

The Supplier and the Customer are sometimes referred to herein collectively as the “**Parties**” and individually as a “**Party**”.

本协议项下供应方和买方合称为“双方”，单独称为“一方”。

Whereas, the Customer intends to purchase certain Products (as defined below) which are manufactured by the Supplier in the Territory based on Specifications and formula provided by the Customer, and the Supplier intends to accept such purchase order.

鉴于，买方有意购买供应方根据买方提供的质量标准及规程于区域内生产的特定产品（定义见下文），并且供应方有意接受该等采购订单。

Therefore, based on the principle of good faith, the Parties hereby agree as follows:

因此，双方基于诚实信用原则达成如下约定：

1. **General**

1. 总则

1.1 Headings or titles of this Agreement are used solely for convenience and shall be given no effect in the construction or interpretation of this Agreement.

1.1 本协议标题仅为方便查阅而设，不影响对本协议的解读或解释。

1.2 Additional agreements necessary to effectuate this Agreement may be executed between the Parties.

In the event of conflicting terms, the terms of this Agreement shall prevail.

1.2 双方可以签署为实现本协议所必需的附属协议。如有冲突，则以本协议的约定为准。

1.3 When used in this Agreement, the following terms shall have the meanings set forth in this section:

1.3 本协议中使用的术语含义解释如下：

(a) “**Affiliate**” means any person or entity which controls, is controlled by or is under the common control of a Party. As used in this Agreement, “**control**” means (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, or (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity.

(a) 关联方：指控制一方、受一方控制或与一方受共同控制的任何个人或实体。在本协议中，“控制”指(i)在公司实体中，直接或间接持有该实体不少于百分之五十（50%）的有权选举董事的投票权的股权或股份；或(ii)在非公司实体中，拥有直接或间接参与该实体的管理、决定或指导该实体管理政策的方向的权力。

(b) “**Applicable Law**” means all ordinances, rules, regulations, laws, and requirements of any authority applicable to the Manufacture, supply, use of the Products and/or other activities under this Agreement, as amended from time-to-time, including cGMP.

(b) 适用的法律：指不时修订的适用于产品的制造、供应、使用和/或本协议项下其他活动的任何监管机构的所有法令、规则、法规、法律和要求，包括cGMP。

(c) “**Confidential Information**” means technical and business information relating to inventions, proprietary ideas and/or patentable ideas, patent applications, background intellectual property, techniques, scientific knowledge, know-how processes, existing and/or contemplated products and services, software, biological material, schematics, research and development, production, costs,

profit and margin information, finances and financial projections, customers, clients, licensees, marketing, and current or future business plans and models, regardless of whether such information is designated as “Confidential Information” at the time of disclosure. The term “Confidential Information” does not include such information which:

- (i) is or becomes generally available to the public, other than through the receiving party’s disclosure,
 - (ii) was within the receiving party’s possession prior to it being furnished by or on behalf of the disclosing party, provided that receiving party’s source had no obligation of confidentiality to the disclosing party,
 - (iii) becomes available to the receiving party on a non-confidential basis from an information provider other than the disclosing party, provided that the information provider did not have a duty of confidentiality to the disclosing party, or
 - (iv) is or becomes independently developed by an employee of the receiving party without access to the Confidential Information and without violating any of the receiving party’s obligations under this Agreement, as can be demonstrated by the receiving party’s written records.
- (c) 保密信息：指与发明、专有思想和/或可转化为专利思想、专利申请、底层知识产权、技术、科学知识、专有技术流程、现有的和/或预期的产品和服务、软件、生物材料、示意图、研究和开发、生产、成本及利润信息、财务和财务预测、顾客、客户、被许可方、市场销售以及当前或未来的商业计划和模式有关的技术和商业信息，无论该等信息在披露时是否被指定为“保密信息”。“保密信息”不包括以下信息：
- (i) 在接收方披露前，已是公开或公众普遍可用的，
 - (ii) 在披露方提供或代表披露方提供信息之前，接收方已拥有的信息，前提是接收方的信息来源对披露方没有保密义务，
 - (iii) 接收方在非保密的基础上已从披露方以外的信息提供方获得的信息，前提是信息提供方对披露方没有保密义务，或
 - (iv) 接收方的员工在未接触保密信息且未违反接收方在本协议项下的任何义务的情况下，已独立开发获得的信息，且有接收方的书面记录证明。
- (d) “**Contract Year**” means each consecutive twelve (12) month period during the Term, the first of which shall commence on the Effective Date and shall end on the first anniversary thereof.
- (d) 合同年：指协议期限内每一连续的十二（12）个月，第一个合同年从生效日开始至一周年后结束。

- (e) “**Force Majeure**” means an event beyond the reasonable control of a Party including but not limited to, a breakdown of machinery or equipment, fire, flood, sabotage, shipwreck, embargo, strike, explosion, labor trouble, pandemic and related restrictions, accident, riot, act of governmental authority (including without limitation, acts relating to raw material or product allocation, and government drug files), acts of God, acts of war and delays or failures in obtaining materials, supplies, equipment or transportation.
- (e) 不可抗力：指超出一方合理控制范围的事件，包括但不限于机器或设备损毁、火灾、洪水、破坏、海难、禁运、罢工、爆炸、罢工、流行病和相关限制、事故、暴乱，政府当局的行为（包括但不限于与原材料或产品分配有关的行为，以及政府药事文件）、天灾、战争行为以及材料、供应品、设备或运输的延误或损坏。
- (f) “**NMPA**” means the National Medical Products Administration and any successor agency having substantially the same functions.
- (f) **NMPA**：指国家药品监督管理局，或具备相同职能的任一下属机构。
- (g) “**Manufacture**” and “**Manufacturing**” means any steps, processes and activities necessary to produce the Products, including without limitation, the manufacturing, processing, bulk packaging and labeling, quality control testing, release and storage of the Products.
- (g) 生产：指产品生产所需的任何步骤、流程及操作，包括但不限于产品的制造、加工、批量包装和贴签、质量控制测试、放行和储存。
- (h) “**PRC**” means the People’s Republic of China, but solely for the purposes of this Agreement, excluding the Hong Kong Special Administrative Region, the Macau Special Administrative Region and the islands of Taiwan.
- (h) 中国：指中华人民共和国，仅为本协议之目的，不包括香港特别行政区、澳门特别行政区和台湾地区。
- (i) “**Products**” mean any or all of the products listed in Appendix A hereof.
- (i) 产品：指本协议附录A中列明的任一或全部产品。
- (j) “**Regulatory Dossiers**” means all registration, permits, licenses, authorizations, approvals, presentations, notifications or filings (together with all applications therefore), which are filed with

or granted by the governing health authority of any country, and which are required to develop, make, use, or sell the Products.

