Impavido ®

CONSIGNMENT AGREEMENT

This Consignment Agreement (this “Agreement”) is made as of this \_\_\_\_ day of \_\_\_\_\_\_\_\_, 20\_\_ by and between Profounda, Inc. a Delaware corporation (the “Company”), and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_., a \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_corporation (the “Consignee”).

WHEREAS, the Company desires to consign to the Consignee certain goods set forth on Schedule 1 attached hereto (the “Consigned Goods”), for the purpose of facilitating a sale of the Consigned Goods by the Consignee; and

WHEREAS, the Consignee desires to accept delivery of the Consigned Goods and to remit payment to the Company upon the use of such goods on the terms and subject to the conditions set forth in this Agreement.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which the parties hereto both acknowledge, the Company and the Consignee hereby agree as follows:

1. Consignment of Goods; The Company shall deliver the Consigned Goods for consignment to the Consignee, F.O.B. the Consignee’s plant. The Consignee shall accept delivery of the Consigned Goods, and ACKNOWLEDGES THAT IT TAKES POSSESSION OF THE CONSIGNED GOODS SOLELY ON A CONSIGNMENT BASIS AND DOES NOT ACQUIRE ANY PROPERTY RIGHT OR SECURITY INTEREST IN SUCH CONSIGNED GOODS BY REASON OF ITS POSSESSION THEREOF. The Company’s consignment of the Consigned Goods is a true consignment in all respects, and not a consignment intended as a security.

2. Independent Contractor. The Consignee is, and shall remain, an independent contractor selling to third-party buyers for its own account. The Company does not appoint the Consignee as its agent or authorize the Consignee to hold itself out as its agent, and does not convey to the Consignee any property interest in the Company’s corporate name, trademarks, or goods.

3. Sale of and Title to Consigned Goods.

a. Purchase of Consigned Goods by the Consignee. The Company shall retain title to, and the right to immediately possess, the Consigned Goods until the Consignee purchases such goods from the Company. The Consignee shall purchase the Consigned Goods in accordance with the price list, set forth in Schedule 1 hereto, as such Schedule may be amended by the Company. The Consignee’s purchase of the Consigned Goods from the Company shall be deemed to occur immediately upon the Consignee’s usage, sale, transfer, further consignment, transfer or disposition of the Consigned Goods (and for purposes of this Agreement, the term “usage” shall also include all sales, transfers, further consignments, transfers or dispositions of the Consigned Goods).

b. Passing of Title. Title to the Consigned Goods purchased hereunder shall pass from the Company to the Consignee upon the Consignee’s usage of such goods.

c. Right to Inspection. The Company has the right to inspect the Consignee’s inventory of Consigned Goods at any time during the Consignee’s normal business hours without prior notice.

4. Reports; Payment by Consignee. At or about the first business day of each month, the Consignee shall furnish the Company with a report that shows the amount and type of Consigned Goods used by the Consignee during the prior month. The Company shall then prepare and send to the Consignee an invoice for the Consigned Goods so used. The Consignee shall remit any and all amounts due and owing to the Company within 10 days of receipt of a properly prepared invoice.

The Consignee shall pay a fee of one-percent (1%) per month on the balance of any amounts due and owing to the Company as a result the Consignee’s purchase of the Consigned Goods pursuant to Section 3.a. above that the Consignee fails to timely remit. The Consignee shall pay all reasonable attorneys’ fees and court costs incurred by the Company in any action or proceeding to collect any amounts due and owing to the Company hereunder.

5. Liability for Misrepresentations. The Company shall not be liable for any misrepresentations or omissions of fact that the Consignee, or any of its agents, makes with respect to the Consigned Goods, nor for any alteration, damage, or defect in the Consigned Goods that results from the Consignee’s improper handling or storage of such goods. The Consignee shall indemnify and hold the Company, its officers, directors, employees, and agents harmless from and against any and all costs, fees, damages, and expenses (including, but not limited to, reasonable attorneys’ fees) resulting therefrom.

6. Liability for Loss or Damage; Insurance. The Consignee shall be responsible for any loss of, or damage to, the Consigned Goods while such goods are on Consignee’s property or otherwise under its control. Following delivery of the Consigned Goods to the Consignee, the Consignee shall take good care of, and shall be responsible for, their safekeeping. The Consignee shall be responsible in case of any loss or damage to the Consigned Goods and shall fully insure the Consigned Goods against loss, theft, damage, or destruction. in an amount at least equal to the purchase price of such Consigned Goods.