- (j) **监管档案**：指产品的研发、生产、销售及使用所需的，向任一国家的卫生政府部门提交的或由任一国家的卫生政府部门授权的所有注册、许可、执照、授权、批准、介绍、通知或备案文件（及其全部申请材料）。
- (k) **“Specifications”** means the specifications set forth in Appendix B hereof, as such specifications may be adjusted from time to time by mutual written consent of the Parties.
- (k) **质量标准**：指本协议附录B列明的质量标准，可经由双方共同书面同意不时调整。
- (l) **“Term”** means the period during which this Agreement is in effect as set forth in Section 11.
- (l) **协议期限**：指本协议第11条所约定的本协议的生效期限。
- (m) **“Territory”** means the PRC.
- (m) **区域**：指中国。
- (n) **“Contract Price”** means, with respect to each Product, the Selling Price for each Product as provided in Appendix A, as such Selling Price may be adjusted based on the terms and conditions of this Agreement.
- (n) **合同价格**：指附录A列明的每项产品的销售价格，可根据本协议的条款和条件进行调整。

2. The Customer’s Rights and Obligations

2. 买方权利义务

2.1 The Customer shall issue purchase orders to the Supplier. The purchase order shall specify the quantity, standard, expected delivery date and other matters mutually agreed by the Parties. The Parties hereby agree that the Customer shall provide the Supplier with a delivery period of no less than ninety (90) days. The Supplier shall confirm within ten (10) business days after receipt of the purchase order.

2.1 买方应向供应方发出采购订单，采购订单中应明确数量、规格、拟要求交付时间以及其他双方共同同意的事项。双方确认，买方应为供应方提供至少九十（90）日的交货周期。供应方应当于收悉买方采购订单后十（10）个工作日内进行确认。

2.2 The Customer is entitled to decide the quantity of Products that it purchases from the Supplier at its own discretion, and the Customer has no obligation to purchase any minimum quantity of

Products from the Supplier.

2.2 买方有权自行决定向供应方购买的产品数量，买方无义务向供应方购买任何最低数量产品。

3. The Supplier's Rights and Obligations

3. 供应方权利义务

3.1 The Supplier shall deliver the Products to the Customer according to the requirements of the purchase orders confirmed by the Supplier, and FCA rules under International Rules for the Interpretation of Trade Terms 2020 (Incoterms 2020) shall apply to such delivery. The Parties hereby agree that the Supplier's additional costs arising from such delivery (including but not limited to, costs for transportation, customs and late receipt of the Customer's designated carrier) shall be borne by the Customer.

3.1 供应方应根据供应方确认的订单要求向买方交付产品，产品交付方式依照《国际贸易术语解释通则（2020年版）》FCA术语规则。双方确认，供应方因产品交付产生的额外费用成本（包括但不限于运输费用、出口清关费用、买方指定承运人逾期收货费用）应由买方承担。

3.2 The Supplier shall Manufacture and deliver the Products in conformance with the Applicable Law and regulations and Specifications.

3.2 供应方应依据适用法律、法规及质量标准的相关规定生产和交付产品。

4. Contract Price, Invoice and Payment

4. 合同价格、开票及结算

4.1 The Supplier shall issue invoices within five (5) business days after shipment, unless the Parties determine that the Products do not conform to the Specifications, payment shall be due thirty (30) days after the date of an invoice from the Supplier.

4.1 供应方应在发货后五（5）个工作日内向买方开具发票，除非经由双方确认产品不符合质量标准，买方应在供应方开具发票后三十（30）日内完成付款。

4.2 During the Term of this Agreement and not more than once during any twelve (12) month period, the Contract Price may be subject to an adjustment, provided that Supplier provides the Customer with two (2) months prior written notice of such proposed Contract Price adjustment and Customer agrees with such adjustment.

4.2 于协议期限内，供应方可经提前两（2）个月向买方发出书面通知并取得买方同意后调整

合同价格，该等合同价格调整在每十二（12）个月内不得超过一（1）次。

4.3 If the Supplier's manufacturing costs rise due to increased costs (e.g., due to increased power or labor costs, increased standards on environmental protection), the Parties shall separately agree on the Contract Price change after the Customer's verification of the increased costs using information supplied by the Supplier. During the negotiation of Contract Price change, the Supplier shall provide the relevant staff salary information, power cost invoices, environmental protection expenditure information, or other supporting materials. If the Customer adjusts the Specifications or relevant requirements unilaterally, or direct the Supplier to purchase designated raw materials and packaging materials, the Contract Price shall be adjusted accordingly.

4.3 如果供应方的生产成本因相关成本增加（例如因能耗、人工成本增加、环境保护标准提高等原因增加），双方应在买方核实供应方提供的成本增加的相关信息后另行商定合同价格的变更。在双方合同价格变更沟通期间，供应方应提供相关人工工资信息、电费发票、环保支出信息等配套材料。如果买方要求单方变更质量标准或产品要求，或向供应方指定原材料、包材的采购，合同价格需相应调整。

5. Supply of the Products

5. 产品供应

5.1 The Supplier shall promptly notify the Customer of any circumstances that result or are likely to result in any failure or delay in the supply or delivery of any Product in writing. If the Parties have a good faith belief, after mutual communication, that such circumstances may result in the failure or delay in the supply or delivery of such Product for more than ninety (90) days from the date of the Supplier's written notice, the Customer shall have the right to terminate such delivery after the full payment of costs and expenses of such Product to the Supplier.

5.1 供应方应将任何导致或可能导致任何产品交付失败或延误的问题及时书面告知买方，双方经沟通后认为该等情形将导致供应方无法于供应方发出书面通知之日起九十（90）日内完成产品交付的，买方有权在支付供应方该等产品成本及费用的情况下终止该等产品的该等交付。

6. Inspection of the Products

6. 产品检验

6.1 All Products received by the Customer will be subject to inspection and testing by the Customer, in accordance with the Customer's quality assurance program, within a period of thirty (30) days

from the date of receipt of such Products (“**Inspection Period**”). The Customer will notify the Supplier if the results of any inspection or testing indicate that the Products do not conform to the applicable Specifications or the other requirements under this Agreement. The Supplier will have ten (10) business days to respond to the Customer’s notice of non-conformance. Disputes between the Parties not resolved within ten (10) business days will be resolved by an independent laboratory selected by mutual consent of the Parties. A laboratory will be appointed not later than fifteen (15) business days after the expiry of the ten (10) business day period. If the laboratory finds the Products to be nonconforming, then at the Customer’s sole discretion, the Supplier shall (a) promptly deliver, at the Supplier’s sole expense, the replacement Products that conform to the requirements under this Agreement, or (b) refund or credit to the Customer all payments made by the Customer with respect of such nonconforming shipment. The Customer will, at the Supplier’s sole discretion, return or destroy the nonconforming Products at the Supplier’s sole expense, including without limitation transportation and handling costs.

- 6.1 收悉产品的三十（30）天内（“**检验期**”），买方将根据其质量保证程序对产品质量进行检验与测试。若检验或测试结果显示产品不符合质量标准或本协议的其他要求，买方将通知供应方。供应方应在十（10）个工作日内进行回复。若在十（10）个工作日内双方未达成一致，争议将通过经双方一致认可的独立实验室解决。双方将在上述十（10）个工作日期限届满后的十五（15）个工作日内就独立实验室的选择达成一致。若实验室检验结果仍不合格，经由买方决定，供应方应：(a)立即进行产品更换且费用自理，更换的产品应满足本协议要求；或(b)将买方就此类不合格产品支付的所有款项退还给买方或调整为对买方的应付款。经由供应方决定，买方将退回或销毁不合格产品，相关费用由供应方承担，包括但不限于运输和处理费用。

7. **Facility Qualification**

7. **设施资质**

- 7.1 The Supplier shall, take all commercially reasonable actions to qualify (and thereafter to maintain qualification of) the facility at which the Supplier Manufactures the Products, as required under Applicable Law, to enable the Customer to obtain and maintain all applicable Regulatory Dossiers in relation to the Products. The Supplier will permit the Customer and its agents, at the Customer’s expense, during normal business hours and upon reasonable prior notice to the Supplier, and no more than once per year, to inspect the Facility where the Products are Manufactured, handled, stored, or tested, as well as all batch records (without making any copies) and processes relating

to the Manufacture, storage, handling, or testing of the Products and all Manufacturing, handling, storage, and test records regarding the Products. The Supplier will respond to any non-conformances noted by the Customer, within thirty (30) business days of the written notification of such non-conformances, by submitting to the Customer a written report stating causes and corrective actions planned, and providing a timetable for the correction.

- 7.1 供应方应根据相关法律要求，采取一切商业上合理的措施使其生产产品的设施获得（并维持）相应资质，以确保买方能够获得并维持所有与产品有关的监管档案。供应方应允许买方及其代理商在事先通知的情况下，在正常工作时间内对与产品生产、处理、贮存或测试相关的设施、或与产品生产、贮存、处理或测试相关的批次记录（不可复制副本）和工艺流程、以及产品的所有生产、处理、贮存或测试记录进行每年不超过一（1）次的检查，相关费用由买方承担。供应方应在收到买方的不合格书面通知后三十（30）个工作日内向买方进行回复，通过纸质报告说明不合格原因与相应改正措施，并提供改正的具体时间安排。

8. Manufacturing Practices

8. 生产操作

- 8.1 The Supplier shall Manufacture the Products in conformance with the Specifications. The Supplier shall provide the Customer with such information, including analytical and manufacturing documentation, requested by the Customer regarding quality control of the Products supplied hereunder. The Supplier will solely be responsible for keeping proper records and documentation of the manufacturing and testing of the Products, intermediates, and starting materials, including batch records, testing records, laboratory notebooks, equipment usage, starting material batch numbers, and certifications. The Supplier will be responsible for investigating any test results or in-process testing of the Products that do not conform with the Specification. The Supplier will conduct such laboratory investigation, which must be approved by the Supplier's quality unit, and the Supplier will promptly notify the Customer of any adverse reactions or other safety or toxicity problems known to or reasonably suspected by the Supplier regarding the Products or its use. The Supplier will promptly notify the Customer of the results of any regulatory inspection, comments, responses or notices received from the NMPA or other applicable regulatory authorities, which relate to or may impact the Manufacture and supply of the Products to the Customer.