7. Encumbrance of Consigned Goods; Financing Statements. The Consignee shall not pledge or encumber any of the Consigned Goods. The Consignee shall execute and deliver to the Company such financing and continuation statements, and all other documentation, that the Company reasonably deems necessary to establish, maintain, and protect its security interests in the Consigned Goods including, but not limited to, any U.C.C.-1 statements.

8. The Company’s Warranties.

a. Good Title. The Company hereby warrants that it has good and marketable title to the Consigned Goods free and clear of any encumbrances, liens or, other restriction, and that any buyer of the Consigned Goods shall receive good and marketable title thereto. The Company further warrants that it has all the requisite power and authority necessary to deliver the Consigned Goods to the Consignee and to sell such goods.

b. Condition of the Goods. The Company warrants that the Consigned Goods: (i) are not adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, (ii) are merchantable, (iii) conform in all material respects to Consignee’s specifications, (iv) comply with all applicable laws and (v) will be replaced upon expiry of the product with replacement unexpired product (upon receipt of expired unused product).

c. Authority. The Company warrants that it has full power and authority to execute, deliver, and perform this Agreement and any agreement, document, or instrument executed and delivered pursuant to this Agreement or in connection with this Agreement. The Company’s execution, delivery, and performance of this Agreement and any agreement, document, or instrument executed and delivered pursuant to this Agreement or in connection with this Agreement, have been duly authorized and approved by all necessary action, including all necessary corporate, board, and stockholder action.

d. No Conflict. The Company warrants that (i) the execution or the delivery of this Agreement, (ii) the consummation of any and all of the transactions contemplated hereby, and (iii) compliance with or fulfillment of the terms, conditions, and provisions hereof will not violate or conflict with, or result in a breach of the terms, conditions, or provisions of, any material instrument, agreement, or other obligations to which the Company is a party.

9. The Consignee’s Warranties.

a. Inspection of the Consigned Goods. The Consignee warrants that it shall, prior to using any products hereunder, examine and inspect the Consigned Goods. Consignee shall inspect all Consigned Goods promptly and shall be deemed to have accepted all Consigned Goods if Consignee has not specifically rejected any portion thereof within 30 days of delivery, such rejection applying only to the portion so rejected. Any rejected portion of the Consigned Goods shall be segregated and clearly marked. Consignee may not reject, and must use, any Consigned Goods which Consignee or any of its agents alter, misuse, improperly store or maintain

b. Authority. The Consignee warrants that it has full power and authority to execute, deliver, and perform this Agreement and any agreement, document, or instrument executed and delivered pursuant to this Agreement or in connection with this Agreement. The Consignee’s execution, delivery, and performance of this Agreement and any agreement, document or instrument executed and delivered pursuant to this Agreement or in connection with this Agreement, have been duly authorized and approved by all necessary action, including all necessary corporate, board, and stockholder action.

c. No Conflict. The Consignee warrants that (i) the execution or the delivery of this Agreement, (ii) the consummation of any and all of the transactions contemplated hereby, and (iii) compliance with or fulfillment of the terms, conditions, and provisions hereof will not violate or conflict with, or result in a breach of the terms, conditions, or provisions of, any material instrument, agreement, or other obligation to which the Consignee is a party.

10. Identity of Ownership of the Consigned Goods. The Consignee shall not co-mingle any of the Consigned Goods with its own property or the property or merchandise of any other consignor. The Consignee shall segregate the Consigned Goods so that they are readily identifiable as belonging to the Company. The Consignee shall not represent to any third-party that it holds title to the Consigned Goods, and shall place a clearly visible tag or other marker on the Consigned Goods which clearly identifies that the Consigned Goods belong to the Company. The Company has the right, in its sole discretion, to inspect the Consigned Goods, with notice to the Consignee, and to place a tag or other marker on any of the Consigned Goods that identifies Company.

11. Remedy of Breach of Representations and Warranties

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OTHER PERSON OR ENTITY UNDER CONTRACT, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY FOR SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATED TO THE SUBJECT MATTER OF THIS AGREEMENT.

12. **Term**

This Agreement shall commence on the date of this Agreement and continue for a period of twelve (12) months, and shall renew automatically every 12 months until cancelled.

13. **Termination**

The Company may terminate this Agreement at any time by giving 30 days prior written notice in the event that the Consignee fails to fulfill any of its obligations hereunder. Upon termination by the Company, the Consignee shall deliver, at the Consignee’s sole expense, in good condition, to the address and in the manner designated by the Company, all of the Products on Consignment then in its possession, which have not been deemed to have been purchased by the Consignee pursuant to this Agreement.