- 8.1 供应方应按照质量标准进行生产，应买方书面要求，供应方应向买方提供本协议项下供应产品质量控制的相关信息，包括分析和生产文件。供应方将负责适当保存与产品、中间体和起始物料的生产与测试有关的记录和文件，包括：审批记录、测试记录、实验记录、设

备使用记录、起始物料批号以及检验报告。供应方将负责调查产品发生任何不符合质量标准的测试结果或过程测试，该等调查采取实验室调查，须经供应方质量部门批准方可进行。供应方将及时通知买方针对产品已知的或合理怀疑的不良反应或其他安全或毒性问题以及自NMPA或其他机构收悉的可能影响产品生产及交付的检查、意见、答复或通知。

9. **Recall**

9. **召回**

9.1 During the Term, if either Party believes that it may be necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar actions with respect to any Product (a “**Recall**”), the Supplier and the Customer shall consult with each other as to how best to proceed. The Parties hereby agree that the final decision as to any Recall of any such Products shall be made by the Customer; provided, however, that the Supplier will not be prohibited hereunder from taking any action that is required by Applicable Law. The Customer shall be in charge of the Recall and establish a product recall system and recall management procedures, and the Supplier shall cooperate with the Customer as required by Applicable Law. In the event of a Recall, the Parties shall jointly find out and confirm reasons for the Recall, and except for reasonable costs borne by the Supplier if a Recall is incurred attributable to it, the Customer shall bear all costs incurred thereby.

9.1 于协议期限内，如果任一方认为有必要对任何产品进行召回、现场更正、市场撤回、库存回收或其他类似行动（“召回”），双方应协商达成最佳解决方案。双方同意，该等方案的最终决定权归买方所有，但前提是供应方也可根据相关法律要求采取相应行动。买方应当建立产品召回体系及召回管理程序，并负责召回工作，供应方在适用法律要求的范围内配合买方。产品发生召回的，由双方共同确认产品召回原因，除因供应方原因导致的产品召回由供应方承担合理费用外，任何与召回有关的费用由买方承担。

10. **Certificate of Analysis**

10. **检验报告**

10. The Supplier shall supply the same information on the certificate of analysis as is listed in the Specifications incorporated as Appendix B. No changes in Specifications will be made unless the Customer and the Supplier have agreed to such changes in writing prior to adoption of the modified Specifications.

10. 供应方应在检验报告中提供与附录B中所列质量标准相同的信息。除非经双方事先书面

同意，否则质量标准不得更改。

11. Term, Amendment and Termination

11. 协议期限、变更、解除或终止

11.1 This Agreement will remain in full force and effect for a period of three (3) Contract Years (the “**Term**”). Prior to the expiry of the Term, the Parties may, in their discretion, agree to extend the Term for a mutually agreed period.

11.1 本协议三个合同年的期限（“协议期限”）内保持完全效力。在协议期限届满之前，双方可经自行决定同意将协议期限延长至双方商定的期限。

11.2 During the Term, due to changes in laws and regulations, Specifications, Manufacturing procedures or other substantive conditions, this Agreement may be amended by the mutual written consent of the Parties. Any Amendment to this Agreement and its appendices hereto shall come into force with an instrument in writing signed by the Parties.

11.2 于协议期限内，因法律法规、质量标准、生产规程或其他实质性条件发生变化，经双方一致同意可对本协议进行变更，对本协议及其附录的修改，须经双方签署书面协议方能生效。

11.3 Unless otherwise provided for herein, either Party (the “**Terminating Party**”) may immediately terminate this Agreement by notifying the other Party (the “**Terminated Party**”) in writing when one of the following situations occurs:

- (a) The Terminated Party breaches this Agreement and (i) does not rectify its default within thirty (30) days on the date of receiving written notice from the Terminating Party requiring for rectification; or (ii) there is no realistic possibility to rectify such default; or (iii) such default has resulted in the inability to achieve the purpose of this Agreement;
- (b) The Terminated Party suffers a Force Majeure event which makes it impossible to achieve the purpose of this Agreement;
- (c) The Terminated Party expresses clearly or by behavior that it will not perform its obligations hereunder, or delays the performance of its obligations and has not fully performed the obligations after being notified;
- (d) The Terminated Party loses the ability to perform its obligations hereunder, including but not limited to, entering bankruptcy proceedings, liquidation proceedings, being dissolved, being winding up, being revoked, or losing appropriate qualifications.

11.3 除本协议另有约定外，任一方（“解除方”）可在出现下述情形之一时书面通知另一方（“被解除方”）立即解除本协议：

- (a) 被解除方违反本协议约定且(i) 在收悉解除方书面通知要求其纠正违约行为之日起三十（30）日内未纠正其违约行为的；或(ii) 实际上已不存在纠正违约行为的可能；或(iii) 存在违约行为导致不能实现协议目的；
- (b) 被解除方遭遇不可抗力且不可抗力致使不能实现协议目的；
- (c) 被解除方明确表示或以行为表明不履行本协议义务，或者迟延履行本协议义务且经催告后仍未全面履行的；
- (d) 被解除方丧失协议履行能力，包括但不限于，进入破产程序、清算程序、被解散、被注销、被吊销、丧失相应资质。

11.4 This Agreement may be terminated by mutual written consent of the Parties.

11.4 本协议可经由双方共同书面同意而终止。

11.5 Upon expiration or termination of this Agreement, the Supplier will promptly complete and invoice for all deliverables of open and accepted purchase orders received from the Customer prior to the termination or expiration of this Agreement, and the Customer shall pay to the Supplier within thirty (30) days from the date of invoice.

11.5 本协议到期或终止时，供应方应根据本协议到期或终止前已接受但未完成的买方采购订单交付产品并开具发票，买方应在供应方前述开票之日起三十（30）日内支付供应方款项。

11.6 Termination or expiration of this Agreement shall not relieve either Party of any obligation accruing prior to such termination or expiration, including, without limitation, any breach of such obligation, or from any surviving obligation under this Agreement.

11.6 本协议的解除、终止或到期不免除任一方在该等解除、终止或到期前产生的任何义务，包括但不限于对该等义务的任何违约，或本协议项下的任何存续义务。

11.7 Either Party shall return or destroy all documents and materials in its possession which contain Confidential Information of the other Party within thirty (30) days after termination or expiration of this Agreement. The receiving party may retain one copy of documents and materials which contain the disclosing party's Confidential Information for the purpose of verifying the receiving party's compliance with its obligations under this Agreement but for no other purpose whatsoever.

11.7 任何一方应在本协议解除、终止或到期后三十（30）日内归还或销毁其持有的包含另一

方保密信息的所有文件和材料。接收方可以保留包含披露方保密信息的文件和材料的一份副本，以核实接收方是否遵守其在本协议项下的义务，但不得以任何其他目的。

11.8 Unless otherwise provided for herein, after termination or expiration of this Agreement, section 1 (*General*), this section 11 (*Term, Amendment and Termination*), section 12 (*Intellectual Property Rights*), section 13 (*Warranties*), section 14 (*Indemnities*), section 15 (*Confidential Information*), section 16 (*Force Majeure*), section 17 (*Notices*), section 18 (*Binding Effect*), section 19 (*Governing Law and Dispute Resolution*), section 20 (*Assignment*), section 21 (*Severability*), section 22 (*Entire Agreement*), section 23 (*Waiver*), section 24 (*Publicity*), section 25 (*Appendices*), section 26 (*Counterparts and Language*) shall survive.

11.8 除本协议另有约定外，本协议解除、终止、到期后，本协议第1条（总则）、第11条（协议期限、变更、解除或终止）、第12条（知识产权）、第13条（保证）、第14条（赔偿）、第15条（保密信息）、第16条（不可抗力）、第17条（通知）、第18条（合同约束力）、第19条（管辖法律及争议解决）、第20条（转让）、第21条（可分割性）、第22条（完整协议）、第23条（弃权）、第24条（公开发布）、第25条（附录）及第26条（副本和语言）仍持续有效。

12. Intellectual Property Rights

12. 知识产权

12.1 The Supplier will retain ownership of all the Supplier's Confidential Information that may be shared with the Customer during the Term of this Agreement, including retention of any manufacturing and production process for the Products (and all know-how of such process).

12.1 供应方将保留在执行本协议的过程中可能与买方共享的所有供应方保密信息的所有权，包括保留任何产品的生产和制作流程（以及相应的专有技术）。

12.2 The Customer will retain ownership of all Confidential Information the Customer shares with the Supplier during the Term of this Agreement.

12.2 买方将保留在执行本协议过程中与供应方共享的所有买方保密信息的所有权。

13. Warranties

13. 保证

13.1 The Supplier warrants that the Products delivered to the Customer and pursuant to this Agreement

shall at the time of such delivery not be adulterated or misbranded within the meaning of the Applicable Law, and that it holds all necessary intellectual property rights and licenses, filings or approvals required by all Applicable Law for the Manufacture, supply, use of the Products and/or other activities under this Agreement. The Supplier represents and warrants that it will comply with all present and future statutes, laws, ordinances and regulations relating to the Manufacture, assembly and supply of the Products being provided hereunder, including without limitation, those enforced by the NMPA.

13.1 供应方保证其根据本协议所交付的产品不会因违背任何法律而被视为假药或贴错标签，并保证其拥有制造、供应、使用产品及/或开展本协议项下的其他活动所有必要的知识产权以及一切适用法律要求的许可、备案或批准。。供应方声明并保证其将遵守与本协议中产品的生产、制备和供应相关的所有现行和未来法令、法律、法规和条例，包括但不限于NMPA的法规。

13.2 The Parties are not authorized to, and shall not, incur any liability for which the other Party may become directly, indirectly or contingently liable, nor shall they, except as explicitly provided in this Agreement, hold themselves out as having authority to represent or act on behalf of the other Party in any capacity whatsoever, nor shall the relationship between the Parties be construed as a co-partnership, joint venture or principal-agent relationship.

13.2 双方无权也不应承担另一方可能直接、间接或偶然承担的任何责任，除非本协议有明确规定，否则双方不得以任何身份自称有权代表另一方或以另一方名义行事，双方之间的关系也不得被解释为合伙、合资或委托代理关系。

14. Indemnities

14. 赔偿

14.1 Unless arising from the willful misconduct of the Supplier, the Customer will defend, indemnify and hold the Supplier and its Affiliates and their respective employees, servants and agents harmless against any liability, judgment, demand, action, suit, loss, damage, cost or other expense (including reasonable attorneys' fees and other costs of defense) resulting from: (i) the Customer's material breach of this Agreement or (ii) the Customer's breach of any warranty made under this Agreement.

14.1 除非因供应方故意不当行为引起，当(i)买方实质性违反本协议；或(ii) 买方违反其在本协议项下的任何保证时，买方应为供应方及供应方关联方、供应方及其关联方的雇员、服务人员、代理商提供抗辩及赔偿，以使得供应方及供应方前述主体免受任何责任、判决、要

求、行为、诉讼、损失、损害或费用支出（包括合理的律师费及其他辩护费用）。

14.2 Unless arising from the willful misconduct of the Customer, the Supplier will defend, indemnify and hold the Customer and their Affiliates and their respective employees, servants and agents harmless against any liability resulting from any third party claims made or proceeding brought against the Customer to the extent that such liability arises from (i) the alleged or actual negligence or wilful misconduct of the Supplier; (ii) the Supplier's material breach of this Agreement; (iii) the Supplier's breach of any warranty made under this Agreement; or (iv) any infringement of any third party intellectual property rights in relation to the Products.

14.2 除非因买方故意不当行为引起，当(i) 供应方存在被指称的或实际的过失或故意不当行为；(ii) 供应方实质性违反本协议；(iii) 供应方违反其在本协议项下的任何保证；或(iv) 供应方存在与产品有关的侵犯任何第三方知识产权的情形，供应方应为买方及买方关联方、买方及其关联方的雇员、服务人员、代理商提供抗辩及赔偿，以使得买方及买方前述主体免受损害。

14.3 Each indemnified party agrees to give the indemnifying party prompt written notice of any matter upon which such indemnified party intends to base a claim for indemnification (an “**Indemnity Claim**”) under Section 14. The indemnifying party will have the right to participate jointly with the indemnified party in the indemnified party's defense, settlement or other disposition of any Indemnity Claim. With respect to any Indemnity Claim relating solely to the payment of money damages and which could not result in the indemnified party's becoming subject to injunctive or other equitable relief or otherwise adversely affect the business of the indemnified party in any manner, and as to which the indemnifying party will have acknowledged in writing the obligation to indemnify the indemnified party hereunder, the indemnifying party will have the sole right to defend, settle or otherwise dispose of such Indemnity Claim, on such terms as the indemnifying party, in its sole discretion, will deem appropriate, provided that the indemnifying party will provide reasonable evidence of its ability to pay any damages claimed and with respect to any such settlement will have obtained the written release of the indemnified party from the Indemnity Claim. The indemnifying party shall apply for a written release from the indemnified party prior to ceasing to defend, settling or otherwise disposing of any Indemnity Claim. If as a result thereof the indemnified party has been subject to injunctive or other equitable relief or the business of the indemnified party has been adversely affected in any matter, the application for exemption will be rejected.