The Consignee may terminate the agreement at any time by giving 30 days prior written notice. Upon termination by the Consignee, the Consignee shall deliver at the Company’s sole expense, in good condition, to the address and in the manner designated by the Company, all of the Products on Consignment then in its possession, which have not been deemed to have been purchased by the Consignee pursuant to this Agreement.

1. **Governing Law**

This Agreement shall be governed by and interpreted in accordance with the laws of the State of Florida applicable therein.

1. **Notice**

Any notice or other documents to be given or sent to the other party hereunder shall be effectively given or sent, if delivered or sent by the prepaid registered mail, addressed to the party for which it is intended at its address or to such other address for such party as may be specified from time to time by written notice given by such party to the other. Notices shall be deemed given when delivered or transmitted by facsimile or, if mailed, within five business days after being deposited in the mail.

1. **Confidentiality**

Company and Consignee acknowledge that any information concerning the business and affairs the other party its agents, employees, clients and patients of which it becomes aware in the course performing its obligations under this Agreement, shall be treated as confidential. Each party agrees to take such measures to protect such information, as it would reasonably be expected to take to protect its own confidential information. This obligation of confidentiality does not apply to information that is or becomes publicly known without fault of the receiving party, or is or becomes lawfully available from another source; or was known to the receiving party before receipt from the disclosing party; or is independently developed by the receiving party as evidenced by contemporaneous written documentation; or is required by law to be disclosed, provided that the receiving party shall use reasonable efforts to notify the disclosing party of such requirement for disclosure in order to provide the disclosing party the opportunity to seek a protective order or other appropriate relief.

1. **Liability** Each party shall be responsible for any and all liability resulting from the acts and/or omissions of their respective directors, officers, employees, agents and Companys. Except as set forth in Section 2.9, neither party shall be responsible for any liability resulting from the acts and/or omissions of the other party’s directors, officers, employees, agents and Companys. The Consignee carries insurance in sufficient amounts to cover its activities under this Agreement.

**The parties hereby execute this Agreement as of the date first written:**

**CONSIGNEE COMPANY**

By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- | --- |
| Emergency CONTACTS | Name | Phone | email |
| Regular Hours |  |  |  |
| After Hours (24 hours) |  |  |  |

*PROFOUNDA CONTACT INFO 407-270-7790*

*24 hr Cell 908-635-2326 (Todd MacLaughlan)*

Schedule 1

**PRODUCT:**

NDC # 69051-0300 Impavido (miltefosine) 50 mg x 28 tablets

* Initiation Fee: $100 (Covers initial product shipment)
* Stocking Fee: none
* Vendor mate or other similar fees charged to Profounda as required by Consignee is either waived by the Consignee or reimbursed to Company.
* Number of boxes to be consigned: one (1)
* Purchase Price (if used): $ 16,000.00 USD per box 28 tablets plus shipping

**INDICATIONS AND USAGE**

IMPAVIDO (miltefosine) capsules are indicated in adults and adolescents ≥12 years of age

weighing ≥ 30 kg for the treatment of:

• Visceral leishmaniasis caused by Leishmania donovani [see Clinical Trials (14.1)].

• Cutaneous leishmaniasis caused by Leishmania braziliensis, Leishmania guyanensis, and

Leishmania panamensis [see Clinical Trials (14.2)].

• Mucosal leishmaniasis caused by Leishmania braziliensis [see Clinical Trials (14.3)].

The treatment duration is 28 consecutive days. Administer with food to ameliorate gastrointestinal adverse reactions.

Miltefosine Dosage Weight Dosage and Administration

* 30 kg to 44 kg One 50 mg capsule twice daily with food (breakfast and dinner)
* 45 kg or greater One 50 mg capsule three times daily with food (breakfast,

**Reimbursement Coding Information:**

ICD-10-CM Diagnosis Code B55: Leishmaniasis

In the new ICD-10-CM coding system, there are four codes referring to leishmaniasis.  (See <http://www.icd10data.com/ICD10CM/Codes/A00-B99/B50-B64/B55> - for details.)

ICD-10-CM Diagnosis B55 is a Non-Specific Code"> B55 Leishmaniasis

B55.0 Visceral leishmaniasis

B55.1 Cutaneous leishmaniasis

B55.2 Mucocutaneous leishmaniasis

B55.9 Leishmaniasis, unspecified