14.3 受偿方同意立即书面通知赔偿方，其根据本协议第14条拟提起的赔偿主张（“赔偿主张”）。

赔偿方有权参与受偿方对任何赔偿的辩护、和解或以其他方式处理赔偿主要的活动。对于任何仅与经济赔偿有关且不会导致受偿方受限于禁令或其他衡平法救济，也不会以任何形式对受偿方的业务活动产生不利影响的赔偿主张，同时赔偿方已通过书面形式确认了其在本协议项下对受偿方的赔偿义务，则赔偿方拥有以其自行认为合理的方式辩护、和解或以其他方式处理上述赔偿主张的权利，但前提是赔偿方提供合理的证据证明其有能力支付任何被主张的损害赔偿，并且就任何此类和解已获得受偿方的书面免责声明。赔偿方应在辩护、和解或其他处理方式结束之前，向受偿方申请书面免责声明，若受偿方已获得禁令、衡平法救济或其业务活动已受到不利影响，免责申请将被拒绝。

14.4 Unless otherwise provided for herein, if the Customer pays the Contract Price under this Agreement which are overdue, the Supplier shall have the right to require the Customer to pay 0.05% interest of the overdue payment per day as liquidated damages.

14.4 除本协议另有约定外，买方逾期支付供应方本协议项下合同价格，每逾期一天，供应方有权要求买方支付逾期付款部分的每日万分之五（0.05%）的利息作为违约金。

15. Confidential Information

15. 保密信息

15.1 The receiving party will treat as confidential and secret all information which has been or may hereafter be disclosed by the disclosing party, directly or indirectly, to the receiving party, either orally, in writing or through inspection. The receiving party shall use the Confidential Information received only to the extent necessary to execute the Purpose of this Agreement. The receiving party will not disclose to anyone any Confidential Information received from the disclosing party, and will use the same degree of care, but no less than a reasonable degree of care, to prevent the disclosure of the Confidential Information to others as it uses to prevent the disclosure of its own Confidential Information. Upon request from the disclosing party, the receiving party will promptly return to the disclosing party or destroy all drawings, data, memoranda and information in physical form relating to the Confidential Information.

15.1 接收方应对披露方直接或间接以口头、书面或检查的形式提供的所有信息（保密信息）进行保密。接收方仅可在履行与本协议目的所必需的范围内使用收悉的保密信息。接收方不得向任何人披露其从披露方收悉的任何保密信息，并将采取任何可行的措施保护保密信息的保密性，程度不得低于其对自身保密内容或同样性质内容的保护，并避免泄露和非授

权使用。在披露方要求下，接收方应立即向披露方返还或销毁所有与保密信息有关的图纸、数据、备忘录和实物形式的信息。

15.2 Each Party agrees to keep the Confidential Information confidential, which includes (but is not limited to) not disclosing the disclosing party's Confidential Information, or any part thereof (except as otherwise may be provided herein), absent the disclosing party's prior written consent, unless required to do so by Applicable Law, act or a valid order of a court or other governing, regulatory body with authority over the receiving party ("**Required Disclosure**"); provided that the receiving party will first give reasonable written notice to the disclosing party prior to any Required Disclosure and will exercise its best efforts to obtain an order or other reliable assurance that the Confidential Information disclosed will be treated at the highest level of confidentiality. Upon receipt of notice from the receiving party of any Required Disclosure, the disclosing party may, at the disclosing party's expense, seek to quash or restrict the disclosure of the disclosing party's Confidential Information and the receiving party will not oppose or seek to impede the disclosing party's efforts to obtain such relief.

15.2 每一方同意对保密信息予以保密，包括（但不限于）不得在未经披露方书面同意（除非本协议另有规定），披露披露方提供的保密信息，除非适用法律、法令或对接收方有管辖权的法院或其他管理、监管机构的有效命令要求披露（“**必要披露**”）。前提是接收方应在任何必要披露前向披露方发出书面通知，且需尽最大努力获得法令或其他可靠保证以确保所披露的信息得到最高级别的保密处理。在收悉接收方发出的任何必要披露的通知时，披露方可在自行承担费用的情况下寻求撤销或限制对披露方保密信息的披露，接收方不得反对或阻碍披露方获得该等救济。

15.3 This provision of confidentiality is not intended to grant or transfer any rights to the Confidential Information to the receiving party and does not transfer or convey any rights under a patent, trademark, copyright, or other intellectual property right to or in the Confidential Information. All Confidential Information (including all copies thereof) will at all times remain the property of the disclosing party. Further, and unless otherwise provided in this Agreement, the disclosure of Confidential Information to a receiving party does not create, and is not intended to create, any form or type of agency by and between the disclosing party and the receiving party.

15.3 本保密条款无意向接收方授予或转让任何保密信息的任何权利，也无意于转让任何专利、商标、版权或其他知识产权项下的保密信息的任何权利。所有保密信息（包括其所有复印件）将始终为披露方所有。此外，除非本协议另有规定，向接收方披露保密信息并不产生，

也无意在披露方和接收方之间产生任何形式或类型的代理。

15.4 The receiving party agrees that its obligations hereunder are necessary and reasonable to protect the disclosing party, and expressly agrees that monetary damages would be inadequate to compensate the disclosing party for any breach of any covenant or agreement set forth herein and that, in addition to any and all other remedies available at law or in equity, the disclosing party will be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any actual or threatened breach of this Agreement, and no bond or other security will be required in connection with any such equitable relief. In the event of litigation relating to this Agreement, if a court of competent jurisdiction determines that a Party has breached this Agreement, then the non-breaching party may seek recovery of its reasonable legal fees, including any appeal, in addition to any other remedies to which the non-breaching party may be entitled.

15.4 接收方同意本协议项下的义务对于保护披露方均为必要且合理的，如违反本协议约定，不仅应赔偿披露方经济损失，除法律或衡平法上可获得的任何和所有其他救济之外，披露方有权针对任何实际或可能违反本协议的行为寻求衡平法救济，包括禁令和特别履行，并且无需对该等衡平法救济提供任何保函或担保。如发生与本协议有关的诉讼，如果有管辖权的法院判定一方违反了本协议，则守约方有权要求获得合理的律师费（含上诉）及采取其他补救措施。

16. Force Majeure

16. 不可抗力

16.1 If the performance by either Party of any obligation under this Agreement, other than the payment of money, is prevented or impaired by a Force Majeure event, such Party will be excused from performance so long as such situation continues to prevent or impair performance, provided the Party claiming such excuse must promptly notify the other Party of the existence, nature, duration and other details of the Force Majeure event and will at all times use reasonable efforts consistent with its normal business practices to resume a complete performance.

16.1 协议双方除履行付款义务外，因不可抗力的持续造成一方无法履行协议约定的义务时，该方可免除履行义务，前提是一方应立即告知另一方不可抗力的性质、持续时间及其他具体细节，并始终依照行业惯例尽合理的商业努力以恢复协议义务的履行。

16.2 In the event of a Force Majeure event, the exempting party will advise the other Party from time to time as to the progress in remedying the situation and as to the time when the exempting party

expects to resume its obligations. The exempting party shall promptly inform the other Party of elimination of such Force Majeure event.

16.2 不可抗力免责方应定期告知另一方补救措施的进展以及预计何时恢复履行义务。不可抗力事件结束后，免责方应立即告知另一方。

17. Notices

17. 通知

17.1. All notices hereunder shall be in writing and shall be delivered personally, mailed by overnight delivery, registered or certified mail, postage prepaid, or given by facsimile to the following addresses of the respective Parties:

If to the Customer: **Address:** Amphastar Nanjing Pharmaceuticals, Inc.
No. 5 Xinghe Road
Nanjing Economic and Technological Development Zone
Jiangsu, China
Attn: General Manager
Post Code: 210038

If to the Supplier: **Address: Nanjing Letop Biotechnology Co., Ltd.**
Building C5, No.9 Weidi Road, Xianlin University Town, Xianlin
Street, Qixia District, Nanjing City, Jiangsu Province
Attn: Eric Xu
Post Code: 210033

17.1. 本协议项下的所有通知均采用书面形式，应通过亲自递送、隔夜递送、挂号信、预付邮资或传真方式发送至双方的地址，具体如下：

买方：美药星（南京）制药有限公司
地址：中国江苏省南京经济技术开发区兴和路5号
联系人：General Manager
邮箱：210038

供应方：南京乐韬生物科技有限公司
地址：中国江苏省南京市栖霞区仙林大学城纬地路9号C5栋

联系人：徐勇刚

邮编：210033

18. Binding Effect

18. 合同约束力

18.1. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective assigns and successors in interest.

18.1. 本协议将对双方及其各自的受让人和利益继承人具有约束力并及于其各自之利益。

19. Governing Law and Dispute Resolution

19. 管辖法律及争议解决

19.1 The Agreement shall be construed, interpreted and governed by the laws of the PRC.

19.1 本协议应受中国法律管辖并解释。

19.2 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) (the “**Disputes**”) shall first be resolved through consultation. If the Disputes cannot be resolved through negotiation, the Dispute (including a Dispute in connection with the validity or continuity of this Agreement) shall be submitted to arbitration in Shanghai under the auspices of the Shanghai International Economic and Trade Arbitration Commission with its then effective arbitration rules. The arbitration tribunal shall be consisted by three (3) members. One (1) arbitrator shall be appointed by the Party initiating the arbitration, one (1) arbitrator shall be appointed by the other Party, and the third arbitrator shall be jointly selected by the two (2) appointed arbitrators.

19.2 本协议以及因本协议及其内容或成立而引起的或与之相关的任何争议或诉请（包括非合同争议或诉请）（以下简称“争议”）应由双方通过友好协商解决。如不能通过协商解决的，则该争议（包括有关本协议有效性或存续性的争议）应提交上海国际经济贸易仲裁委员会，按照其届时有效的仲裁规则在上海进行仲裁。仲裁庭由三（3）名成员组成。其中一（1）名仲裁员由提起仲裁方指定，一（1）名仲裁员由答辩方指定，第三名仲裁员由该两名仲裁员共同选定。

19.3 The award of the arbitration tribunal shall be final and binding upon the Parties, and each Party may apply to a court of competent jurisdiction for enforcement of such award. Except for matters

in the Dispute during a Dispute which is being resolved in accordance with this Agreement, the Parties shall continue to perform their obligations hereunder.

19.3 仲裁裁决应为终局的，对双方均具有约束力，并可根据有关条款规定强制执行。在按照本协议约定解决争议期间，除争议所涉事项外，双方应继续履行其在本协议项下的义务。

20. Assignment

20. 转让

20.1 Neither Party shall assign or transfer its rights and obligations hereunder to any other party without the prior written consent of the other Party. Notwithstanding the foregoing, this Agreement and the rights and obligations herein may be assigned by each Party to any of its Affiliate, and either Party, may assign or sell the same in connection with the transfer or sale of substantially its entire business to which this Agreement pertains or in the event of its merger or consolidation with another company without such consent. Any permitted assignee will assume all obligations of its assignor under this Agreement.

20.1 未经另一方事先书面同意，任何一方均不得转让本协议。尽管有前述约定，一方可将其本协议项下权利义务转让给其关联方，且一方转让或出售其与本协议有关的绝大部分业务或与另一家公司合并时转让本协议则无需征得另一方同意。任一获准受让人应承担其转让人在本协议项下的所有义务。

20.2 No assignment will relieve any Party of the responsibility for the performance of any obligation hereunder.

20.2 任何形式的转让都不会免除任何一方履行本协议项下任何义务的责任。

21. Severability

21. 可分割性

21.1. In the event that any term or provision of this Agreement is held invalid or unenforceable by a court of competent jurisdiction, the remaining terms shall be valid and enforced to the fullest extent permitted by Applicable Law. If any term or provision of this Agreement is deemed by a court to be unenforceable because such provision is too broad in scope, the provision shall be construed in a limited scope to make it enforceable.

21.1. 若本协议的任何条款或约定被有管辖权的法院认定为无效或不可强制执行，其余条款将在适用法律允许的最大范围内有效并可强制执行。如果本协议的任何条款或约定因适用范

围过宽而被法院认定为不可强制执行，则该条款将在有限范围内进行解释以使其具有可强制执行性。

22. Entire Agreement

22. 完整协议

22.1. This Agreement constitutes the entire agreement between the Parties concerning the subject matter and supersedes all prior agreements or understandings between the Parties.

22.1. 本协议构成双方之间关于就本协议主题事项的全部约定，并取代双方之前所有的约定或谅解。

23. Waiver

23. 弃权

23.1. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed a waiver of any rights, nor will a waiver by a Party in one instance be construed as a continuing waiver or a waiver in other instances.

23.1. 除非由双方授权代表书面签署，否则对本协议任何条款的放弃或修改均无效。任何一方未能行使本协议项下的权利不应被解释为在该情况下或任何其他情况下放弃此类权利。任何一方在某种情况下的弃权也不应被解释为持续性弃权或视为在其它情况下的弃权。

24. Publicity

24. 公开发布

24.1. Other than as required by Applicable Law, in the absence of specific agreement between the Parties, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, to stockholders or otherwise relating to this Agreement.

24.1. 除适用法律要求外，在双方间无具体协议或约定的情况下，任何一方不得向公众媒体、股东或以其他方式发起与本协议相关的任何书面或口头的宣传、新闻发布或其他公告。

25. Appendices

25. 附录

25.1. All appendices referenced herein are made a part of this Agreement.

25.1. 本协议中所有附录均构成本协议的一部分。

26. Counterparts and Language

26. 副本和语言

26.1. This Agreement may be executed in several duplicates, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. For the avoidance of doubt, this Agreement is concluded both in Chinese version and English version. In the event of any discrepancy between the Chinese version and the English version, the English version shall prevail.

26.1. 本协议可签署多份副本，每一份副本均应被视为原件，且所有副本应共同构成同一文件。为避免疑义，本协议以中文和英文书就。若中文版本和英文版本之间存在不一致之处，应以英文版本为准。

In Witness whereof, the Parties have executed this Agreement by their duly authorized representatives.

兹证明，双方已由其正式授权代表签署本协议。

Amphastar Nanjing Pharmaceuticals, Inc.

美药星（南京）制药有限公司

Nanjing Letop Biotechnology Co., Ltd.

南京乐韬生物科技有限公司

By/签署: /s/Perky Qiu

By/签署: /s/ Eric Xu

Name/姓名: 邱银华 Perky Qiu

Name/姓名: 徐勇刚 Eric Xu

Title/职位: 总经理 General Manager

Title/职位: 总经理 General Manager

Date/日期: 2022-11-15

Date/日期: 2022-11-15

APPENDIX A: PRODUCTS AND CONTRACT PRICE

附录A：产品及合同价格

No.	Products	Unit	Selling Price/Unit (RMB)
1	Phytol (VK01-A0) 植物醇	kg	[***]
2	α -Tropine α -托品醇	kg	[***]
3	Chloracetyl Catechol 氯乙酰儿茶酚	kg	[***]
4	Epinephrine Bitartrate 酒石酸肾上腺素	kg	[***]
5	Cholic acid 胆酸	kg	[***]
6	N-Isopropyl nortropine N-异丙基托品醇	kg	[***]
7	1-(2, 2-dimethyl-4h-1,3-benzodioxin--6-yl)-2-(1-phenylethylamine)ethanol (SM-8)	kg	[***]
8	1-[4-[(6-Bromohexyl)oxy]butyl]benzene (SM-10)	kg	[***]
9	1-Hydroxy-2-naphthoic Acid 1-羟基-2-萘甲酸	kg	[***]
10	17-BETA CARBOXYLIC ACID; 6a,9a-difluoro-11 α -hydroxy-16 α -methyl-17 α -propionyloxy-3-oxo (F6B-A0) 氟替卡松丙酸酯起始物料	kg	[***]
11	Butyraldehyde 正丁醛	L	[***]
12	Benzenemethanol (S2B-A0) 富马酸福莫特罗起始物料	kg	[***]

“Selling Price” means, with respect to each Product, an amount equal to the sum of (i) the Direct Costs to manufacture such Product, plus (ii) [***]% of the amount of such Direct Costs plus any applicable taxes.

出售价格：指金额等于产品直接成本加上直接成本的[***]%以及所适用税款的总和。

“**Direct Costs**” means, with respect to a Product, the actual cost of raw materials, packaging components, overhead expense applied on a consistent basis with other products manufactured by ANP, and direct labor used to produce such Product. In no event will Direct Costs include expenses related to unutilized facility capacity, or allocations for corporate overheads.

直接成本：指乙方用于产品生产及相关的实际费用，包括：原材料，包装材料，管理及人工费用。任何情况下，直接成本都不包括未参与生产的设施费用，或公司内部管理费用。

APPENDIX B: SPECIFICATIONS

附录B：质量标准